

E-food control: challenges for the UE in the digital era

El control de los @limentos: retos para la UE en la era digital

María José Plana Casado



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E-FOOD CONTROL: CHALLENGES FOR THE UE IN THE DIGITAL ERA

EL CONTROL DE LOS @LIMENTOS: RETOS PARA LA UE EN LA ERA DIGITAL

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BARCELONA, 2018

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ABBREVIATIONS

AAC Administrative Assistance and Cooperation System

AECOSAN Agencia Española de Consumo, Seguridad Alimentaria y Nutrición

ANH Alliance for Natural Health

APHA Animal and Plant Health Agency

AVV-LmH Allgemeine Verwaltungsvorschrift über die Durchführung der amtlichen

Überwachung der Einhaltung von Hygienevorschriften für Lebensmittel und zum Verfahren zur Prüfung von Leitlinien für eine gute

Verfahrenspraxis

AVV-RÜb Allgemeinen Verwaltungsvorschrift Rahmen-Überwachung

B2B Business to Business

B2C Business to Consumer Electronic Commerce

BfR Bundesinstitut für Risikobewertung

BMEL Bundesministerium für Ernährung und Landwirtschaft

BSE Bovine Spongiform Encephalopathy

BTSF Better Training for Safer Food

BÜP Bundesweiten Überwachungsplans

BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

C2C Consumer to Consumer Electronic Commerce

CCP efood Coordinated Control Plan on the Internet sale of food

CHED Common Health Entry Document

CITES Convention on International Trade in Endangered Species of Wild Fauna

and Flora

DAERA Department of Agriculture, Environment and Rural Affairs

DEFRA Department for Environment, Food & Rural Affairs

DENIC Deutsches Network Information Center

DG SANTE Directorate General for Health and Food Safety

DHSC Department of Health and Social Care

ECD E-Commerce Directive

EEA European Economic Area

EFSA European Food Safety Authority

EFTA European Free Trade Association

EU European Union

EVIRA Elintarviketurvallisuusvirasto

FAO Food and Agriculture Organization

FASFC Federal Agency for the Safety of the Food Chain

FBOs Food Business Operators

FLEP Food Law Enforcement Practitioners

FSA Food Standards Agency
FSS Food Standards Scotland
FVO Food and Veterinary Office

G@zielt Zentralstelle Kontrolle der im Internet gehandelten Erzeugnisse des LFGB

und Tabakerzeugnisse

GAIN Global Agriculture Information Network

GFL General Food Law

GMOs Genetically Modified Organisms

HACCP Hazard Analysis and Critical Control Points

ICANN Internet Corporation for Assigned Names and Numbers

IEC International Electro technical Commission

INFOSAN The International Food Safety Authorities Network

ISO International Organization for Standardization

ISPs Internet access and service providers

IT Information Technology

LAV Länderarbeitsgemeinschaft Verbraucherschutz

LFGB Lebensmittel un Futtermittelgesetzbuch

MANCP Multi-Annual National Control Plan

MAPAMA Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente

MNKP Mehrjährigen Nationalen Kontrollplan

MSSSI Ministerio de Sanidad, Servicios Sociales e Igualdad

NTDs Notice-and-take down procedures

OECD Organization for Economic Co-operation and Development

PAFF Plants, Animals, Food and Feed

PNCOCA Plan Nacional de Control Oficial de la Cadena Alimentaria

RAPEX Rapid Exchange of Information System
RASFF Rapid Alert System for Food and Feed

RGSEAA Registro General Sanitario de Empresas Alimentarias y Alimentos

RIPA Regulation of Investigatory Powers Act

ROPO Read Online Purchase Offline

SMEs Small and Medium-size Enterprises
TRACES Trade Control and Expert System

USDA United States Department of Agriculture

WHO World Health Organization
WTO World Trade Organization

IMAGES

- Image 1. Example registration form for food establishments, issued by the Federal Ministry of Food and Agriculture
- Image 2. United Kingdom's Food Hygiene Rating Logo
- Image 3: CCP_Efood, EU Commmission's summary of findings

TABLES

- Table 1. Summary of current challenges, by member state.
- Table 2. Summary of Challenges & Proposals, from December 2019

TABLE OF CONTENTS

Resum	17
Resumen	19
Abstract	21
INTRODUCCIÓN	23
Delimitación del tema	25
Justificación	27
Metodología	30
Sobre el estudio de casos	32
Estructura del trabajo	34
CHAPTER 1. EUROPEAN DIGITAL MARKET OF FOOD	
REGULATORY FRAMEWORK APPLYING TO FOOD E-COMMERCE	
1.1. Food law in the European Union	31
1.1.1. Principles governing food law in the European Union	44
1.1.1.1. Science as the base of food law	44
1.1.1.2. The precautionary principle	46
1.1.1.3. Principle of transparency in public action	48
1.1.2. Distribution of responsibilities	49
1.1.2.1. Responsibility of food businesses	
1.1.2.2. Responsibilities of public powers	
1.1.3. About the legal framework applying to consumer-to-consumer for exchanges	od
1.1.4. The definition of "food law" that applies to this thesis	57
1.2. Policy and regulatory framework of e-commerce in the European Union	60
1.2.1. The concept of electronic commerce	60
1.2.2. Regulating e-commerce in the European Union	
1.2.3. The construction of the Digital Single Market	
1.2.4. Legal framework applying to Consumer-2-Consumer electron commerce	nic
2. CHARACTERISTICS OF THE E-FOOD MARKET IN THE EUROPEA	٩N
UNION	80

2.1. Overview of the market's economic relevance	30
2.2. Actors that place offers of food products in the digital market	33
2.2.1. B2B e-commerce	33
2.2.2. B2C e-commerce	34
2.2.2.1. Store-based retailers in the digital market	35
2.2.2.2. Internet-based retailers	36
2.2.3. C2C e-commerce	38
2.3. Food products available online	0
CHAPTER 2. REGULATION OF OFFICIAL CONTROLS IN THE EUROPEAN	N
UNION: THE CURRENT SITUATION9)7
1. THE LEGAL FRAMEWORK APPLYING TO OFFICIAL CONTROLS IN TH	Έ
EUROPEAN UNION WAS DESIGNED FOR THE TRADITIONAL MARKET O	F
FOOD PRODUCTS9)7
1.1. Official controls under Regulation 882/2004	8
1.2. Principles governing official controls)3
1.3. Rules for the organization of official controls)5
1.3.1. Prioritization of controls result from risk assessment)7
1.3.2. Active food establishments must be registered to ensure they are include in official controls	ed
1.4. Rules governing the performance of official controls	.2
1.5. Activities included in official controls	. 5
1.6. Sampling for analysis	.7
2. MEMBER STATE'S LAW PLAYS A DECISIVE ROLE IN OFFICIAL	L
CONTROLS. SPAIN AS A CASE-CONTROL STUDY	22
2.1. The administrative organization of official controls in Spain	23
2.2. Regulating the organization of official controls	25
2.3. Regulating de performance of official controls	3
3. PROBLEMS ARISE WHEN APPLYING CURRENT LEGAL FRAMEWORK	K
OF OFFICIAL CONTROLS TO FOOD E-COMMERCE	
3.1. Issues regarding the organization of official controls on e-foods	37

3.2.	Issues concerning the performance of official controls	140
3.3.	Issues concerning enforcement of food law	144
СНАРТЕ	ER 3. APPROACH TO E-FOOD CONTROL IN GERMANY AND THE UNIT	ΈD
KINGDO	OM	147
PART 1.	G@ZIELT, A PIONEER IN E-FOOD CONTROL	149
1. GI	ERMANY'S POLITICAL AND ADMINISTRATIVE STRUCTURE AND	ITS
ARRA	NGEMENTS WHEN IT COMES TO OFFICIAL CONTROLS	149
1.1.	Political structure of Germany and distribution of powers when it come	s to
offic	ial controls	149
1.2.	Legislation relevant to the organization and performance of official contractions 152	rols
	2.1. Regulating the organization of official controls	
	2.2. Regulating de performance of official controls	
2. TH	HE GERMAN APPROACH TO OFFICIAL CONTROLS OF E-FOODS	
2.1.	The construction of a central unit for food e-commerce control	161
2.2.	Tasks developed by G@zielt	163
2.3.	G@ziel's surveillance activities	167
	3.1. Mapping the German market of e-foods through food busing entification	
2.3	3.2. Performing official controls	174
2	2.3.2.1. Undertaking searches	178
2	2.3.2.2. Product analysis	180
2	2.3.2.3. Enforcing food law	182
3. RF	ECAPITULATION	185
PART 2.	THE UNITED KINGDOM IS CONTROLLING THE DIGITAL MARKET	AT
THE PRO	ODUCTION AND DISTRIBUTION STAGE	189
1. TH	HE UNITED KINGDOM'S POLITICAL AND ADMINISTRATI	VE
STRUC	CTURE AND ITS ARRANGEMENTS WHEN IT COMES TO OFFICI	AL
CONT	ROLS	189
1.1.	Political structure of United Kingdom and distribution of powers whe	n it
come	es to official controls	190

1.2. Legislation relevant to the organization and performance of official control 194
1.2.1. Regulating the organization of official controls
1.2.2. Regulating de performance of official controls
2. APPROACH TO OFFICIAL CONTROLS OF E-FOODS IN THE UNITED
KINGDOM
2.1. The Food Standards Agency's strategy to improve the safety of the digital
market of foods
2.1.1. Consumer awareness
2.1.2. Improving the safety and quality of the offers y training business 20
2.1.3. Training public officials 20
2.2. The guidance for official controls
2.2.1. Mapping the market of e-foods through food business identification 20
2.2.2. Identifying unsafe products and Enforcing food law to improve consume protection
2.2.2.1. Undertaking searches
2.2.2.1. Ordertaking searches 21 2.2.2.2. Product Analysis 21
2.2.2.3. Enforcing food law
3. RECAPITULATION
PART 3. COMPARATIVE EVALUATION
1. MARKET FINDINGS
2. LEGAL FRAMEWORK
3. OVERCOMING THE TECHNICAL AND LEGAL CHALLENGE
IDENTIFIED IN THIS THESIS
3.1. Tackling the challenges for the organization of official controls (Challenge
n°1 to 5)23
3.1.1. Dealing with peer-to-peer trade of food products online
3.1.2. Fixing registration bugs
3.1.3. Ensuring that the organization of official controls respond to effective and impartial prioritization:
3.2. Tackling the challenges arising for performance of official control
(Challenges nº 6 to 10)

3.2.1. Making sure that surveillance goes unnoticed by operators, to ensure the effectiveness of controls	
3.2.2. Performing controls at the distribution stage while safeguarding the operator's capacity to contest administrative decisions:	
3.3. Tackling the challenges regarding food law enforcement (Challenge n° 10))
240	
4. ABOUT THE POSSIBILITY OF CENTRALISING SURVEILLANCE 24	3
CHAPTER 4. THE ROLE OF THE EUROPEAN UNION: COORDINATION AND	D
SUPPORT24	5
1. FIRST STEPS OF THE EUROPEAN COMMISSION ON E-FOOD CONTROL	L:
PROVIDING TRAINING AND ENSURING KNOWLEDGE-TRANSFER 24	5
1.1. Providing training to public officials in charge of official controls 24	5
1.2. Transferring knowledge through working groups	7
2. 2016-2017: PROVIDING A LEGAL FRAMEWORK THAT OVERCOME	S
THE OBSTACLES ENSHRINED IN MEMBER STATE LEGISLATION 24	8
2.1. Overview of the novelties in Regulation 625/2017, for official controls 24	9
2.2. Food business operators must provide information about their activities in the	ıe
digital market	51
2.3. Harmonised rules for sampling of e-foods at the distribution stage 25	52
2.4. Official controls on e-foods from third countries	5
2.5. Order for cessation	6
3. THE COORDINATED CONTROL PLAN ON ONLINE OFFERED FOOL	D
PRODUCTS25	9
3.1. The definition of the coordinated control plan	;9
3.1.1. Task 1: Identifying food business operators dealing with the targeted foo products 263	od
3.1.2. Task 2: Searching for relevant offers: 26	54
3.1.3. Task 3: Notification of non-compliance	5
3.1.4. Sampling in the framework of CPP_efood:	
3.2. Development and results	6
4. RECAPITULATION27	0'

CONCLUSIONES Y PROPUESTAS
1. CONCLUSIONES RESPECTO DEL MERCADO DIGITAL DE ALIMENTOS
277
2. CONCLUSIONES SOBRE EL MARCO JURIDICO
3. PROPUESTAS DE ACTUACIÓN PARA LOS ESTADOS MIEMBROS 287
3.1. Respecto del control oficial de los @limentos ofrecidos por particulares: 287
3.2. Respecto de cómo "mapear" el mercado digital
3.3. Respecto de la priorización de las actividades de control
3.4. Respecto del control material de los @limentos en la fase de distribución291
3.5. Respecto de las acciones en caso de incumplimiento
3.6. Respecto de la decisión de centralizar el control oficial de los @limentos293
BIBLIOGRAPHY

Resum

El comerç electrònic d'aliments està creixent de manera significativa en el sector dels queviures al detall, però una quantitat important dels productes oferts no compleixen amb els requisits de la legislació alimentària quant a la seva seguretat i qualitat. Els sistemes de control oficial que van dissenyar els Estats Membres respectant les regles bàsiques de legislació de la Unió Europea a principis de segle XXI, no s'adapten a la realitat digital. A més, la popularització de les plataformes digitals ha retornat una importància perduda al comerç entre particulars, que les autoritats no saben com supervisar. Aquesta tesi identifica deu reptes als quals s'enfronten les autoritats competents en l'organització i execució d'activitats de control dels @liments. Les autoritats competents espanyoles, com les de molts altres Estats Membres, no saben com enfrontar-se a ells. Per això es realitza un estudi comparat del marc jurídic d'Espanya, Alemanya i Regne Unit, i s'analitzen els detalls de l'estratègia que aquests dos últims països han adoptat per superar els reptes. L'objectiu és identificar bones pràctiques aplicables a la resta d'Europa. Tot i que la regulació de cada Estat presenta diferències significatives, els obstacles per al control són similars. Tot i això, la forma en la qual Alemanya i Regne Unit s'enfronten als deu reptes és molt diferent. Mentre que Alemanya ha creat una unitat centralitzada que supervisa el mercat digital amb l'objectiu de millorar la seguretat dels @liments, el Regne Unit opta per aclarir el marc jurídic i dotar a les seves autoritats amb eines per normalitzar el control administratiu dels establiments i explotadors actius al mercat digital. D'ambdues experiències, i del paper de coordinació i suport assumit per la Comissió Europea, s'extreuen les conclusions i propostes d'aquesta tesi.

Resumen

El comercio electrónico de alimentos se está desarrollado significativamente en el sector minorista de comestibles, pero una cantidad importante de los productos ofertados no cumplen con los requisitos de la legislación alimentaria en cuanto a su seguridad y calidad. Los sistemas de control oficial que diseñaron los Estados Miembros respetando las reglas básicas armonizadas de legislación de la Unión Europea a principios de siglo XXI, no se adaptan a la realidad digital. Además, la popularización de las plataformas digitales ha devuelto una importancia perdida al comercio entre particulares, que las autoridades no saben cómo supervisar. Esta tesis identifica diez retos a los que se enfrentan las autoridades competentes en la organización y ejecución de actividades de control de los @limentos. Las autoridades competentes españolas, como las de muchos otros Estados Miembros, no saben cómo enfrentarse a ellos. Por ello, se realiza un estudio comparado del marco jurídico de España, Alemania y Reino Unido, y se analizan los pormenores de la estrategia que estos dos últimos países han adoptado para superar los retos. El objetivo es identificar buenas prácticas aplicables al resto de Europa. A pesar de que la regulación de cada Estado presenta diferencias significativas, los obstáculos para el control son similares. Sin embargo, la forma en la que Alemania y Reino Unido se enfrentan a los diez retos es muy diferente. Mientras que Alemania ha creado una unidad centralizada que supervisa el mercado digital, cuyo objetivo es mejorar la seguridad de los @limentos, el Reino Unido opta por clarificar el marco jurídico y dotar a sus autoridades con herramientas para normalizar el control administrativo de los establecimientos y explotadores activos en el mercado digital. De ambas experiencias, y del papel de coordinación y soporte asumido por la Comisión Europea, se extraen las conclusiones y propuestas de esta tesis.

Abstract

E-grocery shopping is increasingly popular, but a significant part of the food products available online do not comply with food law requirements. The official control systems designed by Member States on the basis of the harmonized rules of the European Union, are not adapted to the digital reality. Additionally, digital platforms that allow individuals to share and exchange goods and services have brought peer-to-peer trade back to the political arena in the era of the "collaborative economy," also when it comes to food. However, competent authorities do not know how to supervise this trade. This thesis identifies ten challenges faced by the competent authorities when organizing and performing control activities on e-foods. The Spanish competent authorities, like those of many other Member States, do not know how to overcome these challenges. Building on a comparative study of the legal framework of Spain, Germany and the United Kingdom, I evaluate the strategy that these last two Member States have adopted on e-food control. The objective of the regulatory and policy comparison is to identify good practices applicable to the rest of Europe, including Spain. The legislation is different in each Member State, and so is the approach to e-food control. Germany has created a centralized unit that monitors e-food offers, aiming to improve the overall safety of the digital market. The United Kingdom has focused on clarifying the legal framework that applies to controls online, and on providing competent authorities with tools to ensure that food establishments and active operators in the digital market are included in official controls. The conclusions and proposals of this thesis are based on the analysis of both approaches, and of the coordination and support initiatives that have recently been carried out by the European Commission.

INTRODUCCIÓN

Las nuevas tecnologías de la información y la comunicación han favorecido la aparición de incontables soportes digitales que permiten a los ciudadanos adquirir casi cualquier bien o servicio a través de Internet o de aplicaciones móviles. Con la popularización de estas tecnologías, está cambiando la forma en la que los ciudadanos -consumidores y ofertantes- interactúan. La posibilidad de comprar en cualquier momento y desde cualquier lugar (siempre que tengamos cobertura y fondos) junto con el hecho de que a través de Internet se puede acceder a una variedad mucho más amplia de productos que no estarían al alcance del individuo en su comunidad, convencen progresivamente a los consumidores de comprar digitalmente.

El auge del comercio electrónico también es una realidad en cuanto a alimentos se refiere. Aunque la compra de alimentos en el mercado digital sigue siendo minoritaria en toda Europa, en la última década el comercio electrónico se ha desarrollado significativamente en el sector minorista de comestibles.

Pero una cantidad importante de productos alimenticios ofertados en el mercado digital no cumplen con los requisitos de la legislación alimentaria. La naturaleza del incumplimiento varía, pero dos son los problemas más acuciantes que las autoridades han tratado de contener: la disponibilidad de productos alimenticios no seguros y de los que se comercializan mediante prácticas fraudulentas o engañosas.

Contener la distribución en el mercado digital de alimentos que no cumplen con la legislación alimentaria, debe ser una prioridad para las autoridades competentes en materia de control oficial. Hasta ahora, los principales esfuerzos se han centrado en hallar fórmulas efectivas para contener la distribución *online* de complementos alimenticios y nuevos alimentos que incorporan ingredientes no autorizados y que pueden acarrear riesgos para la salud humana. Pero con la popularización de las plataformas digitales, otros alimentos con altas tasas de incumplimiento escapan al control público. Por ejemplo, los productos frescos o altamente perecederos que han sido manipulados y entregados sin respetar las reglas básicas de higiene y seguridad alimentaria, están cada vez más presentes online.

Sin embargo, hasta la fecha, el papel desempeñado por las autoridades responsables de la verificación del cumplimiento de la legislación alimentaria ha sido anecdótico en gran

parte de los Estados miembros de la Unión Europea. Dicha inactividad no se ha debido a dejadez sino a las dificultades técnicas y a los obstáculos legales para llevar a cabo actividades de control oficial sobre ofertas digitales. Hay que tener presente que las tecnologías que han hecho posible el auge del comercio electrónico se han popularizado según avanzaba una crisis económica, que ha mermado los recursos humanos y económicos para la capacitación de los responsables del control, redundando en las dificultades para que las autoridades competentes se involucren en la aplicación de la legislación alimentaria en el mercado digital.

Las autoridades competentes españolas, como las de muchos Estados miembros de la UE, albergan dudas respecto de cómo aplicar el marco jurídico actual al mercado digital, y respecto de si el nuevo Reglamento de control oficial (aplicable a partir del 14 de diciembre de 2019) les permitirá controlar los @limentos de forma eficaz e imparcial. Ante la falta de orientación por parte de las Instituciones comunitarias, varios Estados miembros han intentado establecer sus propias iniciativas para el control de los alimentos electrónicos, con Alemania y Reino Unido a la cabeza.

Esta tesis tiene como objetivo identificar los obstáculos que deben superar las autoridades competentes para realizar controles oficiales de los alimentos ofrecidos en el mercado digital, y proporcionar recomendaciones a los Estados Miembros de la UE sobre cómo superar esos desafíos. De esta forma, las autoridades competentes deberían poder definir un protocolo que guíe a los funcionarios públicos a través del proceso de monitoreo, inspección y muestreo de @limentos, garantizando el cumplimiento del marco jurídico aplicable.

Para ello, previa investigación y descripción de las características del mercado digital de alimentos, se realizará un análisis jurídico del marco aplicable, en la actualidad y orientado al futuro. Partiendo del marco jurídico armonizador de la Unión Europea, que únicamente establece los principios y características esenciales del control oficial, en esta tesis tiene un papel primordial el derecho de los Estados Miembros puesto que son ellos quienes tienen la competencia para regular, organizar y ejecutar el control oficial. El objetivo es identificar los diez principales desafíos a que se enfrentan las autoridades competentes. Para ello, se analiza el impacto de la normativa Española (caso control), Alemana y del Reino Unido (sujetos del estudio comparado) afectan al control oficial de alimentos. De esta manera, identificados los retos a atender, se analizan las iniciativas puestas en marcha por Alemania y Reino Unido para integrar los @limentos en el sistema

de control oficial, así como las acciones implementadas por la Comisión Europea para sumarse a los esfuerzos nacionales en este campo (como la adopción del nuevo reglamento de controles oficiales que se aplicará a partir de diciembre 2019 en la Unión Europea y el plan de control coordinado sobre complementos alimenticios que tuvo lugar durante el último trimestre del año). Asimismo, derivadas del análisis realizado, se incluyen propuestas para que aquellos Estados Miembros que se incorporan ahora al control del mercado digital de alimentos puedan organizar y ejecutar controles sobre los @limentos de forma eficaz y dentro de la ley.

Es necesario destacar que la última fase de la realización de la tesis ha coincidido, en paralelo, con la puesta en marcha de diversas iniciativas en este campo, por parte de la Comisión Europea y de una parte de los Estados Miembros. En 2014, cuando comienza la fase de investigación, este campo estaba por desarrollar. Alemania acababa de concluir un proyecto piloto llevado a cabo entre 2011 y 2013 sobre monitoreo de @limentos no seguros (analizado en la sección -- del capítulo 3 de esta tesis) y a penas existían comentarios doctrinales -o incluso políticos- respecto de cómo llevar a cabo control oficial de alimentos en el mercado digital. Las siguientes iniciativas no llegaron hasta 2016, cuando la Comisión Europea realizó primeras propuestas en este sentido y el Reino Unido decidió elaborar una guía para facilitar el cometido de las autoridades y esclarecer el marco jurídico aplicable.

Delimitación del tema

Esta tesis analiza los obstáculos que el Derecho Alimentario impone al control oficial de @limentos, y realiza propuestas para que los Estados Miembros puedan llevar a cabo actuaciones de control oficial sobre el mercado digital. Por lo tanto, las referencias en esta tesis a Europa y el Derecho Europeo deben entenderse realizadas en relación a la Unión Europea. Quedan fuera del objeto de estudio de esta tesis, entre otros, los aspectos relativos al control del cumplimiento de la legislación en materia de protección de los consumidores y de la normativa aplicable con carácter general al comercio electrónico, que es sabido también está poniendo a prueba la capacidad del ordenamiento jurídico y de las autoridades de control para adaptarse al entorno digital.

Quedan igualmente fuera del ámbito de estudio de esta tesis las consideraciones respecto de cómo el crimen organizado está actuando en el mercado digital de alimentos. A pesar de se constata que la venta de alimentos falsificados y de suplementos alimenticios ilegales por estos grupos aumenta cada año, la respuesta a este fenómeno debe analizarse desde la perspectiva penal. La problemática entorno a la actividad criminal en el mercado digital de alimentos es sin duda relevante, y requiere de una respuesta conjunta por parte los poderes públicos. Sin embargo, existe un mercado legítimo digital que, a pesar de ser cada vez más atractivo para los consumidores, ha quedado fuera del control de las autoridades. Es urgente conseguir que el mercado legítimo (protagonizado por supermercados, tiendas de barrio y gourmet, e iniciativas "colaborativas") quede sujeto al control administrativo regular por parte de las autoridades competentes, puesto que en la actualidad los ofertantes digitales tienden a incumplir de forma alarmante la normativa alimentaria. Sobre esto último pone el foco esta tesis.

Dentro del ámbito del Derecho Alimentario es necesario, también, limitar el objeto de estudio. Si bien el control oficial implica a menudo la puesta en marcha de mecanismos de cooperación administrativa o de respuesta ante situaciones de emergencia o crisis, este trabajo analiza cómo llevar a cabo actuaciones rutinarias de control oficial por parte de la autoridad competente dentro de su jurisdicción. Como se analiza a lo largo de los capítulos de esta tesis, a pesar de que el comercio electrónico de alimentos es un fenómeno trasnacional, los datos obtenidos por Alemania -en 2014- y por la Comisión Europea -en 2017- acreditan que las ofertas de @limentos que incumplen la legislación alimentaria a las que acceden los consumidores europeos - en más de la mitad de las ocasiones- proceden de ofertantes situados dentro de la misma jurisdicción territorial, y únicamente en el 15% de los casos son de fuera de la Unión Europea. Por lo tanto, se argumenta que si cada Estado Miembro de la Unión Europea mantiene las actividades que se llevan a cabo en su territorio bajo control, el impacto puede ser notable.

A la hora de definir el tema de esta tesis se ha hecho una elección arriesgada pues (sabiendo que ya existen excelentes obras generales de derecho alimentario -o también, de derecho de los consumidores, o de derecho administrativo o, incluso, de derecho penal y de bioética- que pueden enmarcar el tratamiento del tema) se ha decidido tratar el problema no desde lo general a lo particular, sino partiendo de los hechos y de las prácticas concretas que generan conflictos para los en cargados del control. Y, a partir de ahí, ir ascendiendo por las pautas que el derecho suministra y, así, ir desde los casos concretos a los elementos comunes que permiten hallar una solución. Se ha tratado de delimitar el problema concretando al máximo las preguntas de investigación y de

responderlas aportando soluciones concretas, prácticas e imaginativas, dentro del marco jurídico y las posibilidades técnicas. De esta forma, trasportándola al ámbito alimentario, se ha tomado prestado como aval la conocida opinión de Norberto Bobbio quien -en el ámbito filosoficojúridico- consideraba preferible una "filosofía del derecho de los juristas", que conociendo los casos concretos se elevaban a la filosofía, a una "filosofía del derecho de los filósofos" que, desde concepciones generales y abstractas del mundo descendían al tratamiento de los casos, por considerar que los segundos contraían castillos en la arena, sin los sólidos cimientos que proporciona el conocimiento profundo de lo que en la realidad práctica sucede.

Justificación

El interés del tema objeto de esta tesis y sus repercusiones justifican la realización de este trabajo y, más aún, si del mismo pueden derivarse modificaciones en las prácticas de las autoridades competentes actividades de control oficial en el mercado digital de alimentos y si de las conclusiones extraídas pueden existir repercusiones de alcance doctrinal u normativo.

Esta tesis parte de que existe la necesidad de esclarecer cómo llevar a cabo actividades de control oficial en el mercado digital de alimentos, las cuales, como exige el marco jurídico, sean a la vez eficaz e imparciales. En la primera fase de esta investigación, a pesar de que la popularidad de la adquisición digital de alimentos iba creciendo, los poderes públicos en la Unión Europea evitaron posicionarse respecto de cómo debe llevarse a cabo el control oficial de alimentos en el mercado digital. Ello a pesar de que el personal encargado de esta tarea ya entonces expresaba su incertidumbre al respecto, y solicitaba en variados foros soporte técnico y formación para poder adaptar sus protocolos y el marco jurídico a la realidad digital. Además, si bien la administración alemana había emprendido en 2011 un proyecto piloto para abordar la cuestión, los resultados del mismo no fueron difundidos hasta 2014 y los foros escogidos para hacerlo fueron nacionales durante todo un primer año, lo cual dificultó enormemente la transferencia del conocimiento y de las buenas practicas generadas. Todavía a fecha de cierre de esta tesis, no existe una estrategia europea para abordar el control oficial de @limentos, y la mayoría de Estados Miembros (incluida España) solamente empiezan a analizar cómo abordar esta cuestión.

Por lo tanto, se espera que esta investigación suponga una contribución relevante que la justifique y que contribuya a que los poderes públicos puedan poner en marcha actividades de control oficial adaptados a la realidad digital. Las propuestas efectuadas en esta tesis pueden ser aplicadas, con carácter general, en toda la Unión Europea. Además, tanto por la influencia política y económica de la Unión Europea, como por el papel que está jugando la Organización Mundial del Comercio en la homogeneización de legislación alimentaria, la legislación alimentaria presenta importantes similitudes en los diversos países. Consecuentemente, a pesar de que el marco jurídico de referencia sea el europeo, esta tesis quiere ser una contribución a la problemática del control administrativo de los alimentos a nivel global.

Por otra parte, dado que esta tesis se presenta en la Línea de Doctorado de Bioética y Derecho del Programa de Derecho y Ciencia Política, es necesario justificar la relación del tema de esta tesis con los contenidos propios de la Bioética:

Los temas alimentarios entran de lleno en una concepción global de la bioética. Ciertamente, por una serie de acontecimientos impredecibles hace tan solo tres o cuatro décadas, las preocupaciones por las cuestiones alimentarias han acabado en el seno de la bioética, precisamente a medio camino entre el ecologismo y la ética clínica. Con respecto al ecologismo, la ética alimentaria se enfrenta al problema de cómo alimentar a una población humana cada vez más numerosa sin deteriorar al mismo tiempo el planeta. El desarrollo sostenible, el calentamiento global, el desigual reparto de la riqueza, etc., son temáticas sobre las que la ética alimentaria tiene mucho que aportar. Con respecto a la bioética clínica, la ética alimentaria se enfrenta al problema de cómo inciden en la salud las nuevas tecnologías. Así, los efectos de una dieta desequilibrada, una alimentación inadecuada, la publicidad engañosa, etc., superan el ámbito estrictamente privado del ciudadano hasta repercutir en las políticas públicas. La salud colectiva es algo más que la suma que la salud de los individuos de una sociedad, y los profesionales del campo alimentario pueden aportar sus conocimientos y experiencia en un plano de igualdad con el personal sanitario. Las reflexiones milenarias acerca de la vida, la salud y la muerte, proporcionan al campo alimentario las armas adecuadas para abordar los retos del presente.

Si estos dos ejes, ecologismo y ética clínica, no fuesen ya de por sí suficientes para justificar la incorporación de lo alimentario en la bioética, es conveniente reflexionar sobre el contexto tecnológico en que se mueve actualmente la alimentación. Así, internet,

los *big data* y la biología sintética son materias o disciplinas que han cambiado completamente el escenario tradicional en que se ha movido históricamente la alimentación y su control. El tránsito del huerto al mercado de abastos ha sido sustituido por las impresoras en tres dimensiones y la comida sintética. En este contexto, la falta de control oficial sobre los *@limentos* no es baladí, ya que actualmente supone no poner barreras a la distribución de alimentos no seguros o que vulneran los intereses de los consumidores.

Llegar tarde y, frecuentemente, mal parece ser la condena de la regulación sobre tecnología pues la velocidad creciente de los cambios tecnológicos sigue agrandando la distancia que los separa de los reguladores. Este problema es una constante en la reflexión bioética y biojurídica: desde el ADN a la nanotecnología, los transgénicos o la inteligencia artificial. Existe un problema de decalage en el ritmo de desarrollo tecnocientífico y el del análisis ético y el establecimiento de consensos que permitan su regulación. Hasta los primeros años 2000 nuestro país no empezó a establecer como objetivo el desarrollo de las tecnologías de la información y el uso de las redes de telecomunicaciones para intentar que la economía española basándose en el conocimiento se convierta –junto con las europeas- en competitiva y capaz de lograr un crecimiento sostenible. Pero los avances biotecnológicos la ley siguen ritmos distintos; la velocidad de los cambios aumenta cada vez más y la distancia con las regulaciones obsoletas crece existen temas básicos que no están todavía legislados de acuerdo a la nueva realidad sino que la regulación sigue parámetros pretecnológicos. Esto es evidente en el tema de este trabajo pero también en otros ámbitos de la bioética que van desde el inicio de la vida, e incluso su "creación" biotecnológica, a las implicaciones del big data, la inteligencia artificial o el medio ambiente.

Los retos son enormes y este es el contexto en que se plantea la presente investigación. Tal y como afirmó la Comisión Europea en 2015, es necesario discutir con los Estados miembros cómo mejorar la eficacia de los controles sobre las ventas en Internet. Es voluntad de esta tesis aportar información y argumentos a este debate.

Metodología

El método empleado para la elaboración de esta tesis doctoral ha combinado enfoques diversos a lo largo de las distintas fases recorridas en el proceso:

La investigación ha requerido llevara cabo un trabajo estrictamente jurídico de análisis normativo que ha permitido definir de manera precisa el marco jurídico aplicable; marco que combina el derecho comunitario y los derechos de distintos estados miembros de la UE. Paralelamente, la elaboración de esta tesis ha requerido efectuar un análisis comparado de la legislación sobre el tema, se ha acudido a las metodologías propias del derecho comparado. Para ello se ha llevado a cabo un intenso trabajo de campo, empírico y descriptivo para determinar las diferencias con las prácticas que se llevan a cabo en el ámbito del control de los @limentos en la UE en la era digital. El estudio casos cuya metodología se especifica al final de este apartado, ha permitido obtener conclusiones relevantes. Asimismo, también, se ha empleado un método constructivista que ha permitido formular propuestas de medidas concretas para que los Estados que se planteen establecer un sistema de control de @limentos no tengan que partir de cero y puedan construir su estrategia sobre las aportaciones de esta tesis. En cuanto a la bibliografía sobre el tema específico de la tesis, se ha llevado a cabo un análisis que condujo a la constatación del muy escaso tratamiento de la cuestión por la doctrina y a la observación de que, si bien existe bibliografía general, no se encuentran aún aportaciones relevantes en este campo concreto.

Ante esta situación, a lo largo de todo el proceso de elaboración de esta tesis, ha tenido gran relevancia la *ley en acción* (que incluye el análisis de datos empíricos, económicos y sociológicos, así como las interpretaciones llevadas a cabo por los poderes públicos y los tribunales):

- Se ha llevado a cabo una recopilación de datos económicos del mercado digital, para dar marco al estudio. Para ello se han utilizado informes correspondientes a estudios de mercado, elaborados por consultoras (Nielsen, por ejemplo), datos en prensa generalista, comentarios de blogs económicos e informes de la Comisión Europea, la Organización mundial del comercio y el USDA (departamento de agricultura de EEUU).
- Se ha accedido a la información *open access* de las plataformas *Amazon*, *Alibaba*, *eBay*, *Facebook y Compartoplato*. Estos datos se recogen en formato de tabla en el capítulo 1, sobre cómo organizan la venta de alimentos en sus plataformas.

- Se ha analizado el marco jurídico del control oficial de alimentos en la UE, basado en el Reglamento 882/2004 de control oficial. Asimismo, se ha estudiado la estructura y las bases del derecho alimentario europeo, para poner el reglamento en contexto y se ha llevado a cabo un estudio de las publicaciones académicas para profundizar sobre conceptos clave.
- Se ha examinado la evolución y el marco jurídico que regula el comercio electrónico en la UE, desde el año 2000 a 2017. Se ha hecho un estudio de publicaciones académicas sobre la cuestión para profundizar sobre conceptos clave.
- Se ha analizado el marco jurídico estatal en España, Reino Unido y Alemania en cuando a organización e implementación del control oficial en estos Estados.
- Se han determinado y analizado las publicaciones de la Comisión Europea sobre control oficial de alimentos en el mercado digital; dichas publicaciones, en realidad, están recogidas en forma de sinopsis de conferencias y se constata que no hay ningún informe sistemático.
- Se ha efectuado una revisión bibliográfica de los *papers* sobre control oficial de alimentos, casi todos ellos publicados en Alemania y en la mayoría de casos por el propio equipo que lleva a cabo el Proyecto piloto que en esta tesis se analiza.
- Se han analizado las guías de la administración alemana e inglesa sobre control oficial de alimentos.
- Se ha continuado llevando a cabo trabajo de campo a lo largo de toda la tesis y para ello se ha realizado numerosas entrevistas personales y también telefónicas o vía email. Así, en España, con AECOSAN, Icíar Fierros (Jefe de Servicio del Área de Planificación de la Subdirección General de coordinación de alertas y programación del control oficial); en Alemania, con G@zielt, Dr Peter Kranz (oficial científico de G@zielt, la unidad central alemana para la supervisión del mercado digital); en los Países Bajos, con la autoridad holandesa de seguridad alimentaria Nederlandse Voedsel- en Warenautoriteitcon, el inspector Jan Homma; en el Reino Unido, con la Food Standards Agengy, entre otros Alex Lisle and Julie Smith. También debe mencionarse el intercambio realizado con Dr Schreiberx, de la Unidad G3 Controles oficiales y erradicación de enfermedades en animales de la Comisión Europea. Además, se han efectuado contactos puntuales con las autoridades de la República Checa, Eslovaquia,

Francia, Italia y Suecia. Se han identificado iniciativas a pequeña escala en varios de esos Estados miembros, pero la mayoría carece de información confiable.

Si bien todas estas entrevistas fueron útiles para el propósito de esta investigación, las respuestas específicas no se citaron en la tesis por expresa petición de los entrevistados.

- Se han llevado a cabo dos estancias de investigación en universidades de reconocido prestigio y cuya investigación es relevante a los efectos de esta tesis:
 - Law and Governance Group de la Universidad de Wageningen, grupo que lidera en Europa la investigación en el campo del Derecho Alimentario, y
 - Centro Interdipartimentale di Ricerca in Storia del Diritto, Filosofia e Sociologia del Diritto e Informatica Giuridica dell'Università di Bologna "Guido Fassò - Augusto Gaudenzi" (CIRSFID), referencia internacional en bioética y en la joven disciplina de la informática jurídica.

Sobre el estudio de casos

Puesto que el poder de decisión en cuanto a control de oficial de los alimentos recae en manos de los Estados Miembros, esta tesis pone el foco en la normativa estatal, interpretada en base a los principios del derecho Europeo. Se ha llevado a cabo un estudio comparado de cómo el marco jurídico español, alemán y del Reino Unido afectan al control oficial, y se plantean propuestas para que las autoridades competentes de estos tres países, y del resto de Estados Miembros, puedan mejorar su capacidad de control sobre el mercado digital de alimentos. Por tanto, el objetivo del estudio comparado es explorar cómo diferentes administraciones han intentado implementar una política que resuelva esta cuestión.

A pesar de que la organización política y administrativa, y la tradición jurídica de los tres Estados seleccionados son dispares, ello no genera obstáculos a la comparación. La regulación del control oficial en los tres casos de estudio parte de la armonización llevada a cabo por Reglamentos de la Unión Europea. A nivel Europeo se han establecido los principios básicos y los límites a la actuación de la autoridad competente, que deben respetarse por el legislador estatal.

La justificación de la selección de Alemania y Reino Unido para este estudio comparado es sencilla. En primer lugar, Alemania ha sido el primer país (no solamente en la Unión Europea sino a nivel mundial) que ha afrontado el reto de definir una política pública para llevar a cabo controles administrativos sobre el comercio de @limentos. Es un país pionero, y sus primeros pasos se remontan a 2011. Lo que empezó como un proyecto piloto de 24 meses sobre una cuestión específica (cómo rastrear aquellos que ofertan alimentos en Internet a pesar de no estar registrados como explotadores alimentarios, como los define la ley), ha evolucionado hasta tal punto que no solamente hoy en Alemania existe una unidad específica que centraliza la supervisión de este mercado, sino que las autoridades de este país quieren exportar su modelo y que en Europa haya una única institución responsable de la supervisión del mercado digital europeo. Además, el apoyo que actualmente está prestando la Comisión Europea al resto de Estados para establecer sistemas eficaces de control en cada uno de ellos se basa en la experiencia alemana (hasta tal punto que hoy lidera el equipo de la Comisión quien creó y lideró durante cinco años la unidad alemana).

Por otro lado, la selección del Reino Unido como segundo caso de estudio a pesar de la inminencia del Brexit, responde a que es el único estado que ha definido una estrategia sistematizada para que los responsables del control oficial puedan supervisar el mercado, declarar la existencia de incumplimientos de la normativa alimentaria, y exigir el cumplimiento de la ley respetando todas las garantías del administrado y por lo tanto minimizando las posibilidades de que sus decisiones queden invalidadas. La iniciativa puesta en marcha por la Food Standard Authority constituye una hoja de ruta para el agente inspector, que si sigue minuciosamente su guía podrá completar un procedimiento de inspección legal.

Las perspectivas alemanas y del Reino Unido son bien distintas: mientras la primera vigila el mercado y utiliza la diplomacia como herramienta para mejorar la seguridad del mercado digital, la segunda se centra en mostrar (uno a uno) cómo realizar una inspección en la era digital. Se trata de iniciativas complementarias, sobre las cuales el resto de socios del club europeo puedan diseñar un sistema de control oficial de los @limentos adecuado que combine la eficacia con la protección de los derechos de los sujetos implicados y de los distintos intereses en juego.

Estructura del trabajo

Tras la introducción, la tesis se divide en cuatro capítulos de análisis y uno de conclusiones y propuestas, además de la correspondiente bibliografía. Las principales observaciones sobre las cuales se asientan las conclusiones de esta tesis aparecen destacadas en cuadros a lo largo del texto.

El Capítulo 1 analiza el mercado digital de alimentos en la Unión Europea como fenómeno social nuevo cuyo funcionamiento debe desarrollarse dentro de un marco jurídico concreto. Respecto del marco jurídico, a los efectos de la cuestión en estudio, se considera fundamental entender que la puesta en circulación y el control de los @limentos debe llevarse a cabo con arreglo a las reglas generales aplicables al comercio electrónico si bien siendo el objeto de comercio un alimento, es necesario también cumplir con las pormenorizadas reglas del Derecho Alimentario. Efectivamente, como toda actividad alimentaria, queda sujeta al Derecho Alimentario europeo, sistema jurídico complejo que impone obligaciones de los explotadores de las empresas alimentarias y los poderes públicos para garantizar la seguridad y la calidad de los alimentos, en el mercado digital igual que en el tradicional. En este sentido, en la primera parte del Capítulo 1 se identifican los objetivos, los principios y la estructura del Derecho Alimentario europeo, ya que estos condicionan las previsiones legales de la legislación de control oficial objeto de esta tesis. Por el otro, se da un repaso cronológico a la política de la UE en cuanto a comercio electrónico, y se presentan los elementos principales del marco legal actual para el comercio electrónico, en aquello relevante para la cuestión del control del comercio electrónico de alimentos.

La segunda parte de este primer capítulo proporciona una descripción de las características actuales del mercado digital de alimentos, basada principalmente en observación empírica complementada con datos obtenidos en estudios de mercado y en las entrevistas realizadas durante la fase de investigación de la tesis. En esta sección describe el tipo de explotadores de empresas alimentarias activos en el mercado digital, distinguiendo entre aquellos que operan exclusivamente a través de internet y de plataformas digitales y los que están presentes también en el mercado físico tradicional. Como se identifica en las conclusiones de esta tesis, esta distinción es importante en tanto que el hecho de que una oferta dependa de un explotador que únicamente opera en el mercado digital parece tener un impacto significativo en la seguridad y calidad de la oferta. A continuación, la descripción del fenómeno social analiza el papel de las

plataformas digitales en la distribución de @limentos, prestando especial atención a las normas que dichos intermediarios imponen a aquellos que quieren vender alimentos en su plataforma y comparando su planteamiento con el de otras plataformas llamadas de la economía colaborativa creadas para permitir a los particulares no profesionales ofertar alimentos online. Finalmente, la sección final del capítulo detalla el tipo de alimentos disponibles en el mercado digital, en particular en aquellos tres grupos de productos considerados de mayor riesgo y que son causa de preocupación para autoridades públicas.

El Capítulo 2 analiza la legislación aplicable al control oficial de los productos alimenticios y su aplicación al mercado digital. Los principios generales del control oficial de alimentos están actualmente regulado a nivel de la Unión Europea en el Reglamento 882/2004. Este Reglamento establece un marco básico común para todos los Estados Miembros, si bien sobre la base de sus preceptos cada Estado debe adoptar sus propias normas en cuanto a la organización y ejecución de estos controles. Es por eso que el capítulo analiza primero el marco legal europeo, y a continuación, se estudia el papel de la regulación de los Estados Miembros, utilizando la legislación Española como caso control. El estudio de la normativa nacional presta especial atención a la regulación del registro de establecimientos alimentarios y al procedimiento establecido para realizar las actividades de control material (toma de muestras) en la fase de distribución, puesto que son dos elementos clave a la hora de adaptar el control al mercado digital. Finalmente, se examina cómo debe aplicarse este complejo marco jurídico al comercio electrónico de alimentos, identificando los desafíos a los que se enfrentan las autoridades competentes para poder controlar el mercado digital sin vulnerar los principios y obligaciones establecidos en la legalidad vigente.

En el Capítulo 3 se lleva un cabo el estudio y valoración de los dos casos que pueden considerarse más relevantes y adecuados para efectuar un estudio comparativo que permita extraer resultados aplicables: Alemania y Reino Unido. Las estrategias de ambos países son diversas, pero las dos están encaminadas a mejorar la seguridad y calidad general del mercado digital de los alimentos a través del control oficial. En ambos casos, esta tesis analiza el marco legal estatal que regula la organización administrativa y la ejecución de los controles oficiales en su territorio, con una estructura paralela a la utilizada en el Capítulo 2 a la hora de analizar el marco legal Español.

El primer caso estudiado es el de Alemania, a la cabeza mundial en el control del mercado digital de alimentos. Su estrategia se basa en centralizar el monitoreo en una única unidad

especializada que lidera el control de los @limentos en todo el territorio. La segunda iniciativa que se analiza es la estrategia del Reino Unido para controlar los @limentos; en este caso, en lugar de construir un cuerpo o estructura administrativa nueva, toda la responsabilidad recae sobre las espaldas del personal individual de cada autoridad competente. Aunque pueda parecer inicialmente contradictorio, esta tesis argumenta que ambos enfoques son en realidad complementarios. Esta conclusión se desarrolla en la tercera parte de este capítulo, que lleva a cabo una comparación de ambas estrategias e identifica sus fortalezas y debilidades.

Dado que la tesis sigue un orden cronológico en la aparición de iniciativas para el control del mercado digital de alimentos, las tardías iniciativas de la UE se tratan en el Capítulo 4 de esta tesis. En él se describe y analiza las iniciativas de la Comisión Europea en relación con el control oficial de los @limentos. Para ello, se efectúa primero una revisión histórica de las actuaciones llevadas a cabo entre 2013 y 2018, incluido el reciente plan de control coordinado CCP_efood. A continuación se examina el nuevo Reglamento 625/2017 de control oficial que será de aplicación a partir del 14 de diciembre de 2019 y su impacto en la materia de estudio. Finalmente, la tercera parte de este cuarto capítulo lleva a cabo una evaluación de las iniciativas de la Comisión Europea en relación con los obstáculos identificados en los capítulos anteriores.

El capítulo de Conclusiones recopila las alcanzadas a lo largo de este trabajo de investigación, tanto en relación con las características del mercado digital de alimentos como sobre la situación jurídica actual del control de los @limentos en la Unión Europea. En este capítulo, derivadas del análisis realizado, se incluyen propuestas concretas encaminadas a que aquellos Estados Miembros se plantean ahora establecer un sistema de control de @limentos, no tengan que partir de cero y puedan construir su estrategia sobre las aportaciones de esta tesis.

Finalmente, la bibliografía se articula en los siguientes apartados: en el inicial se recogen los libros y artículos citados así como las obras de referencia básica para el trabajo; en el segundo se aportan las páginas web citadas; en el tercero se recogen los informes de organismos públicos de referencia; a continuación, figura la normativa citada y, para finalizar, la jurisprudencia.

CHAPTER 1.

EUROPEAN DIGITAL MARKET OF FOOD

1. REGULATORY FRAMEWORK APPLYING TO FOOD E-COMMERCE

The electronic trade of food products is a relatively new social phenomenon, but those that engage in food e-commerce must play by the rules that are already in place for the trade of food in the traditional market, as well as specific regulation of e-commerce.

In order to ensure proper comprehension of the particularities of the legal framework that applies to food trade, the first part of this section analyses the goals, principles and structure of Food Law, the responsibilities that the European Union's food safety policy assigns to food businesses and to public authorities, and defines the concept of "food law" that is used in this thesis. The second part of this section describes the evolution of the EU's policy and regulatory framework on e-commerce and its application to the digital market of foods.

1.1. Food law in the European Union

The food system is "an interconnected web of activities, resources and people that extends across all domains involved in providing human nourishment and sustaining health, including production, processing, packaging, distribution, marketing, consumption and disposal of food"¹. The regional food system in the European Union relies on a complex legal framework that aims at protecting consumer interests and health in particular.

A significant number of pieces of legislation governing food safety in Europe were adopted following the Bovine Spongiform Encephalopathy (BSE) crisis of the mid-1990². Between 1996 and 2010 more than 220 people were affected by Creutzfeldt-Jakob

² Van der Meulen, B. (2013). The Structure of European Food Law. *Laws*, 2(2): p.20. Retrieved from http://www.mdpi.com/2075-471X/2/2/69/

¹ Grubinger, V., Berlin, L., Berman, E., Fukagawa, N., Kolodinsky, J., Neher, D., Parsons, B., Trubek, A., & Wallin, K. (2010). *Transdisciplinary Research Initiative Spire of Excellence Proposal: Food Systems*. Vermont: University of Vermont. Retrieved from https://www.uvm.edu/~tri/pdf/FoodSystemsFinal_Profs.pdf

disease, a variant of BSE that since 1986 had been sickening cattle in the United Kingdom. European authorities determined that these patients had become infected by eating beef from infected cattle. This episode, known as the mad cow disease crisis, is considered the most significant food safety crisis that the European Union has faced and the origin of its current "From farm to fork" approach to food safety policy.

Even though many other food safety concerns have grasped the attention of public authorities, industry and individuals' attention, most of the political and legal tools of the EU food safety policy are still today based on the initiatives adopted after that first major crisis, which were defined in the European Commission's White Paper on Food Safety adopted on the 12th January 2000.

The White Paper stated that the European Union's food policy should "be built around high food safety standards, which serve to protect, and promote, the health of the consumer." Food safety is therefore at the very core of the European regulation of the regional food system and public interventions on the food market must be based on safeguarding public health.

EU policy for the assurance ensures the safety of food through comprehensive actions from a global and inclusive perspective that targets all stages of the food chain, regardless of the origin and destination of the food product.

The guiding principle throughout this White Paper is that food safety policy must be based on a comprehensive, integrated approach. This means throughout the food chain ('farm to table'); across all food sectors; between the Member States; at the EU external frontier and within the EU; in international and EU decision-making fora, and at all stages of the policy-making cycle. The pillars of food safety contained in this White Paper (scientific advice, data collection and analysis, regulatory and control aspects as well as consumer information) must form a seamless whole to achieve this integrated approach³.

This guiding principle became law in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁴ (hereinafter, "Regulation 178/2002" or

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³ Paragraph 8 of the Annex of European Commission. COM/1999/0719 final of 12 January 2000 on the White Paper on food safety.

⁴ Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food

"General Food Law" or "GFL"). Adopted on the 28th January 2002, the General Food Law provides the legal definitions of key concepts of European food law. The first article of Regulation 178/2002 states that its main goal is to ensure

a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.

The General Food Law requires that all food-related public initiatives must "pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests"⁵, while ensuring free movement of foods⁶. As repeatedly discussed by academia⁷, EU food law prioritizes protection of the health and other interests of the consumer over free trade. This prioritization is based on the "specificity of food as a commodity, with its life-necessity component and its special socio-cultural value"⁸. Fundamental economic freedoms in general and free movement of

safety. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&qid=1519664164571&from=EN

⁵ Article 5.1 of Regulation (EC) 178/2002 of 28 January 2002.

⁶ In particular, article 5 GFL, on the general objectives of food law, states the following: 1) Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment. 2) Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter. 3) Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.

⁷ Among others: Negri, S. (2009). Food safety and global health: an international law perspective. *Global* Health Governance, Retrieved 3(1). from https://www.researchgate.net/profile/Stefania Negri/publication/265435966 Food Safety and Global H ealth_An_International_Law_Perspective/links/54e515a30cf29865c336006b.pdf; Purnhagen, K.P. (2013). Beyond threats to health: may consumers' interest in food safety trump fundamental freedoms in information on foodstuffs? Reflections on Karl Berger V Freistaat Bayern. European Law Review. Wageningen Working **Papers** in Law and Governance 2003/03. Retrieved http://dx.doi.org/10.2139/ssrn.2276899 and Van der Meulen, B. (2010). The Function of Food Law: On the objectives of food law, legitimate factors and interests taken into account. European Food and Feed Law Review, 5(2), 83-90. Retrieved from http://www.jstor.org/stable/24325791

⁸ Zurek, K. (2016). Food Sharing in Europe: Between Regulating Risks and the Risks of Regulating. *European Journal of Risk Regulation*, 7(4), p. 676. Retrieved from https://doi.org/10.1017/S1867299X00010114

goods in particular should be "achieved only for foods that are in compliance with the legislation pursuing protection of health or (other) consumer interests".

Protection of business interest is not specifically mentioned as an objective of the food law¹⁰. Case law from the Court of Justice of the European Union¹¹ reflects how – when it comes to food law - "the challenge is to work out how the difficult interface between [trade and health] can be managed"¹². Legislators, administrative bodies and courts must carry out a cost-benefit analysis that balances health risks that a decision seeks to mitigate and its negative impact on business interests.

The first requirement of food law is that food must not be placed in the market if it is unsafe. Although Regulation 178/2002 provides a definition of the most relevant concepts involved in food safety, this regulation nor any other European Union's piece of legislation or policy document provides a definition of "food safety" itself¹³. Instead of

⁹ Van der Meulen, B. (2010). The Function of Food Law: On the objectives of food law, legitimate factors and interests taken into account. *European Food and Feed Law Review*, 5(2), p. 85. Retrieved from http://www.jstor.org/stable/24325791

¹⁰ Ibid.

¹¹ The Hückel Case 242-/2002, that resulted in the decision to article evoke the authorization to commercialize virginiamycin, antibiotic as a feed additive for growth in pigs and poultry. In its Judgement, the ECJ revoked the original authorisation because, "despite uncertainty as to whether there was a link between the use of antibiotic additives and increased resistance to those antibiotics in humans, the withdrawal of authorisation for the products was not a disproportionate measure given the need to protect public health" at Australian Pesticides and Veterinary Medicines Authority. (2004). Findings of the reconsideration of the registration of products containing virginiamycin, and their labels: these findings form the basis for regulatory action to be taken by the APVM, p.18. Retrieved from http://www.apvma.gov.au/chemrev/virginiamycin findings.pdf

Negri, S. (2009). Food safety and global health: an international law perspective. Global Health Governance, 3(1), p. 6. Retrieved from https://www.researchgate.net/profile/Stefania_Negri/publication/265435966_Food_Safety_and_Global_Health An International Law Perspective/links/54e515a30cf29865c336006b.pdf

¹³ There is also no legal definition of this concept at the international level. The World Health Organization's Program for Food Safety does not provide a definition of the term. However, it does define "food hygiene" as "(...) conditions and measures necessary to ensure the safety of food from production to consumption. Food can become contaminated at any point during slaughtering or harvesting, processing, storage, distribution, transportation and preparation. Lack of adequate food hygiene can lead to foodborne diseases and death of the consumer." This definition suggest that food products which are not hygienic are unsafe, but it does not clarify if lack of hygiene is the only cause to consider a food unsafe. Only the independent, non-governmental international organization (ISO) provides a working definition of "food safety" in article 3.1 of ISO Standard 22000:2005 on Food safety management systems. This definition has no legal validity and is only applicable when deciding if a facility complies with this standard during an audit. According to ISO 22000:2005, food safety may be defined as follows: "3.1. Food safety: concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use. [...] Food safety is related to the occurrence of food safety hazards and does not include other human health aspects related to, for example, malnutrition." The significance of this definition is clear: a foodstuff is considered safe under ISO 22000:2005 provided it will not sick consumers that eat it following manufacturer's use guidelines and that it has not been exposed to hazardous substances or situations (such

defining "safe food" article 14 (2) of the General Food Law provides a set of requirements that should allow for a definition of what constitutes "unsafe food" together with a set of presumptions on the safety of food¹⁴. The key concepts to establish if a food product is "unsafe" are the "injurious to health" and "unfit for human consumption," which have been extensively discussed and analysed both by public authorities¹⁵ and academia¹⁶. This thesis does not aim at furthering this debate, and will take into consideration the following:

- a. A food product introduced in the market in compliance with EU or national food law is considered safe unless a risk assessment proves otherwise.
- b. A food product is "injurious to health" when consumption under normal conditions of use can potentially harm human health.
- c. A food product that has been placed in the market in compliance with food regulations and that is not potentially harmful for humans may be considered "unfit for human consumption" because of "the presence of foreign objects, unacceptable taste or odour" among others.

Thus, the term "safe food" will be used to refer to the fact that a food product (i) has been produced and introduced in the market in compliance with EU or national food law, and (ii) no circumstances have turned it injurious to health (potential to harm human health) nor unfit for human consumption (unacceptable).

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as high temperatures that may allow for the proliferation of microorganisms that may pose a threat to human health).

¹⁴ Article 14.2 of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Retrieved from http://eurlex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&qid=1519664164571&from=EN

¹⁵ European Commission. (2010). *Guidance on the implementation of articles 11, 12, 14, 17, 18, 19 and 20 of regulation (EC) 178/2002 on general food law. Conclusions of the standing committee on the food chain and animal health.* Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf

¹⁶ Among others: Polinski, D. (2017). *Application and Interpretation of the concept 'unfit for human consumption' according to Article 14 (2) (b) Regulation (EC) No 178/2002 in the European Union*. Thesis Msc. Food Safety Law. Law and Governance Group of Wageningen. Retrieved from http://edepot.wur.nl/421921

¹⁷ European Commission, *op. cit*.

However, latest research¹⁸ shows that this definition (although useful to limit the scope of official controls) falls short according to consumers' insight:

The consumer's view of safety may be different—and broader—than how we typically define it in the food industry. When considering the scope of "safety," consumers' perception includes absence of allergens; fewer ingredients; and detailed, accurate labelling. (...) The report notes that consumers remain concerned with the short-term, and long-term, impacts of food on their health, (...) This reinforces that a consumer's view of food safety is quite different from our own. The report goes on to say that consumers intimately tie safety to health and wellness and supports the idea that consumers take much more holistic view of safety and health than ever before¹⁹

The General Food Law assigns food businesses the primary responsibility of ensuring the foods their place in the market are safe. It also the legal basis for the organization of the control system, which assigns both EU and national authorities with the responsibility of enforcing food law and of verifying if businesses that comply with food law requirements and of managing food risks.

Additionally, Regulation 178/2002 created the Food Safety Authority (hereinafter "EFSA"), which provides scientific advice and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. Based in Parma, Italy, EFSA is in charge of providing competent authorities at the European and national level with independent scientific opinions "which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission." EFSA is therefore the head risk assessor in food matters in the European Union, while the European Commission and Member States remain risk managers in the field.

Moreover, the Regulation defined the Rapid Alert System for Food and Feed (hereinafter "RASFF"). Enshrined in articles 50, 51 and 52 of the General Food Law²⁰, it is a tool that ensures cross-border, constant and transparent flow of information on food related risks

¹⁹ McEntire, J. (2016, April 8). Consumers broaden the definition of food safety. Quality Assurance & Food Safety [Web log post]. Retrieved from http://www.qualityassurancemag.com/article/consumers-broaden-the-definition-of-food-safety/

¹⁸ Ringquist *et al.*, (2016). *Capitalizing on the shifting consumer food value equation*. Deloitte. Retrieved from https://www2.deloitte.com/us/en/pages/consumer-business/articles/us-food-industry-consumer-trends-report.html

²⁰ RASFF's regulation is further developed by Commission Regulation (EU) 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed. Retrieved from http://eurlex.europa.eu/legal-content/EN/TXT/?qid=1520700770092&uri=CELEX:32011R0016

between competent authorities in all EU Member States, the Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland. RASFF is "an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed"²¹. It helps authorities to contain or eliminate potential risks to human health. RASFF notifications include Alerts Notifications (information on specific food products that entail serious health risk and that are already on the market and about which rapid action by competent authorities in each Member State is required), Information Notifications (that do not require immediate action), and Border Control Rejections (which entail that a food consignment has been tested is rejected before entering the EU because a health risk has been identified).

As provided for in the White Paper on food safety, food law requirements and the obligations assigned in Regulation 178/2002 to business and authorities, "relate to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals"²². The legal framework does not only focus on foods once they are made available to the final consumer, but instead it applies to "the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed"²³.

This was a fundamental change regarding how Europe deals with food safety, because previous policy focused only on ensuring food safety once foodstuffs were made available to the final consumer. Today, regulation includes extensive legislation applicable to primary production stages, such on the as raw materials that can be used in the preparation in feed for animals intended for human consumption. With this new approach, public authorities seek to avoid a new mad cow disease crisis by ensuring the health of animals that will potentially become food for human consumption.

Lastly, acting "from farm to fork" safeguards the safety not only of food within the European frontiers, but of those food products that are exported to other regions ("unless otherwise requested by the authorities of the importing country or established by the laws,

European Commission. (n.d.). *How does RASFF work*. Retrieved from https://ec.europa.eu/food/safety/rasff/how_does_rasff_work_en

²² Article 14.2 of Regulation (EC) 178/2002 of 28 January 2002.

²³ Regulation (EC) 178/2002 of 28 January 2002.

regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country")²⁴. Given that the food chain today has become a global system, focussing on what happens inside the European territories would mean disregarding potential threats to EU food safety. The current strategy aims at exporting the European model of food risk management to other geographical areas. The European Union and its Member States must contribute to the development of international regulations and encourage coordination among international stakeholders to ensure food safety²⁵.

1.1.1. Principles governing food law in the European Union

Following the mandate of the White Paper, the General Food Law states that food law and policy is to be governed by three principles: (i) science-based risk assessment is the basis for law, (ii) the precautionary principle allows public powers to define mechanisms that prevent or contain unacceptable risks for consumers, and (iii) food law shall ensure that intervention on the food system remains transparent.

1.1.1.1. Science as the base of food law

According to Regulation 178/2002, food law protecting human health should be based on risk analysis, thus on science²⁶. By application of this first principle, any public action taken to ensure food safety should be based on the existence of indirect or direct objective risks identified by strong scientific and technical evaluations developed according to independent and transparent action protocols. Article 6 of the General Food Law states that public powers must rely on science when adopting measures that affect the food system:

- 1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
- 2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
- 3. Risk management shall take into account the results of risk assessment (...).

²⁴ Article 10 of Regulation (EC) 178/2002 of 28 January 2002.

²⁵ Recuerda Girela, M.A. (2014). Los principios generales del derecho alimentario europeo. *Revista de derecho de la Unión Europea*, 26; p. 180. Retrieved from https://dialnet.unirioja.es/servlet/articulo?codigo=4598554

²⁶ Van der Meulen, B. (2009). The System of Food Law in the European Union. *Deakin Law Rev*, 14(2): p. 18. Retrieved from https://ojs.deakin.edu.au/index.php/dlr/article/viewFile/145/144

For example, food safety targets, which are defined as the "legislation setting limits to the presence of undesirable substances (contaminants, toxins, residues of pesticides or veterinary drugs) or organisms in food"²⁷, must be based on scientific knowledge. A good example of the above is Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. The Regulation, which sets the European list of food additives and their conditions for use, states that decision to include a substance as a food additive must be taken "on the basis of the scientific evidence available", and that it may be revised "in the light of scientific progress and technological development."

Actions by public administrations and their representatives and staff, both during the performance of controls or while managing an emergency and crisis situation, must be based on scientific risk assessment. Deciding to perform inspections or to sample specific food products should be based on a risk-based approach, and measures such as product recalls must respond to the evaluation of scientifically-identified risks which may threaten consumer health.

Leading scientific risk assessment is part of the mission of EFSA. The Authority must "express independently its own conclusions and orientations"²⁸. However, EFSA's independence has been repeatedly questioned, as "and there has been criticism from some non-organizations and the European Parliament that EFSA's scientific committees and Management Board are not sufficiently independent"²⁹. Possible conflict of interest of EFSA's managers and scientists have been reported, resulting in a severe reputation crisis. In order to tackle allegations about conflicts of interest within the organization, and after an open consultation carried out during the spring of 2017, in June of that year EFSA published a new independence policy. Nevertheless, both the European Parliament and the organisations that brought the issue of independence in the first place were not satisfied. For example, the Corporate Europe Observatory warned:

Our analysis of the new policy shows that actual improvements are likely very limited. The scope for assessing conflicts of interests for experts on EFSA's

²⁷ Van der Meulen, B. (2013). The Structure of European Food Law. *Laws*, 2(2): p. 14. Retrieved from http://www.mdpi.com/2075-471X/2/2/69/

²⁸ Article 23 (k) of Regulation (EC) 178/2002 of 28 January 2002.

²⁹ Alemanno, A., & Gabbi, S. (2014). Foundations of EU Food Law and Policy. Ten Years of the European Food Safety Authority. Routledge, New York.

scientific advice panels appears to remain much too narrow, which would render it unfit to phase out financial conflicts of interests in the agency³⁰.

Other groups have also shown concerns regarding the new policy's effectiveness when it comes to reducing conflicts of interest may be limited.

1.1.1.2. The precautionary principle

The precautionary principle is referred to in article 7(1) of Regulation $178/2002^{31}$:

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

This principle provides "an option open to risk managers when decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way"³².

When a complete scientific evaluation on a potential food-related risk is still pending, or when scientific uncertainty prevails, public officials must consider if action needs to be taken in order to avoid or minimize risks to consumer health. The precautionary principle provides legal basis for public powers to interfere in the market of foods when facing a possible threat to health, in a setting where public action is normally not present. Decision-makers must assess the costs and benefits of their intervention, both in the long-and short-term. The decision to act must not only be based on economic considerations, but also on such factors as the acceptability of the measures by the public, or its impact in public health. As acknowledge by the European Commission,

As indicated in Paragraph 3 of the European Commission's Communication on the precautionary principle COM/2000/0001 final, the application of the precautionary principle in food law is not included in the Treaty for the Functioning of the European Union, (...) which prescribes it only once – to protect the environment. But in practice, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community.

³⁰ Corporate Europe Observatory. (2017, June 22). New EFSA independence policy likely rejects most Parliament demands. Retrieved from https://corporateeurope.org/pressreleases/2017/06/new-efsa-independence-policy-likely-rejects-most-parliament-demands

³² Food and Agriculture Organization of the United Nations. (2002, February 28). *General Principles of Food Law in the European Union* presented at FAO/WHO Pan-European Conference on Food Safety and Quality, Budapest. Retrieved from http://www.fao.org/tempref/docrep/fao/Meeting/004/ac340e.pdf

Under varying degrees of pressure from public opinion - decision-makers have to respond. (...) The appropriate response in a given situation is thus the result of an eminently political decision, a function of the risk level that is "acceptable" to the society on which the risk is imposed³³.

The precautionary principle does not only inform public initiative when dealing with an emergency or crisis situation, or when in the framework of controlling business' compliance with, food a potential direct or indirect risk to health is observed. The precautionary principle also legitimates legislative decisions to limit or prohibit the use of specific substances or ingredients which risk assessments have not been completed or have been proven inconclusive.

However, it cannot be used to justify all kinds of intervention from public powers. As prescribed in the General Food Law³⁴, actions must be

proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), subject to review, in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment³⁵.

When considering taking action on the basis of the precautionary principle, authorities must not only consider if actions need to be taken, but must also analyse what actions are better suited to eliminate or limit the potential hazard while not imposing unnecessary burdens to business, all while using scientific evidence to inform their choices for a course of action.

Lastly, measures taken on the basis of the precautionary principle must be limited in time. They "should be maintained as long as the scientific data are inadequate, imprecise or

³³ European Commission. COM/2000/0001 final. Communication of 2 February 2000 on the precautionary principle. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=EN

³⁴ Article 7 (2) of Regulation (EC) 178/2002 of 28 January 2002, reads as follows: Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

 $^{^{\}rm 35}$ Paragraph 6 of COM/2000/0001 final of 2 February 2000.

inconclusive and as long as the risk is considered too high to be imposed on society"³⁶. Therefore, even though in some situations it may be necessary to set a specific end date for these measures, in most cases they will be lifted when scientific knowledge exists to settle the matter in consideration.

1.1.1.3. Principle of transparency in public action

Public action must be conducted in a transparent manner to ensure consumer confidence in the food safety system.

La transparencia es esencial al menos por dos razones: primero porque permite a los ciudadanos formarse una opinión sobre los problemas que manejan los poderes públicos y las decisiones que adoptan, y consiguientemente les facilita la participación con conocimiento en tales decisiones, a través de distintos cauces, y la exigencia de responsabilidades o rendición de cuentas³⁷.

The premise behind the transparency principle is simple: concealment of information - or consumer perception that such concealment exists- increases consumers' mistrust in the system. This is not only true during a crisis but also applies to all public action intended to ensure food safety. To comply with the principle of transparency, authorities should provide individuals, businesses and civil society in general with access to accurate, complete and clear information about the food system and its management.

In order to fulfil the obligations that arise from the transparency principle analysed in the next subsection, the information generated by the RASFF system is made accessible to citizens and industry via the "RASFF Portal"³⁸, which only excludes from publication information protected by confidentiality obligations. Users can browse through all existing notifications, identified and use search criteria to filter those referring to a specific hazard, food product or country.

Transparency requires constant communication between authorities and citizen. The dialogue should be continuous, and not limited to the adoption of new legislation.

³⁶ COM/2000/0001 final of 2 February 2000

³⁷ Recuerda Girela, M.A. (2014). Los principios generales del derecho alimentario europeo. *Revista de derecho de la Unión Europea*, 26; p. 182. Retrieved from https://dialnet.unirioja.es/servlet/articulo?codigo=4598554

³⁸ European Commission. (n.d.) *RASFF Portal*. Retrieved from: https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1

La experiencia demuestra especialmente en el sector alimentario que cuando las decisiones se adoptan en la oscuridad, y se trata de ocultar lo que está sucediendo, por ejemplo ante un incidente alimentario, se incrementa la desconfianza de los consumidores. El mantenimiento de confianza de los consumidores es muy importante en el ámbito alimentario porque habitualmente cuando se genera desconfianza se suele producir un mayor rechazo, que puede ser generalizado, a todos los lotes o productos de una marca, y esto suele tener consecuencias económicas nefastas³⁹.

However, EU institutions and national authorities do not always correctly assess what information individuals may consider of public interest and therefore should be publicly available. But lack of communication erodes consumer trust, which can affect the food sector and its institutions significantly. This was recently made clear regarding the public disclosure of the risk assessment of the toxicological profile of the active substance glyphosate⁴⁰, which resulted in severe damage not only to EFSA's reputation but to European risk assessment procedures in general.

1.1.2. Distribution of responsibilities

Food products must be safe, and for that all stakeholders must have a proactive role. Thus, when it comes to ensuring the safety of the European single market of food products, Article 17 of the General Food Law assigns responsibilities to those that offer food products, and to public authorities.

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³⁹ Recuerda Girela, M.A. (2014). Los principios generales del derecho alimentario europeo. *Revista de derecho de la Unión Europea*, 26; p. 183. Retrieved from https://dialnet.unirioja.es/servlet/articulo?codigo=4598554

⁴⁰ As described by EFSA, "Glyphosate is an active substance that is widely used in pesticides. Glyphosatebased pesticides – i.e. formulations containing glyphosate and other chemicals – are used in agriculture and horticulture primarily to combat weeds that compete with cultivated crops. They are typically applied before crops are sown and as a pre-harvest desiccating treatment, accelerating and evening the ripening process." It is also the active substance of the popular plant protection product Roundup (trade name of the produced by Monsanto, whose patent expired in 2000). By the end of 2015, the Authority published its favourable opinion to the renewal of the approval of this active substance for its use in plant protection products for agriculture. Risk assessment at the EU level was contested by non-governmental organizations because of the initial decision to maintain part of the dossier for evaluation unpublished and later, because part of the conclusions in the risk assessment report were extracted from Monsanto's risk assessment reports included in the dossier. In a climate of tension, in January 2017 and just before the EU's Standing Committee for Food Chain and Animal Health voted on the regulation to renew the approval based on EFSA's conclusions, the citizen initiative for the "Ban glyphosate and protect people and the environment from toxic pesticides" was registered. The political crisis was apparently put to an end in November 2017 when the Committee voted on a five-year renewal period for the active substance glyphosate, leaving EFSA's reputation severely damaged even if the legal validity of its risk assessment was never contested.

1.1.2.1. Responsibility of food businesses

Compliance with food law requirements is responsibility of those who engage in food trade, regardless of the legal nature of their "undertaking"⁴¹. Private or public companies are considered food business operators and must ensure compliance with food law.

The "food business operator" (also, "operators" and in Spanish "explotadores"), a concept which is defined in article 3 of the General Food Law, is the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control⁴². Even if the word "business" is part of the concept, this does not mean that food law applies only to commercial activities.

The General Food Law defines a "food business" as any "undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food." All of those in charge of any food-related activity are considered a food business, and the fact that the business is carrying out its activities for profit or for none is not relevant.

The General Food Law applies to all undertakings regardless of their trading form. The fact that it is a corporation, a professional service provider or a charity is not relevant to food law. All of them can be food business operators. This includes of course food brokers, who are not in possession of the food or components they own, but still

(...) purchase or take ownership of food for resale to other businesses, such as manufacturers, retailers, caterers or other brokers, you may be operating as a food broker. Even though you may or may not take physical possession of food, you are supplying food to other businesses and would be classed a food business operator⁴³.

⁴¹ The concept of "undertaking" has a specific definition in food law, as will be explained in section 1.3.2 of Chapter 2 of this thesis.

⁴² However, responsibility in the context of GFL should not be confused with allocation of liability, which "will not be based on Article 17 of GFL but on a legal basis to be found in the national legal order and in the specific infringed legislation; in other terms this Article does not have the effect of introducing a Community regime regulating the allocation of liability among the different links of the food chain. Determining the facts and circumstances which may render an operator liable to criminal penalties and/or civil liability is a complex matter which depends very much on the structure of the different national legal systems". At Lex Studio Legale Alimentaria. (2010). Shortcomings in enforcing EU food law. What does EU food law stand for? p.21. Retrieved from http://regulation.upf.edu/dublin-10-papers/2F4.pdf

⁴³ Food Standards Agency. (2016d). *Food Brokers Questions & Answers Document*. Retrieved from https://www.food.gov.uk/sites/default/files/food-brokers-qa.pdf

Food law obligations do not only apply to those making food products available to the final consumer, but to all food business operators in the food chain, from farm to fork.

Once the nature of an undertaking as a food business has been established, however its responsibilities are clearly set in article 17(1) of the General Food Law:

Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

Food businesses must be proactive and adopt the role of inspector, checking the materials and ingredients received are safe, that they are properly handled, and then transfer the information necessary to the next phases the food chain to ensure that potential problems can be detected early. As acknowledge by the European Commission,

Article 17 (1) imposes on food business operators an obligation according to which they must actively participate in implementing food law requirements by verifying that such requirements are met. This general requirement is closely linked to other mandatory requirements laid down by specific legislation (i.e. HACCP implementation in the field of food hygiene) ⁴⁴.

The General Food Law lists the three essential responsibilities of food business operators⁴⁵:

- A control system must exist in order to ensure that food products are safe, as required by article 17. The requirements of such food safety management system are further developed in the Food Hygiene⁴⁶ Regulation, which identifies the Hazard Analysis and Critical Control Points system (hereinafter, "HACCP") and sets what documentation and verification procedures are required.
- A traceability system must ensure that withdrawal or recall of food products is done efficiently. Traceability systems are used to allow operators to quickly identify who supplied them the food product ("one step back") and who they

⁴⁴ Regulation (EC) 178/2002 of 28 January 2002.

⁴⁵ As will be analysed further in this thesis, other pieces of legislation provide additional responsibilities and obligations, such as registration requirements.

⁴⁶ Regulation (EC) 852/2004 of 29 April 2004.

transferred it to ("on step forward"), and are a requirement of article 18 of Regulation (EC) 178/2002.

Recent food scares (BSE and dioxin crisis) have demonstrated that the identification of the origin of feed and food is of prime importance for the protection of consumers. In particular, traceability helps facilitate the withdrawal of food and enables consumers to be provided with targeted and accurate information concerning implicated products. Traceability does not itself make food safe. It is a risk management tool to be used in order to assist in containing a food safety problem⁴⁷.

Traceability also is a useful tool for competent authorities when verifying the origin of a food product. For example, traceability documents can be used when dealing with organic food products in order to assess if they have been grown by a certified agent. In order to comply with traceability requirements, information about the name and address of the supplier or buyer must be kept, together with a list of the products received or transferred. It must be noted that "a food business operator must identify only the other businesses (legal entity) to whom it provides its products (excluding final consumers)"⁴⁸. Indeed, "food crises in the past have shown that tracing the commercial flow of a product by keeping invoices was not sufficient to follow the physical flow of the products, as food/feed could be, for example, sent for storage"⁴⁹.

Collaboration with competent authorities in the event of food scares is a responsibility enshrined in article 19 of the General Food Law. This provision mandates that in the event of an operator suspecting that a food product is not safe, "steps must be taken immediately to withdraw the product from the market and inform the competent authorities." The extent of this collaboration varies on a case-by-case basis, and can range from informing the public, to withdrawing a product from the market or making a product recall.

Because food law does not differentiate between the digital and the traditional food chain and market of foods, these general obligations (as well as all the responsibilities enshrined

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⁴⁷ Regulation (EC) 178/2002 of 28 January 2002.

⁴⁸ Ibid

⁴⁹ Lex Studio Legale Alimentaria. (2010). *Shortcomings in enforcing EU food law. What does EU food law stand for?* p. 19. Retrieved from http://regulation.upf.edu/dublin-10-papers/2F4.pdf

in other pieces of food law) are also applicable to food business operators that engage in food e-commerce.

1.1.2.2. Responsibilities of public powers

The General Food Law assigns food businesses the responsibility to prevent unsafe food products from reaching the market, and to public authorities that of verifying "that this responsibility is adequately met by the producers to protect the health and well-being of consumers"⁵⁰. This "verification role"⁵¹ is secondary to the obligations of businesses, ⁵² but still has entailed the configuration of a complex control system in every Member State under the supervision of the European Commission.

Article 17 (2) of the General Food Law requires Member States to "maintain a system of official controls" that allow for proper monitoring and verification of compliance with food law, as well as to "lay down the rules on measures and penalties applicable to infringements of food and feed law [that are] effective, proportionate and dissuasive."

This provision is the legal basis of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (hereinafter, "Regulation 882/2004"). Also known as the Compliance Regulation⁵³, this piece of legislation "contains the general obligations Member States have to comply with in carrying out official control of food," which include "obligations concerning: verification by the Member States; measures to be taken in case of infringement; a framework for cooperation between national authorities and the Commission; and the

⁵⁰ Ministry of Agriculture, Nature and Food Quality and the Food and Consumer Product Safety Authority of the Netherlands. (2005). *European food safety control systems: new perspectives on a harmonized legal basis*. Retrieved from http://www.fao.org/docrep/meeting/008/y5871e/y5871e0l.htm#bm21

⁵¹ Nieto Martín, A., Quackelbeen, L., & Simonato, M. (Eds.). (2016). *Food Regulation and Criminal Justice*. Maklu-Publishers, Belgium, p.74.

 $^{^{52}}$ Van der Meulen, B. (2013). The Structure of European Food Law. Laws, 2(2):72. Retrieved from $\underline{\text{http://www.mdpi.com/2075-471X/2/2/69/}}$

⁵³ Purnhagen, K.P. (2013). Beyond threats to health: may consumers' interest in food safety trump fundamental freedoms in information on foodstuffs? Reflections on Karl Berger V Freistaat Bayern. *European Law Review.* Wageningen Working Papers in Law and Governance 2003/03, p. 8. Retrieved from http://dx.doi.org/10.2139/ssrn.2276899.

⁵⁴ Lex Studio Legale Alimentaria. (2010). *Shortcomings in enforcing EU food law. What does EU food law stand for?* p. 5. Retrieved from http://regulation.upf.edu/dublin-10-papers/2F4.pdf

Commission's monitoring of the performance of national authorities in the Member States and in third countries" 55.

The Compliance Regulation is the European piece of legislation that currently applies to official controls, and described in section -- of Chapter 2 of this thesis.

The legal framework established in the Compliance Regulation will be replaced in December 14th 2019 by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (hereinafter, "Regulation 625/2017" or "Official Controls Regulation").

This thesis analyses official controls in the European Union under the Compliance Regulation, because it is the piece of legislation that is currently framing public authorities' activities regarding food law compliance. Nevertheless, Chapter 4 focuses on the impact of the new Official Controls Regulation, the forthcoming legal framework for official controls.

1.1.3. About the legal framework applying to consumer-to-consumer food exchanges

The General Food Law does not differentiate between natural and legal persons. Sole traders, free lancers, and "autónomos" in Spanish law are considered food businesses which have responsibilities as operators. But, it is unclear if private individuals offering food products online on an occasional basis should also be considered undertakings with

⁵⁵ Van der Meulen, B. (2009). The System of Food Law in the European Union. *Deakin Law Rev*, 14(2): p. 27. Retrieved from https://ojs.deakin.edu.au/index.php/dlr/article/viewFile/145/144

food law obligations. In other words, is consumer-to-consumer (or peer-to-peer) trade subject to food law? And to official controls?

This question has no easy answer. On the one hand, Regulation 178/2002 states that "primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption"⁵⁶ is excluded from the scope of food law. The food an individual grows and cooks at home, to be consumed by himself, his family and friends is outside the scope of food law. This is the only handling of food that is excluded from the scope of the General Food Law.

In accordance, article 14 of Regulation 178/2002 mandates that food products that are placed in the market must not be unsafe, making it a general premise regardless of who makes the placement. Also, Member States have the responsibility "to enforce the food law" regardless of how the product got to the market. Monitoring and verifying "that the relevant requirements of food law are fulfilled by food and feed business operators" is a relevant but complementary obligation of public authorities.

Peer-to-peer food exchanges appear to be included within the scope of the General Food Law and must therefore comply with food law.

But on the other hand, Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (hereinafter, the "Hygiene Regulation" or "Regulation 852/2004"), which further develops operators' responsibilities when it comes to food hygiene, raises doubts about this interpretation.

Regulation 852/2004 excludes from its application the following food-related activities:

- (a) primary production for private domestic use;
- (b) the domestic preparation, handling or storage of food for private domestic consumption;
- (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
- (d) collection centers and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatin or collagen⁵⁸.

⁵⁶ Article 1.3 of Regulation (EC) 178/2002 of 28 January 2002.

⁵⁷ Article 17.2 of Regulation (EC) 178/2002 of 28 January 2002.

⁵⁸ Article 1.2 of Regulation (EC) 852/2004 of 29 April 2004.

While exceptions a) and b) coincide with the exclusion of domestic preparations already present in the General Food Law, the Hygiene Regulation also excludes small quantities of primary products⁵⁹ and collections centers and tanneries from its scope. These two activities are still within the scope of food law and, while they don't have to comply with the specific obligations that hygiene law imposes to food business operators,⁶⁰ the food products placed in the market must still be safe as General Food Law mandates.

Thus, Regulation 852/2004 does not explicitly exclude peer-to-peer food trade from its scope. However, Recital 9 of the same piece of legislation states the following:

Community rules should not apply either to primary production for private domestic use, or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, they should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organization.

About this passage, the EU Commission interpreted in 2012 the following:

Somebody who handles, prepares, stores or serves food occasionally and on a small scale (e.g. a church, school or village fair and other situations such as organized charities comprising individual volunteers where the food is prepared occasionally) cannot be considered as an "undertaking" and is therefore not subject to the requirements of Community hygiene legislation⁶¹.

Given that consumer-to-consumer trade entail that somebody handles, prepares, stores or serves food occasionally and on a small scale, it is my view that food products traded by private individuals on an occasional basis still need to be safe in accordance with the General Food Law, but do not have to comply with the specific obligations that Hygiene Regulations impose to food business operators.

⁶⁰ Article 1.3 of Regulation (EC) 852/2004 of 29 April 2004, indicates that Member States can decide to regulate their hygiene requirements.

provisions of Regulation (EC) No 852/2004 On the hygiene of foodstuffs, p. 9.

http://trade.ec.europa.eu/doclib/docs/2013/june/tradoc_151371.pdf

Retrieved from

⁵⁹ This concept has been analyzed by the European Commission: In general terms, the notion "small quantities" should be broad enough to allow inter alia: 1) Farmers to sell primary products (vegetables, fruits, eggs, raw milk, etc.) directly to the final consumer e.g. farm gate sales or sales at local markets, to local retail shops for direct sale to the final consumer and to local restaurants. 2) Individuals who collect products in the wild such as mushrooms and berries to deliver their yield directly to the final consumer or to local retail shops for direct sale to the final consumer and to local restaurants at European Commission. Health and Consumers Directorate-General. (2012). *Guidance document on the implementation of certain*

⁶¹ European Commission. (2012b). *Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 On the hygiene of foodstuffs*, p. 11. Retrieved from http://trade.ec.europa.eu/doclib/docs/2013/june/tradoc_151371.pdf

Food products placed in the market by consumers (or peers) fall within the scope of the General Food Law thus must be safe. However, they fall outside the scope of the Hygiene Regulations.

Only those individuals whose activity "implies a certain continuity of activities and a certain degree of organization" must comply with the Hygiene Regulations. However, it is not clear how to interpret this passage.

Peer-to-peer commerce of food products has a relevant role in the digital world⁶². Digital platforms enable amateur cooks and other private individuals to offer food products to their peers. Food sharing has always been present in society, but doing it online implies that food products (and the risks they may entail) "move from the scale of local community of neighbours, to the online community of strangers" Offers are often placed regularly by the same person, and it is common that platforms do not identify those offers as coming from non-professional individuals. As a result, it is difficult for consumers to differentiate between food business operators and home-based offers.

Given that this thesis deals with challenges official controls of food products offered online, it falls within its scope to analyse the challenges of controlling e-foods placed in the market by consumers (or peers). To that end, the comparative study in Chapter 3 refers not only to how Germany and the United Kingdom are dealing with controls on traditional operators, but also with offers placed by private individuals offering services on an occasional basis.

1.1.4. The definition of "food law" that applies to this thesis

The General Food Law defines the legal concept of food as any "substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans." As stated in article 2, this includes any

Drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It

⁶² As will be described in section 2.2.3 of Chapter 1.

⁶³ Zurek, K. (2016). Food Sharing in Europe: Between Regulating Risks and the Risks of Regulating. *European Journal of Risk Regulation*, 7(4), 681. Retrieved from https://doi.org/10.1017/S1867299X00010114

includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

The Regulation goes further, listing all types of substances and products of different nature that should not be considered as food⁶⁴, such as plants before harvest and medicines⁶⁵. Given this definition of food, the concept of food law does not only refer to technical regulations defining the characteristics of a specific food product (such as those on olive oil or dairy products), but includes all

The laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals⁶⁶.

Food laws do not only have to do with ensuring the safety of food. They also aim at the protection of other consumer interest (such as healthy eating and environmentally friendly food production), and shall provide a basis for consumers to make informed choices in relation to the foods they consume⁶⁷. The prevention of fraudulent or deceptive practices, including adulteration as well as "any other practices which may mislead the consumer," also fall within the scope of food law.

Given the vast scope of food law and the significant the amount of pieces of legislation it includes, EU food law has been described as "a very impressive set of rules covering a

⁶⁴ The following are not considered food: (a) feed; (b) live animals unless they are prepared for placing on the market for human consumption; (c) plants prior to harvesting; (d) medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2); (e) cosmetics within the meaning of Council Directive 76/768/EEC (3); (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4); (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971; (h) residues and contaminants.

⁶⁵ Also, medicines are explicitly excluded from the scope of the General Food Law, and have a separate regulatory framework based on Directive (EC) 2001/83 of the European Parliament and the Council, of 6 November 2001, on the Community code relating to medicinal products for human use.

⁶⁶ Paragraph 1 of article 3 of Regulation (EC) 178/2002.

⁶⁷ As stated in article 8 of Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&qid=1519664164571&from=EN

large number of aspects of the food chain and of activities of public authorities (...), a great baroque cathedral whose entry is hidden"68. But,

On a closer look, however, this legislation can be structured in a rather straightforward manner, into public powers of implementing the law, law enforcement and incident management on the one hand, and legislation addressing food businesses on the other. The latter legislation can mostly be grouped in one of three categories: legislation on the product, legislation on the process, and legislation on the presentation of food products ⁶⁹

Either through regulations or directives, food law in the European Union includes essentially five types of rules:

- Product standards, which regulate the characteristics that a certain food product must meet in order to be marketed in the EU with a specific legal name. A product standard establishes a legal definition for a food, indicates which ingredients should or should not be present in the product and in what quantity, as well as other aspects that may be relevant (such as acidity, in the case of olive oil). Few EU product standards exist. They are only adopted for food products for which it is understood that a homogenization of characteristics and labelling is necessary to ensure the proper functioning of the internal market. A paradigmatic example of food whose commercialization is subject to a community product standard is olive oil, for which the EU establishes the legal definitions of different olive oil categories, and other elements such as the adjectives that can be included on the label to praise the oil without causing confusion in the consumer. The decision to regulate this product is not accidental, since it is a foodstuff frequently traded internationally with history of misleading practices.
- Rules relating to production methods, which aim at protecting food products
 manufactured following practices that are considered worth protecting. It
 includes laws on organic production, the regulation of Designations of Origin,
 and Protected Geographical Indications, among other.

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⁶⁸ Lex Studio Legale Alimentaria. (2010). *Shortcomings in enforcing EU food law. What does EU food law stand for?* p. 32. Retrieved from http://regulation.upf.edu/dublin-10-papers/2F4.pdf

⁶⁹ Van der Meulen, B. (2010). The Function of Food Law: On the objectives of food law, legitimate factors and interests taken into account. *European Food and Feed Law Review*, 5(2), 86. Retrieved from http://www.jstor.org/stable/24325791.

- Rules on safety targets focus on the conditions of use of certain substances or
 materials that are used in the manufacture of food products. A relevant
 example of those is Regulation no 1333/2008, of December 16, 2008, on food
 additives, which states what additives can be used in the production of food
 products. Also, Regulation no 10/2011 establishes which substances can be
 incorporated into plastic materials intended to come into direct or indirect
 contact with food.
- Finally, Regulation No. 1169/2011, on food information to the consumer, is at
 the top of a last type of food laws dealing with the labelling and advertising of
 food products. Mandatory, voluntary and prohibited information practices are
 regulated in order to ensure consumer protection and to prevent misleading
 practices.

This thesis deals with the legal framework for official controls undertaken by competent authorities. Section – of this thesis identifies the few pieces of food legislation that are not monitored in the framework of official controls today. Section – of Chapter 4 identifies those that will be included in the control system by December 2019. Therefore, in this thesis, the concept of "food law" must be understood as to all of the pieces of legislation that are included in official controls.

1.2. Policy and regulatory framework of e-commerce in the European Union

1.2.1. The concept of electronic commerce

Since the declaration on global electronic commerce adopted by the Second Ministerial Conference of the World Trade Organization (WTO) on 20 May 1998, this organization has defined e-commerce in its working documents as "the production, advertising, sale and distribution of products via telecommunications networks"⁷⁰. In 2009, this definition adopted by the European Parliament resolution on international trade and the internet⁷¹,

⁷⁰ World Trade Organization. (2018). *Understanding the WTO: cross-cutting and new issues. Electronic Commerce*. Retrieved from https://www.wto.org/english/thewto-e/whatis-e/tif-e/bey4-e.htm

⁷¹ European Parliament and the Council of the European Union. European Parliament Resolution of 5 February 2009 on International trade and the Internet, (2008/2204 (INI)), p. 112. Retrieved from http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0049&language=EN

but no other European Union document or piece of legislation has come close to providing a European legal definition of this concept.

Given that definition, food e-commerce is defined in this thesis as the advertising, sale and distribution of food products via telecommunications networks. This leaves room for categorization of different types of electronic commerce⁷² based on the role of the actors in the transaction, the channels used and the type of agent making the food product available online.

Both regulators and academics take into consideration three main types of electronic transactions based on the role of the actors engaging in e-commerce:

- Business to Business (B2B) electronic commerce: The most important type of electronic commerce worldwide⁷³ in economic terms, which consists of two economic operators intervening in the food chain prior the foodstuff being made available to the final consumer. For example, B2B electronic commerce occurs when a manufacturer buys raw ingredients from a farmer online.
- Business to Consumer electronic commerce (B2C): B2C online commerce occurs
 when a consumers purchases goods or services online for domestic consumption.
 When it comes to grocery shopping, B2C entails that the consumer purchase food
 products online instead than by visiting a brick-and-mortar retail store.
- Consumer to Consumer electronic commerce (C2C or User to User): This last type of transaction takes place when an individual offers a product online for other peers to buy. It is the digital version of classified advertisements in specific sections of the traditional press and is mostly conducted through third-party platforms such as the auction website *Ebay* or the Spanish real state platform *Idealista*.

Regarding the channels through which a transaction is completed, e-commerce can be "direct" or "indirect". It is considered "direct" when transactions are carried out exclusively through electronic channels (the order, the delivery and the payment are done

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⁷² The second part of this Chapter will make use of this categories to identify the challenges that food e-commerce entails for competent authorities in charge of official controls.

⁷³ E-Commerce Statistics and Market Data about E-commerce. (n.d). Retrieved from https://www.statista.com/markets/413/e-commerce/

online, as it occurs when purchasing digital content). "Indirect" e-commerce occurs when the delivery of the good is done off-line through mail, courier, or any equivalent method.

Throughout this thesis the concept e-commerce refers exclusively to indirect e-commerce, given that the transaction – the purchase food products (or their ingredients and raw materials) for human consumption- can only be completed off-line.

Lastly, it is relevant to distinguish between "internet-based" operators (referring to those businesses only operate through electronic commerce), and "store-based" operators (that engage in e-commerce in addition to their activity from a traditional brick-and-mortar store offline). As is analysed in Part 2 of Chapter 3 of this thesis, the fact that a food business operator is only present in the digital market shapes in good measure the capacities that public authorities have when it comes to enforcing current food safety regulations in the digital market.

1.2.2. Regulating e-commerce in the European Union

The origins of the current EU strategy for electronic commerce are found in the European Commission's Communication "E-europe: An information society for all" adopted in 2000. This Communication aimed at ensuring that individuals, industry and governments maximised the benefits of the information society, by

bring[ing] every citizen, home and school, every business and every administration into the digital age and online; creat[ing] a digitally literate Europe, supported by an entrepreneurial culture ready to finance and develop new ideas; [and] ensur[ing] that the whole process is socially inclusive, builds consumer trust and strengthens social cohesion⁷⁴.

One of the specific objectives of the Communication was to foster the growth of electronic transaction in the European market:

Accelerating e-commerce: Europe needs to accelerate the growth of e-commerce, especially for SMEs. To this end, a reliable legal framework for the internal

content/EN/TXT/?uri=LEGISSUM%3Al24221

⁷⁴ It must be noted that Commission Communication on a Commission initiative for the special European Council of Lisbon, 23 and 24 March 2000 - eEurope - An information society for all, COM (1999) 687, was not published in the Official Journal of the European Union. Nevertheless, the European Commission's summary on this initiative. Retrieved from http://eur-lex.europa.eu/legal-

market must be established as soon as possible (notably the Directive on the legal aspects of e-commerce)⁷⁵.

It is in that context that, less than eight months later, came the adoption of the Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on e-commerce'). This Directive is still today applicable to e-commerce.

During the second part of the nineties the European institutions adopted several Directives that tackled specific issues related to e-commerce such as e-signature⁷⁶, but this was the first horizontal and comprehensive act adopted at the EU level concerning the regulation of electronic commerce.

The Directive applies to 'information society services', as defined in Directive (EC) 98/48,

(...) any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services. For the purposes of this definition:

- "at a distance" means that the service is provided without the parties being simultaneously present,
- "by electronic means" means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means, "at the individual request of a recipient of services" means that the service is provided through the transmission of data on individual request.

The electronic commerce of consumer goods in general, and food products in particular, is under the scope of the Directive, which is considered a "minimum harmonisation directive, which applies inter alia to online contracts, including contracts for the online sale of consumer goods"⁷⁷.

Directive (EC) 1999/93 of 13 December 1999 on a Community framework for electronic signatures. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1519751881240&uri=CELEX:01999L0093-20081211

⁷⁵ European Commission. COM/1999/687 final. eEurope - An information society for all Communication of 8 December 1999 on a Commission initiative for the special European Council of Lisbon, 23 and 24 March 2000. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al24221

⁷⁷ European Parliament Research Service. (2016). *Briefing EU Legislation in Progress February 2016. Contracts for online and other distance sales of goods*, p. 3. Retrieved from

The goal of the Directive was to ensure "the equivalence of e-contracts, the protection of the e-consumer with pre-contractual information, the definition of the place of establishment independently of the place of the server as well as the obligations of certification providers."

To that end, it establishes that electronic commerce –when dealing with sales of goods–should function with respect to the following principles⁷⁸:

• No prior authorisation:

Member States shall not require service providers a prior authorisation to engage in electronic commerce in their territory, "without prejudice to authorisation schemes which are not specifically and exclusively targeted at information society services"⁷⁹. Therefore, if an undertaking requires an authorisation to operate in the traditional store-based market, its digital version is not exempt from complying with that prior authorisation requirement. For example, food establishments that deal with meat products require the prior approval of the competent food safety authority in order to operate legally⁸⁰. Therefore, those offering meat products online must also comply with that requirement, regardless of article 4 of the e-commerce Directive.

• Mandatory information provision:

Service providers (defined in article 2 of the Directive as "any natural or legal person providing an information society service") must make available information that allows for their clear identification. Mandatory information includes among other "the name of the service provider, the geographic address

 $\underline{http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/577962/EPRS_BRI\%282016\%29577962_EN_\underline{pdf}$

⁷⁸ It must be noted that one of the most significant elements of the Directive is that electronic service providers (defined as "any natural or legal person providing an information society service,") must comply with the regulations of the member state they are established in. Nevertheless, this does not apply to contract for consumer goods, including foods. Indeed, when it comes to consumer contracts must comply with legal requirements applicable in the country the offer is addressed to.

⁷⁹ European Parliament Research Service. (2017) *Providers Liability: From the eCommerce Directive to the future*. Paragraph 2 of article 4. Retrieved from http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_IDA(2017)614179

⁸⁰ The obligation to register food establishments enshrined in Food Law is analysed in Chapter 2 of this thesis.

at which the service provider is established and the details of the service provider, including his electronic mail address, which allow him to be contacted rapidly and communicated with in a direct and effective manner⁸¹". Also, prior to the order being placed, accurate, clear and complete information about the terms of the contract should be provided:

The different technical steps to follow to conclude the contract, whether or not the concluded contract will be filed by the service provider and whether it will be accessible, the technical means for identifying and correcting input errors prior to the placing of the order and the languages offered for the conclusion of the contract 82

• The role of intermediary service providers:

The Directive refers to specific information society services consist of mere electronic intermediation. Although used repeatedly in the Directive, the concept of "intermediary" has no legal definition in EU law nor in EU policy documents. It has become frequent instead to refer to the working definition already provided by the OECD in 2010, that identifies intermediaries as those that

bring together or facilitate transactions between third parties on the Internet. They give access to, host, transmit and index content, products

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⁸¹ Article 5. General information to be provided: 1) In addition to other information requirements established by Community law, Member States shall ensure that the service provider shall render easily, directly and permanently accessible to the recipients of the service and competent authorities, at least the following information: a)the name of the service provider; b) the geographic address at which the service provider is established; c)the details of the service provider, including his electronic mail address, which allow him to be contacted rapidly and communicated with in a direct and effective manner; d) where the service provider is registered in a trade or similar public register, the trade register in which the service provider is entered and his registration number, or equivalent means of identification in that register; e) where the activity is subject to an authorisation scheme, the particulars of the relevant supervisory authority; f) as concerns the regulated professions: i) any professional body or similar institution with which the service provider is registered; ii) the professional title and the Member State where it has been granted; iii) a reference to the applicable professional rules in the Member State of establishment and the means to access them; g) where the service provider undertakes an activity that is subject to VAT, the identification number referred to in Article 22 (1) of the sixth Council Directive 77/388/EEC of 17 May 1977 on the harmonisation of the laws of the Member States relating to turnover taxes - Common system of value added tax: uniform basis of assessment (29). 2) In addition to other information requirements established by Community law, Member States shall at least ensure that, where information society services refer to prices, these are to be indicated clearly and unambiguously and, in particular, must indicate whether they are inclusive of tax and delivery costs.

⁸² European Parliament Research Service. (2017) *Providers Liability: From the eCommerce Directive to the future*. Paragraph 1 of article 10. Retrieved from http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL IDA(2017)614179

and services originated by third parties on the Internet or provide Internet-based services to third parties⁸³

In particular, the Directive⁸⁴ identifies as intermediaries the providers of services consisting of:

- o mere conduit, i.e., transmission over a communication; network of information, or access to a communication network
- o caching, i.e., automatic, intermediate and temporary storage of transmitted information, to increase efficiency;
- o hosting, i.e., storage of information.

A variety of service providers may, in practice, be considered intermediaries. The list includes, among other, the following:

- o Internet access and service providers (ISPs)
- Data processing and web hosting providers, including domain name registrars
- o Internet search engines and portals
- E-commerce intermediaries, where these platforms do not take title to the goods being sold
- o Internet payment systems, and
- Participative networking platforms, which include Internet publishing and broadcasting platforms that do not themselves create or own the content being published or broadcast⁸⁵.

As acknowledge by the European Commission in several policy and soft law initiatives⁸⁶, online platforms that facilitate the placement in the market of consumer goods (such as food products) offered by third parties (i.e. marketplaces) may be considered intermediaries.

Articles 12 to 14 of the Directive state that intermediaries may not be liable for any illegal activities of their users while they remain unaware of them and

⁸³ OECD. (2010). *The economic and social role of internet intermediaries*, p. 9. Retrieved from https://www.oecd.org/internet/ieconomy/44949023.pdf

⁸⁴ European Parliament Research Service. (2017) *Providers Liability: From the eCommerce Directive to the future.* Retrieved from http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_IDA(2017)614179

⁸⁵ Perset, K. (2010). The Economic and Social Role of Internet Intermediaries. *OECD Digital Economy Papers*, N. 171, p. 9. Retrieved from http://dx.doi.org/10.1787/5kmh79zzs8vb-en

⁸⁶ Such as the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Online Platforms and the digital single market, opportunities and challenges for Europe COM /2016/288/2.

provided that they take down the illegal content once they have knowledge of its existence. In order to apply this secondary liability exemption, the intermediary must takes down or blocks access to that content, and must do so "expeditiously."

What exactly "expeditiously" means is a source of uncertainty around the ECD regime, especially for small ISPs and platforms. No guidance is given in the Directive as to what 'expeditious' means and whether it allows enough time to, e.g. check facts, consult an in house lawyer, find an external lawyer or request counsel's opinion⁸⁷.

As recently stated by the Commission, "what this means in practice depends on the specifics of the case at hand, in particular the type of illegal content, the accuracy of the notice and the potential damage caused" For example, removal of illegal hate speech online must be completed in less than 24 hours, according to the Code of Conduct on countering hate speech online adopted in May 2016 No such code exists when it comes to food products that are traded in breach of food law.

The procedure leading to the blocking or removal of content by the intermediary is known as "notice and take-down procedure" (hereinafter, "NTD") regime. NTD procedures are "a peculiar kind of internet content self-regulatory measure (...) which sets forth that the parties hosting content agree to remove content in case of a legitimate notice by the consumer [or authority], without having to prove the legality of the content before a court of law"90. The usefulness of NTDs in food e-commerce come from the fact that too many times competent authorities cannot carry out an administrative procedure that would result in non-compliance being established and the offer legally removed. Be it for lack of legal base or merely

⁸⁷ Edwards, L. (2010) *Role and responsibility of internet intermediaries in the field of copyright and related rights*, p. 10. Retrieved from http://www.wipo.int/publications/en/details.jsp?id=4142&plang=EN

⁸⁸ European Commission. COM/2017/555 final. Communication of 28 September 2017 on Tackling Illegal Content Online - Towards an enhanced responsibility of online platforms. Retrieved from https://ec.europa.eu/digital-single-market/en/news/communication-tackling-illegal-content-online-towards-enhanced-responsibility-online-platforms

⁸⁹ Jourová, V. (2017). *Code of Conduct on countering illegal hate speech online: One year after*. Retrieved from http://ec.europa.eu/newsroom/document.cfm?doc id=45032

⁹⁰ Ahlert, C., Marsden, C., & Yung, C. (2004). How 'Liberty' Disappeared from Cyberspace: The Mystery Shopper Tests Internet Content Self-Regulation, p. 7 Retrieved from http://www.akgul.web.tr/akgul/Sansur/liberty disappeared from cyberspace.pdf

because the time needed to complete it would turn the action useless, NTDs have the potential to impact significantly the safety of the e-food market.

As has been widely discussed by stakeholders, academia and the Court of Justice of the European Union⁹¹, identifying that a service provider is acting as a mere intermediary protected by the secondary liability exemption requires a study of the particulars of the specific service provided. In order for the exemption to apply, the service provider must have kept a neutral role, entailing that its service has consisted only of "merely technical, automatic, and passive interventions in the dissemination of information within a digital network"⁹². Thus, the application of the exemption of secondary liability requires a case-by-case analysis of the role that the service provider plays in the availability of the illegal content.

On the other hand, "if the platform intervenes in the configuration of the underlying transaction it bears responsibility for any liabilities arising from both the electronic service provided and the underlying transaction"⁹³.

The exemption of secondary liability plays a significant role, as article 15 of the Directive establishes that intermediaries have no general obligation to monitor that their users are not engaging in illegal activities through the service provided⁹⁴. This prevents Member States from demanding that intermediaries actively search for illegal activities carried out through their systems. The rationale of article 15, which "goes hand in hand with the Directive's liability shields under which conduits, hosts and network caches have various degrees of protection from

⁹¹ See in particular joint cases C-236/08 and C-238/08 Google France and case C-234/09 L'Oréal versus eBay. Court of Justice of the European Union. Google vs Luis Vuitton. Joined Cases C-236/08, and C-238/08. Judgement of 23 March 2010. Retrieved from http://curia.europa.eu/juris/document/document.jsf?docid=83961&doclang=en

⁹² Corrales, M., Fenwick, M., & Forgó, N. (2017). *New Technology, Big Data and the Law*. Springer, Singapore, p. 231-32.

⁹³ Martínez Mata, Y. (2017). Bolkestein revisited in the era of the sharing economy. *Revista Electrónica de Estudios Internacionales (REEI)*, 20;(33): p. 6. Retrieved from https://dialnet.unirioja.es/servlet/articulo?codigo=6062577

⁹⁴ Article 15 of the eCommerce Directive (EC) 2000/31 states that "Member States shall not impose a general obligation on providers (...) to monitor the information which they transmit or store, nor a general obligation actively to seek facts or circumstances indicating illegal activity."

criminal and civil liability for the activities of their users"⁹⁵, is to avoid excessive interference from intermediaries with their users. The argument is that

The fear of sanction for illegal activities of the users could induce intermediaries to impede or even obstruct lawful activities. Excessive collateral censorship is likely to take place when there is legal or factual uncertainty and sanctions are high⁹⁶.

But, back to food e-commerce, the "fear of collateral censorship" entails that Member States cannot impose on marketplaces the obligation to establish a system to check that consumer goods such as food products offered via their platform comply with applicable legislation.

1.2.3. The construction of the Digital Single Market

Although a valuable instrument to foster the digital economy, the Directive on e-commerce could not remove existing obstacles to the construction of a digital single market by itself. "The fragmentation of online markets, ill-adapted intellectual property legislation, the lack of trust and interoperability, the lack of high-speed transmission infrastructure and the lack of digital skills"⁹⁷, had become significant obstacles to free movement of goods and services but had remained un-tackled by public authorities. Thus, since the adoption of the e-commerce Directive, the European Union has gradually moved forward on its way to develop a digital single market.

On June 9th 2010, Mario Monti's report on a new strategy for the single market gave a new push to EU's activities in the field of e-commerce. The report identified three main needs at the European level: improving of the legal framework for electronic communications and its infrastructure, updating of copyright and broadcasting legislation to digital content provision, and breaking up the fragmentation of consumer protection regulations that were making of electronic commerce an unfriendly territory for cross-

⁹⁶ European Parliament Research Service. (2017) *Providers Liability: From the eCommerce Directive to the future*, p. 6. Retrieved from http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_IDA(2017)614179

⁹⁵ Smith, G. (2017, May 23) Time to speak up for Article 15 of the ECommerce Directive. The International Forum for Responsible Media Blog. [Web log post] Retrieved from https://inforrm.org/2017/05/23/time-to-speak-up-for-article-15-of-the-ecommerce-directive-graham-smith/%0A

⁹⁷ Monti, M. (2010). A new strategy for the single market at the service of Europe's economy and society, p. 44-46. Retrieved from http://ec.europa.eu/internal market/strategy/docs/monti report final 10 05 2010 en.pdf

border transactions. Harmonisation of delivery, warranty and dispute resolution rules, and the simplification of "the business environment for cross-border retail transactions, including VAT rules, the cross border management of recycling rules and of copyright levies on blank media and equipment" 98, became priorities of the EU Commission's work on e-commerce.

The European Commission's Digital Agenda for Europe⁹⁹ was adopted on the 26th August 2010. But building the single market became even more pressing for the European Commission in 2012 under the persistent economic crisis. In an uncertain economic environment, public authorities considered that electronic commerce could stimulate growth and employment. Doubling the volume of e-commerce in Europe by 2015¹⁰⁰ became a high priority.

The Agenda is based on seven pillars, with the establishment of the Digital Single Market its first and more ambitious. Within this pillar, the Communication aims at

The removal of barriers that block the free flow of legal digital content and online services across national borders and boost the music download business, establish a single area for online payments, and further protect EU consumers in cyberspace¹⁰¹.

The European Commission acknowledged that the establishment of the digital single market requires a high level of confidence of EU consumers in the security of online transactions. Protecting e-consumers is a strong need, and to that end decision was made on the adoption of Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (hereinafter, "Consumer Rights Directive").

⁹⁸ Monti, *op. cit.*, p. 46

⁹⁹ European Commission. COM/2010/0245 final. Communication of 19 May 2010 on A Digital Agenda for Europe. Retrieved from http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52010DC0245

¹⁰⁰ European Commission. (2011). Stimulating growth and employment: an action plan for doubling the volume of e-commerce in Europe by 2015. Retrieved from http://europa.eu/rapid/press-release IP-12-10 en.htm?locale=en

¹⁰¹ Anagnostopoulou, D. (2013). *E-commerce in International and European Union Law: The Policy of the European Union on Digital Agenda and Strategy 2020*, p. 14. Retrieved from http://afroditi.uom.gr/jmc/wp-content/uploads/2013/06/Research-Essay-No-11.pdf

This piece of legislation aims at achieving a high level of consumer protection across the EU and to contribute to the proper functioning of the internal market. The Directive's angle, on the other hand, is "to approximate certain aspects of Member States' laws, regulations and administrative provisions concerning contracts concluded between consumers and traders¹⁰²". It does specify that it covers contracts concluded using distance communication which are identified as "distance contracts".

"Distance contract' means any contract concluded between the trader and the consumer under an organised distance sales or service-provision scheme without the simultaneous physical presence of the trader and the consumer, with the exclusive use of one or more means of distance communication up to and including the time at which the contract is concluded" 104.

Chapter III of the Directive specifies the information to be provided by traders prior to the conclusion of distance contracts (information that adds up to mandatory particulars established in the e-commerce Directive, such as the details of the service provider or the technical steps to follow to conclude the contract), as well as specific provisions regulating the right of withdrawal for online transactions. Essentially, it mandates that within distance contracts, the goods must be delivered within thirty days, that consumers have the right to cancel the purchase within a fourteen days cooling off period (although some exceptions apply, particularly regarding being the purchase of foodstuffs), that delivery costs must be refunded in the event of cancelation of the contract, and that pricing must include the detail of applicable taxes.

One year later, in December 2012, the EU Commission publishes the EU Code of Online Rights. The Code does not grant EU citizens new rights, it is a compilation of consumer rights already recognised in EU legislation. Only this time, their application to the digital environment is exposed. As indicated in the foreword of the EU Code of Online Rights:

EU Commission Guidance Document, last accessed on 10/06/2016 link: http://ec.europa.eu/justice/consumer-marketing/files/crd_guidance_en.pdf

¹⁰³ The Consumer Rights Directive builds on the definition of distance contract provided by its predecessor Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts: Distance contract means any contract concerning goods or services concluded between a supplier and a consumer under an organized distance sales or service-provision scheme run by the supplier, who, for the purpose of the contract, makes exclusive use of one or more means of distance communication up to and including the moment at which the contract is concluded.

¹⁰⁴ As defined in paragraph 7 of article 2 of Directive 2011/83/EU 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive (EC) 1999/44 of the European Parliament and of the Council. Retrieved from https://ec.europa.eu/info/sites/info/files/crd_guidance_en_0.pdf

These rights and principles are not always easy to grasp because they are not exclusive to the digital environment and are scattered across various directives, regulations and conventions in the areas of electronic communications, ecommerce and consumer protection. (...) While the majority of these rights are not in themselves new, due to the complexity of the legal framework many online consumers might not be aware of them. This is precisely the reason for establishing this Code: to make citizens aware of their minimum rights and the principles recognised in EU law when going online, being online, and when buying and consuming services online. This Code is not about creating new rights but about compiling existing rights and principles¹⁰⁵.

Neither the Consumer Rights' Directive nor the Code do not establish any mechanism or recommendation to Member States that is specific to enforcement of those rights in the digital environment¹⁰⁶. As it is the case in the traditional market, it is the role of national competent authorities to ensure enforcement under their national administrative regulations and through the general consumer protection international cooperation mechanisms.

In 2015, the European Commission gave another step forward regarding electronic commerce with the adoption in May of the "Digital Single Market Strategy" ¹⁰⁷. The European Commission's Communication recognises that "electronic commerce in the EU is not functioning as smoothly as it could. As a result, consumers and retailers are missing out on opportunities. The value of e-commerce in the EU is growing, but its full potential still remains untapped" ¹⁰⁸. Facing this reality, the new strategy is a significant step further when it comes to stimulating cross-border e-commerce and deals with the improvement of both consumer protection and of legal framework that businesses operate in.

The Communication included different legislative proposals referred to as the "ecommerce package," which aim at tackling the high level of non-compliance with the key consumer rules when purchasing goods and services online. As stated by the EU

¹⁰⁵ European Commission. (2012c). *Code of EU online rights*. Retrieved from https://ec.europa.eu/digital-single-market/sites/digital-agenda/files/Code%20EU%20online%20rights%20EN%20final%202.pdf

¹⁰⁶ Indeed, it is not until 2017 that the EU Commission outlines enforcement recommendations for competent authorities in charge of surveillance of the digital single market from a consumer law perspective. This initiatives are dealt with in Chapter 4 of this thesis.

¹⁰⁷ COM/2015/0192 final. Communication of 19 May 2010 on A Digital Single Market Strategy for Europe. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1447773803386&uri=CELEX%3A52015DC0192

European Commission. (2017b). *Boosting e-commerce in the EU*. Retrieved from http://europa.eu/rapid/press-release MEMO-16-1896 en.htm

Commission, the rate of "business non-compliance with the EU consumer acquis shows that enforcement is suboptimal because based on conservative estimates 37% of e-commerce or booking websites do not respect basic consumer rights." ¹⁰⁹

The package¹¹⁰ referred to a set of priorities for the European Union, including among other, the proposal of a new directive for online and other distance sales of goods that should leave behind the current fragmentation in the legal framework that applies to those contracts (as to the date four pieces of legislation apply to them: the Consumer Sales Directive, the Consumer Rights Directive, the Unfair Practices Directive, and finally the e-Commerce Directive) that is still being negotiated.

Also, it referred to the need to discuss the role of online platforms that began in 2016. The European Commission's comprehensive assessment of the role and liability regime of online platforms that is still in progress and has recently produced relevant documents, such as the Communication on a European agenda for the collaborative economy¹¹¹, the Communication on Online platforms and the Digital Single Market-Opportunities and challenges for Europe¹¹², and the Communication on Tackling Illegal Content Online Towards an enhanced responsibility of online platforms¹¹³.

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European Commission. COM/2016/320 final. Communication of 25 May 2016 a comprehensive approach to stimulating cross-border e-Commerce for Europe's citizens and businesses. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016SC0163

¹¹⁰ The Communication on the Digital Single Market Strategy also forecasted the following initiatives: a) A legislative proposal to address unjustified geo-blocking and other forms of discrimination on the grounds of nationality, residence or establishment; b) A legislative proposal on cross-border parcel delivery services to increase the transparency of prices and improve regulatory oversight; c) A legislative proposal to strengthen enforcement of consumers' rights through a revision of the Regulation on Consumer Protection Cooperation; d) A guidance to clarify, among others, what qualifies as an unfair commercial practice in the digital world.

¹¹¹ European Commission. SWD/2016/184 final. Commission staff working document of 2 June 2016 on accompanying the document Communication COM/2016/356 final of 2 June 2016 on A European agenda for the collaborative economy – supporting analysis. Retrieved from http://ec.europa.eu/transparency/regdoc/?fuseaction=list&coteId=10102&year=2016&number=184&version=ALL&language=en

¹¹² COM/2016/288 final. Communication of 25 May 2016 Online Platforms and the Digital Single Market Opportunities and Challenges for Europe. Retrieved from https://ec.europa.eu/digital-single-market-opportunities-and-challenges-europe

¹¹³ European Commission. COM/2017/555 final. Communication of 28 September 2017 on Tackling Illegal Content Online - Towards an enhanced responsibility of online platforms. Retrieved from https://ec.europa.eu/digital-single-market/en/news/communication-tackling-illegal-content-online-towards-enhanced-responsibility-online-platforms

In these Communications, the European Commission analyses how online platforms play a significant role in the digital economy but have remained on the side-lines when it comes to enforcement of the law thanks to the secondary liability exemption enshrined in the e-commerce Directive.

Recent technology developments have fostered the rise in number and shape of online platforms:

online platforms come in various shapes and sizes and continue to evolve at a pace not seen in any other sector of the economy (...and) cover a wide-ranging set of activities including online (...) marketplaces, search engines, social media and (...) platforms for the collaborative economy¹¹⁴.

Many of them enable third parties to offer food products and other consumer goods. It is common for some platforms to intervene – with different degrees of intensity- in the configuration of the offer of the good, i.e. by setting rules on how to determine its price. In other models, the platform acts as an hybrid: remaining neutral when storing the offer of a third party, while also placing in the market goods by itself. Amazon is paradigmatic example of that hybrid form.

Regardless of the role that the platform plays in a transaction, its role protecting its users must be stimulated. To that end, the European Commission asks platforms to engage in a more protective role, and interprets that creating safeguards to protect consumer would not "automatically lead to the online platform losing the benefit of the liability exemption provided for in Article 14 of the E-Commerce Directive"¹¹⁵. Thus it recommends the use of automatic detection and filtering technologies to identify, block and remove illegal content. The European Commission's Communication and Recommendation on tackling illegal content online underline that "online platforms which mediate access to content for most internet users carry a significant societal responsibility in terms of protecting users and society at large," and that they should put into place voluntary, proactive mechanisms to monitor and contain illegal contain.

¹¹⁴ European Commission. COM/2016/288 final. Communication of 25 May 2016 Online Platforms and the Digital Single Market Opportunities and Challenges for Europe. Retrieved from https://ec.europa.eu/digital-single-market/en/news/communication-online-platforms-and-digital-single-market-opportunities-and-challenges-europe

¹¹⁵ COM/2017/555 final of 28 September 2017

Article 15 of the e-commerce Directive, which that prevents Member States from mandating that intermediaries monitor the activity of their users, is thus one of the hot topics to be discussed. The European Commission wants to analyse the possibility of requiring Internet platforms "to take a more active role in policing user content" This proposal has been considered by most "ill-advised from both an economic and human rights standpoint" given the implications it may have on human rights such as freedom of speech. But, on the other hand, if intermediaries were to use technology to proactively identify and remove offers of sensitive products (such as non-compliant foodstuffs) that may threaten consumer health, it is undeniable that the overall safety of the digital market would be dramatically improved.

When it comes to notice-and-take down procedures, the Commission recommendations do not include any on how to interpret that a take-down of a non-compliant offer of goods is done "expeditiously." It does on the other hand provide relevant insight on how to carry out the NTD procedure. In particular, it states that only "where it is manifest that the content concerned is illegal content and relates to serious criminal offences involving a threat to the life, or safety of persons" should it be removed before the content provider to contest the removal decision. If the notification deals with illegal content which does not entail a serious criminal offence, the content provider should be granted the possibility of contesting the decision to remove or block its content via a counter-notice. The clarification of the steps that need to be followed to complete NTD procedures is of high interest for competent authorities controlling food products, as will be analysed in Chapter 3 and 4 of this thesis.

Lastly, a significant issue identified by the European Commission is the difficulty to enforce law online. Significant difficulties arise when competent authorities try to ensure that offers in platforms comply with EU law requirements "such as competition, consumer protection, protection of personal data and single market freedoms" ¹¹⁸.

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¹¹⁶ O'Connor, D. (2015, July 9). The digital single market and a duty of care: preserving the transatlantic legal foundation of a thriving internet. Disruptive Competition Project [Web log post]. Retrieved from http://www.project-disco.org/competition/070915-the-digital-single-market-and-a-duty-of-care-preserving-the-transatlantic-legal-framework-for-a-thriving-internet/#.WpbQNmZDmqB

¹¹⁷ European Commission. C/2018/1177 final. Commission Recommendation of 1 March 2018 on measures to effectively tackle illegal content online. Retrieved from http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=50095

¹¹⁸ COM/2016/288 final of 25 May 2016

Although effective enforcement is considered crucial, engaging platforms in enforcement is still a pending task.

But even before reaching the enforcement stage, how to properly organize and perform market surveillance is proven a challenge. This is an issue that must be solved. In order to ensure that competent authorities can act online, laws may need to be updated to the particulars of these new technologies but also, as acknowledged by the Commission, "investments in new technology that supports public action" must be done. However, to date e-government actions plan and initiatives on the digitalization of the public administration have been focusing on digitalization of public services, but neglecting research on how to enforce legal requirements in a digital context.

Most of the difficulties that arise when tempting to monitor the market and to enforce the law online (such as the difficulty to identify the operator, or to ensure that administrative decisions are complied with) are common to all consumer goods¹²⁰. But when dealing with food products, specific challenges arise and common challenges need to be overcome based on the specificities of food law. It is the final purpose of this thesis to provide competent authorities with recommendations on how to overcome the challenges that enforcing food law online entails, while shedding some light on how enforcement of law online can be fostered.

1.2.4. Legal framework applying to Consumer-2-Consumer electronic commerce

Both the Directive of e-commerce and European consumer law apply to those transactions completed between a business and a consumer. Consume-to-consumer trade, also known as peer-to-peer commerce, remains outside the scope of this legal framework. This is justified by the fact that these instruments were designed to protect the consumer, which has a weaker position in the commercial transaction.

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Market surveillance of non-food products sold online was recently analyzed by a European Commission's Communication, which provides recommendations to public authorities on how to perform surveillance. It must be noted that its content is mostly based in the experience of the German administration when dealing with food products, and which is analyzed in section 2.3.2 of Part 2 of Chapter 3.

In consumer-to consumer transactions, both parties are supposed to be equal and therefore any issues arising from the transaction are to be dealt with based on the law of the contract.

The outburst of digital platforms that allow individuals to share and exchange goods and services has brought peer-to-peer trade back to the political arena in the era of the "collaborative economy." This new economic model is "also a cultural and social phenomenon" which rose by the combination of technological evolution and the global financial crisis. The collaborative economy has

blur[ed] the lines between consumers and business since there is a multisided relationship that may involve business-to-business, business-to-consumer, consumer-to-business, and consumer-to-consumer transactions. In these relationships, it is not always clear who the weaker party requiring protection may be. 122

Food trade has not been an exception, today there are uncountable online platforms that connect non-professional individuals to share and exchange food products¹²³.

However, the consideration of C2C trade of food products as part of the collaborative economy is not clear, as the trade of food products entail a permanent change of ownership. It is commonly understood that "collaborative economy transactions generally do not involve a change of ownership and can be carried out for profit or not-for-profit" In that spirit, recent policy documents and reports issued or commissioned by EU institutions explicitly exclude food sharing platforms from their scope. Keeping this in mind, this thesis will deal with food products traded in those platforms referring to the general concept of consumer-to-consumer (or peer-to-peer) trade.

This thesis is not strange to the fact that the popularity of collaborative economy online platforms has forced both EU institutions and Member States to discuss if excluding peer-to-peer trade from consumer law should be reconsidered given that the relationship between

¹²¹ Hatzopoulos, V. (2018). *The Collaborative Economy and EU Law*. Bloomsbury Publishing, London, p. 1.

¹²² SWD/2016/184 final of 2 June 2016, p. 5.

¹²³ Described in section 2 of this Chapter.

¹²⁴ European Commission. COM/2016/356 final. Communication of 2 June 2016 on A European agenda for the collaborative economy. Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2016%3A356%3AFIN

both parties when a transaction is completed through a digital platform is frequently unbalanced, and resembles to the one that would exist in business-to-consumer transactions.

Currently there are no European rules on when "a peer becomes a professional service provider," and Member States use different criteria to settle the matter in specific areas such as transportation or sharing of private accommodation services. For the rest, a transaction is considered C2C or B2C based on a case-by-case analysis that (as suggested by the EU Guidance¹²⁵ document on the application of the unfair commercial practices directive) evaluates the continuity of the activity, the motive of the individual (generating a profit or a compensating of the costs undergone to obtain the good or skill "shared"), and the level of turnover.

Although this is a relevant question that must be dealt with in a horizontal manner for all economic sectors where C2C commerce is present, in peer-to-peer food e-commerce the issue must be evaluated with the goals of food law in mind.

Food law applies to all food products except food preparation for private domestic use (what I cook for me and my family at home), and the underlying justification is that food does not "circulate" in the market. The nature of the transaction and the operator is not relevant because the goal is to protect human health and other consumer interests that have been considered priorities of the European Union. Even charity or community food events must comply with food law. C2C commerce must comply with General Food Law, thus peers placing food products in the market must ensure they are safe.

However, C2C food trade is excluded from the scope of the Hygiene Regulation as long as it consists of undertakings that do not have a certain degree of continuity and organization. The evaluation if and undertaking has reached a degree of organization and continuity that requires compliance with Hygiene rules shall not be based on the need to rebalance a relationship between parties. This evaluation shall be based on the need to ensure that food safety and therefore of containing potential food-related risks.

¹²⁵ European Commission. COM/2016/320 final. Communication of 25 May 2016 a comprehensive approach to stimulating cross-border e-Commerce for Europe's citizens and businesses. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016SC0163

This thesis provides an assessment of the issues that C2C entail, based on EU regulations and policy documents relating to food law, as well as on how competent authorities in Member States are dealing with this issue.

2. CHARACTERISTICS OF THE E-FOOD MARKET IN THE EUROPEAN UNION

Individuals are increasingly using the Internet, and as IT structures and regulation are updated, website registration and the number of businesses engaging in e-commerce also increase. At the European level, electronic trade raised more than 350 billion euros in 2013, with the United Kingdom, France and Germany leading the way, as they amount for more than 79% of e-commerce in the territory. E-commerce is only going up since, as new technologies such as mobile applications for commerce and social media commerce becomes popular among younger generations.

When it comes to the digital trade of food products, e-commerce has the potential for transforming markets and supply chains because it brings additional value to both consumers and operators. Consumers appreciate that buying anything online is easy, fast and can be done 24-7 regardless of the good or service purchased. Moreover, e-commerce gives customers access to a wider range of food products of different origins, qualities and prices. It is becoming a tool that allows individuals to better customize their diet as it makes available foods that might not be found in traditional stores.

On the other hand, manufacturers and distributors entering the digital market can reach a new share of customers that provide additional sales. Also, a significant number of sales carried out through traditional channels are made after researching information about the product online. This behaviour, known as "ROPO" (read online – purchase offline), is becoming mainstream.

But food e-commerce today also has the potential to endanger public health, as public authorities are acknowledging that there is limited control over the safety of the products offered online.

This second part of Chapter 1 provides an overview of the characteristics of the digital market of food products, the type of businesses and other agents that offer food products online, and of the e-foods that are challenging competent authorities' capacity to control unsafe food products.

2.1. Overview of the market's economic relevance

During the beginning of the research phase of this thesis, prospects for food e-commerce were unclear, as food e-commerce remained "a relatively underdeveloped retail channel globally,"

although already in 2013 total business-to-consumer e-commerce transactions added to more than 1.2 trillion US dollars¹²⁶. Some countries such as the United States, France and the United Kingdom were already forecasting significant growth in the next years.

The United Kingdom leads e-grocery shopping in the European Union. It accounts for most 7% of the digital grocery shopping worldwide. It leads the way for other Member States (and most of the world) when it comes to online grocery shopping. In 2017, 8% of the total sales for grocery shopping were done through digital channels. In June of that same year, "internet food sales increased 3.6 percent with respect to the same month a year earlier" and the forecast is that it will increase its share by "68% between 2016 and 2021 to represent £17.6 billion of sales" Almost half of the customers already engage in e-grocery shopping, while less than 16% of the Germans do so 129.

The rate is even lower in Spain, where during in 2017 only 12,5% of consumers ordered their groceries online occasionally. Almost three out of four of those purchases are done through the web shop of traditional supermarkets¹³⁰. E-grocery shopping is less popular in the south than in the north of Europe, and Spain is a good example of that, as the market share of e-foods is still less than 3% of the total turnover for e-commerce in the country, and less than 1% of the turnover of the Spanish food sector¹³¹.

This difference between countries is partly explained by the traditional of shopping at the local supermarket in Spain, which allows very frequent and quick purchases with smaller tickets and smaller baskets. On the other hand, in countries

E-Commerce Statistics and Market Data about E-commerce. (n.d). Retrieved from https://www.statista.com/markets/413/e-commerce/

¹²⁷ Percentage change in monthly internet food sales value in the United Kingdom (UK) from January 2013 to December 2017. (2018). Retrieved from https://www.statista.com/statistics/286361/internet-food-sales-value-trend-monthly-in-the-united-kingdom-uk/

¹²⁸ Dunning, A. (2017, May 4). The UK is named the world's third largest online grocery market. Nielsen Brandbank [Web log post]. Retrieved from https://www.brandbank.com/blog/uk-third-largest-online-grocery-market/

¹²⁹ Share of individuals who purchased food or groceries online in Great Britain in 2017, by age and gender. (2018). Retrieved from https://www.statista.com/statistics/286116/food-and-groceries-online-purchasing-in-great-britain-by-demographic/

Fernández, J.G. (2017, April 19) Así compran los españoles alimentación por Internet. *Expansión*. *Economía Digital*. Retrieved from http://www.expansion.com/economia-digital/innovacion/2017/04/19/58ecf440468aeb367a8b45ac.html

¹³¹ According to Comisión Nacional de los Mercados y la Competencia. (2015, May 18). El comercio electrónico supera en España los 4.100 millones de euros en el tercer trimestre de 2014, un 25% más que el año anterior. Retrieved from https://www.cnmc.es/2015-05-18-el-comercio-electronico-supera-en-espana-los-4100-millones-de-euros-en-el-tercer

such as France or the United Kingdom, the hypermarket is very common, which entails a more voluminous purchase, for which the Internet stands as a very convenient alternative 132.

Nevertheless, there is a consensus¹³³ that food e-commerce in Spain is going to increase gradually in the next decade because traditional stores are discovering that the digital market can possibly impact their sales. According to market studies carried out during 2017, "the sale of online food will skyrocket over the next three years, going from bringing together a quota just over 1% currently to reach between 4% and 6% of the total billing of the sector"¹³⁴.

Between 2014 and 2015 online e-grocery purchases in Spain increased value over 7%. This market is "expected to continue to be prosperous in the medium term, as more store-based companies move to online commerce¹³⁵". Market value is increasing faster, given the number of transactions completed through mobile e-commerce fostered by the strong *smartphone* penetration in the country.

The Spanish digital consumer who buys food products online is in most cases a working middle class woman (more than half¹³⁶ the digital customers for food), a young single man or a couple with no children.¹³⁷ The same study identifies a very specific e-shopping behaviour: groceries are done in the first week of the month, when the monthly payroll arrives:

¹³² Nielsen report. What'sin -store for onl inegrocery shoppingomnichannel strategies to reach: crossover shoppers. January 2017 Translation is mine.

¹³³ Among others, Los hogares que compran alimentación online en España crecen el 25%. (2015). Retrieved from http://www.nielsen.com/es/es/press-room/2015/Los-hogares-que-compran-alimentacion-online-en-Espania-crecen-el-25-porciento.html

Osorio, V.M. (2018, January 16). La venta de alimentos online se multiplicará por seis en tres años. Expansion. Retrieved from https://amp-expansion.com/empresas/distribucion/2018/01/16/5a5d13f1e2704e520d8b45f5.html

¹³⁵ According to the US Department of Agriculture, Gain Report NOV2016 report SP1542, Spain, Retail Foods Annual 2015, accessed through http://www.eurofresh-distribution.com/news/new-face-grocery-retail-spain

Fernández, J.G. (2017, April 19) Así compran los españoles alimentación por Internet. Expansión. Economía Digital. Retrieved from http://www.expansion.com/economia-digital/innovacion/2017/04/19/58ecf440468aeb367a8b45ac.html

¹³⁷Los hogares que compran alimentación online en España crecen el 25%. (2015). Retrieved from http://www.nielsen.com/es/es/press-room/2015/Los-hogares-que-compran-alimentacion-online-en-Espania-crecen-el-25-porciento.html

[In 2017,] the majority of the respondents, 36%, place their orders once a month, compared to 25% who do it every 15 days and 12% who visit the super online once every two months. Only 14% say they buy food online more than once a week 138

Spanish e-shoppers prefer the purchase to be home delivered. Only 23% choose click and collect options, that imply purchasing products digitally but picking groceries up at a brick-and-mortar store. "Traditional retailers, recognising today's shoppers are multi-channel shoppers, are working to integrate their physical, online and mobile shopping offer."

Spanish food business operators are attempting to satisfy this integration need using different formulas. While some prepare and deliver digital orders from their traditional retail stores, other like Valencian leader Mercadona¹³⁹ has recently decided to use a specific food establishment that will only deal with its customers' digital orders.

2.2. Actors that place offers of food products in the digital market

There are three main categories of e-commerce: business-to-business (B2B), business-to-consumer (B2C) and consumer-to-consumer (C2C)¹⁴⁰. All of three types are present in the digital market of food products.

2.2.1. B2B e-commerce

The Internet is most suited for the development of Business to Business electronic commerce to the point that this type of electronic commerce¹⁴¹ is significantly more developed today. Online, food business operators can access a huge variety of ingredients, raw materials and components that would be much more difficult to obtain locally: operators gain access to a wider market where they can get their supplies from.

The digital environment helps business reduce costs and increase the efficiency of their protocols when purchasing the materials needed to obtain their final product:

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¹³⁸ Fernández, J.G, Op. Cit

¹³⁹ Mercadona did not acknowledge until 2017 the relevant role that e-grocery shopping was going to play, to the point that its president stated that "nuestra página web es una mierda." Delgado, C. (2017, March 2). Juan Roig: "Nuestra página web es una mierda, pero en 2018 saldremos mejor". Retrieved from: https://elpais.com/economia/2017/03/02/actualidad/1488457101 569764.html

¹⁴⁰ For details on those categories, see Chapter 1, section I.2.

E-Commerce Statistics and Market Data about E-commerce. (n.d). Retrieved from https://www.statista.com/markets/413/e-commerce/

This use of [B2B] e -commerce is the most highly developed and widely adopted. It allows retailers to share information about consumers' purchases and preferences with food manufacturers and farmers and for tracking food products' characteristics, source, and movement from production to consumer. This circle of information allows high quality and consistent products to be consumed at lower prices¹⁴².

In 2013, a study carried out in the United States indicated that "88 percent of B2B purchasers agree or strongly agree that if given the option to buy a product online, ecommerce would be their preferred shopping channel"¹⁴³.

However, in the European Union data suggests that it is still mostly large multinational corporations that engages in B2B food e-commerce. "The difficulty of examining the quality and safety of food products, (...) and the (perceived) risk of performing a transaction via e-commerce" preventing small and medium-sized enterprises from entering the digital food market.

But still, current B2B in Europe is only growing and competent authorities must be ready to ensure compliance with food law in the digital arena. Indeed, General Food Law insists on the fact that the responsibility to comply with food law applies to all operators along the food chain, so Member States must make sure that their control system is suited not only for control of the final product as offered to consumers, but along all the stages of the food chain. B2B food e-commerce must therefore be subject to scrutiny by public powers.

2.2.2. B2C e-commerce

When it comes to business-to-consumer food e-commerce, the digital market of food is characterized by a high diversity of operators. Traditional retailers (also known as store-based operators) are coexisting with new businesses that have no brick-and-mortar stores (internet-based operators).

¹⁴² Kinsey, J., & Buhr, B. (2004). E-commerce: A New Business Model for the Food Supply/Demand Chain. *The Food Industry Center*. Working Paper 03-01. University of Minnesota Retrieved from https://www.researchgate.net/publication/5105126 E-commerce_A_New_Business_Model_for_the_Food_SupplyDemand_Chain

¹⁴³ Chavie, R. (2013, November 11). B2B E-Commerce Transforms the Role of Sales Reps. Food Manufacturing [Web log post]. Retrieved from https://www.foodmanufacturing.com/article/2013/11/b2b-e-commerce-transforms-role-sales-reps

¹⁴⁴ Canavari, M.; Fritz, M.; & Schiefer G. (2016). *Food supply networks: trust and e-business*. Available from https://www.cabi.org/cabebooks/ebook/20153402647

Operators include farmers, producers, and distributors that use technology to offer their products to the final consumer without having to invest in a traditional store, but also brick-and-mortar stores that now have a digital presence, and catering services that access a larger consumer base thanks to the Internet.

2.2.2.1. Store-based retailers in the digital market

Traditional grocery stores, as well as large supermarkets, are gradually entering the digital market of food products. For brick-and-mortar supermarkets, not offering an online shopping option is quickly becoming the exception rather than the rule. Retailers are discovering that

Using a shopping portal delivers several benefits to traditional retailers in terms of marketing synergies, site traffic generation, access to web site management and fulfilment services, and the ability to offer customers a multichannel retailing experience¹⁴⁵.

Among the obstacles that remain for store-based retailers are the costs of the logistics of e-shopping, which can sometimes difficult to assume:

selling groceries online means taking on additional costs—in labour, delivery vehicles, and fuel—that are higher than the fees customers are willing to pay for delivery (which, according to our research, is between \in 4 and \in 7 per transaction, depending on the market). Profitability can thus seem an unattainable goal¹⁴⁶.

Still, in most European countries traditional store-based retailers are leading the way for smaller businesses. In the United Kingdom, online grocery shopping is now offered by all the largest supermarket chains. The rest of "the market is mainly populated by a wide range of niche, specialized retailers, many of which offer products that are not always available in major supermarkets" ¹⁴⁷. In Germany, according to USDA reports, it is traditional large discount stores such as Lidl that are leading the way when it comes to e-grocery

146 McKinsey & Company. (2013) Perspectives on retail and consumer goods. Number 2, Winter 2013/2014. Available from: https://www.mckinsey.com/~/media/mckinsey/industries/consumer%20packaged%20goods/our%20insig hts/get%20the%20strategy%20and%20the%20team%20right%20an%20interview%20with%20the%20ce o%20of%20henkel/perspectives_on_retail_and_consumer_goods_number%202.ashx

¹⁴⁵ Kennedy, A., & Coughlan, J. (2006). Online shopping portals: an option for traditional retailers? *International Journal of Retail & Distribution Management*, 34(7):516-528. Retrieved from https://doi.org/10.1108/09590550610673590

 $^{^{147}}$ USDA Foreign Agricultural Service. (2016a). USDA GAIN report, United Kingdom Food Retail. United Kingdom.

shopping¹⁴⁸. In Spain, where consumers are still reluctant to do their groceries online, B2C food e-commerce is led by store-based retailers that are already known to consumers and that can be made accountable when unacceptable food products delivered 149.

Smaller store-based businesses such as bakeries, butchers or specialty shops are gradually gaining a share of the e-grocery market. Research indicates that,

On a value basis, large supermarkets and hypermarkets account for just over half (51%) of global sales, but smaller formats such as traditional, drug and convenience grew at a faster rate over the past 12 months. In fact, year-over-year sales growth in drug stores (+6%), small supermarkets (+5%) and traditional stores (+4%), doubled, or more than doubled, that of large supermarkets and hypermarkets, which grew a modest 2% each¹⁵⁰.

Internet-based retailers 2.2.2.2.

Even though they are if still less popular than store-based retailers, Internet-based operators are gradually gaining consumer trust. There are several types of exclusively digital retailers that offer food products online.

Some are small undertakings that range from farmers to producers of artisan foodstuffs that do not wish or do not have the capacity to open a retail store. They have a small production that is easier to manage from a storing facility and send it to the customers they get online. Connecting directly with their clients, and therefore avoiding the additional costs of intermediaries, represents not only an economic saving but an advantage, as they build stronger relationship with customers – that may even often receive detailed information about the produce they get.

Internet-based retailers can operate from a corporative website, through digital marketplaces (such as Amazon or Alibaba), auction websites (as eBay) or social networks such as Facebook. All major platforms that deal with food have created ad hoc channels for law enforcement agents to report non-compliance of an offer and request its elimination via a notice-and-take down procedure. When it comes to smaller platforms,

¹⁵⁰ Nielsen Company. (2015, April). The future of grocery e-commerce, digital technology and changing preferences around the world. Retrieved shopping

https://www.nielsen.com/content/dam/nielsenglobal/vn/docs/Reports/2015/Nielsen%20Global%20E-

from

¹⁴⁸ USDA Foreign Agricultural Service. (2017). USDA GAIN report, Germany Food Retail. Germany.

¹⁴⁹ USDA Foreign Agricultural Service. (2016b). USDA GAIN report, Spain Food Retail. Madrid.

there are no specific channels available to competent authorities, which will normally have to contact the intermediary using its contact details.

Digital marketplaces, auction sites and social networks puts competent authorities in a difficult position when it comes to verifying compliance with food law. Their popularity foster the number of transactions and of operators, but the information that is available about the identity those responsible for a food product is scarce to the point that competent authorities cannot properly track down the identity of the operator and the location of the establishments it is responsible for.

If the operator is not properly identified when placing an offer, competent authorities are not able to visit their establishments in order to perform official controls or to initiative the appropriate administrative procedure to enforce the law.

As is analysed in Chapter 3 of this thesis, this situation entails that frequently competent authorities are not able to enforce food law by themselves. Instead, competent authorities have to resort to requesting the platform for the removal or blocking of the non-compliant offer.

This is not a small issue, because research suggests that internet-based operators have more possibilities of placing in the market non-compliant offers than store-based operators. Indeed, the between 2011 and 2013 the German administration identified more than 3,000 online food establishments that were not known to competent authorities but were used for e-commerce, and 1,200 online offers of 450 suppliers were identified as non-compliant. Also, the data obtained suggests that a significant amount of internet retailers (almost 40%) are not known to competent authorities because they fail to register before proper (a requirement set in the official controls regulation that is analysed in Chapter 2 of this thesis), and so remain outside the administration's radar when planning controls. Moreover, surveys on compliance of candy, meat products, and food supplements, carried out in the United Kingdom in 2015 resulted in a failure rate 90% across all surveys¹⁵¹. Such non-compliance rates are unthinkable in the brick-and-mortar market.

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¹⁵¹ Details on both initiatives are provided in Chapter 3 of this thesis.

Given that offers from internet-based operators are currently more likely to be non-compliant, public authorities should prioritize controls on their premises and food products.

2.2.3. C2C e-commerce

The Internet connects individuals who offer food products. In some platforms, the food product "shared" was initially bought from traditional retailers and cooked at home, but in others, it is merely groceries that have not been touched by the consumer and that he is not going to use.

Particulars usually use online platforms such as marketplaces, social networks or specialised phone applications to offer food online. Signing up in those platforms is easy, as in most of them there is no screening process for prospective operators.

There are three major types of food sharing digital platforms "representing three different forms of food: primary products (harvest), ready meals and unmarketable processed products or leftovers"¹⁵².

Also, it is useful to differentiate between platforms that only deal with food products and those that allow their members to trade food among other services and consumers goods.

Amazon, Alibaba, eBay and Facebook are commonly used to share food products. Those four popular platforms allow for offer of food products, although conditions and procedures to become a food operator are different between the platforms. Only Amazon states that operators must request permission to offer food products, although no details about the procedure are available open access. Alibaba and Facebook apparently treat food products the same way as any other consumer good (no specific rules for food products are stated), and include in their general terms and conditions statement a warning that it is the operator who is responsible for compliance with legal requirements and that those offers that do not comply with applicable legislation may be removed. Interestingly

¹⁵² Zurek, K. (2016). Food Sharing in Europe: Between Regulating Risks and the Risks of Regulating. *European Journal of Risk Regulation*, 7(4), p. 678. Retrieved from https://doi.org/10.1017/S1867299X00010114

enough, *Alibaba* advertises to operators located in China the possibility of requesting the performance of a third-party inspection that will certify that the goods being produced and shipped reach quality standards¹⁵³. Based on the results of this voluntary inspection, operators can advertise that the compliance of their products has been verified by *Alibaba*.

The platform *Menu next door*, created in Brussels, is a good example of the platform that deals exclusively with food products (in this case, ready meals). It connects users in the same neighbourhood and turns amateur cooks into professional chefs. The platform's slogan is clear about its goal: "order a takeaway menu cooked by a neighbour." Regardless of the legal status of users and their legal obligations when it comes to food safety, it already has "2000 chefs, of whom less than 15% are professionals, and offering 100.000 meals per year¹⁵⁴". Thus, business-to-consumer and consumer-to-consumer trade coexist.

Lastly, platforms such *Compartoplato*¹⁵⁵ (also known as *Shareyourmeal*), that operate in Spain, the Netherlands, Portugal and Belgium identify as "socially engaged entrepreneurs" that have built an undertaking of the sharing economy and therefore only peer-to-peer trade is allowed:

Shareyourmeal therefore fits in well with the trend of a sharing economy. More and more consumers work together by borrowing, exchanging, renting or buying things, money and services of each other. CDs and books are exchanged on-line through Swaptree; people rent out their car to others through Snappcar and through Peerby neighbours can borrow or rent things from each other like drilling machines. Such initiatives make traditional dividing lines disappear between producer and consumer. On-line technology allows for matching supply and demand between consumers on a local level. In essence it is all about making something valuable (like leftover food) end up where it is needed (with hungry neighbours). The sharing economy makes our society more social and more sustainable! A trend worth being part of!¹⁵⁶

From the perspective of these platforms, the greatest challenge they face is

The absence of a distinction between food safety & hygiene standards for restaurants and commercial enterprises and those for home cook food sharing models. For example, in Belgium, the food hygiene authority conducted visits to some home cooks [using the platform "Shareyourmeal"] to verify that they were

¹⁵⁴ The terms and conditions that must be signed to place offers in this platform is analysed in Chapter 3 of this thesis.

^{153 &}quot;Inspection Service" from Alibaba.com. Retrieved from https://inspection.alibaba.com/

¹⁵⁵ The terms and conditions that must be signed to place offers in this platform is analysed in Chapter 3 of this thesis.

^{156 &}quot;About Us" from Shareyourmeal. Retrieved from https://www.shareyourmeal.net/about-us/item42196

applying food hygiene standards. This news rapidly spread to other home cooks, deterring them from joining the platform and curtailing their presence in Belgium¹⁵⁷.

According to the General Food Law, all undertakings must ensure that food placed in the market is safe, but only those that have a certain degree of continuity and of organization must comply with hygiene regulations. But in practice, it is not easy for competent authorities to identify when to require compliance with hygiene requirements and of the role that official controls should play in the monitoring of these foods. Taking into account that it is frequent that consumers cannot identify if the offer is placed by a professional or by a peer, providing an answer to the question of how to ensure that consumers do not obtain unsafe foods by peer-to-peer trade is even more urgent.

2.3. Food products available online

The variety of food products that are offered online has evolved over the last three years significantly: while at the beginning of this thesis most commonly bought groceries were beverages and non-perishable or canned foods, today they have been joined by the purchase of fruits, vegetables, meat and fish that are slowly finding their way into the shopping cart ¹⁵⁸.

For example, in Spain, during 2017,

The most purchased categories online are milk, milk products and household hygiene (more than 70%), followed by sausages and beers (60%), wines and other alcoholic beverages (46%) and, finally, fresh products (among 14% and 24%)¹⁵⁹.

¹⁵⁷ Vaughan, R., & Daverio, R. (2016). Assessing the size and presence of the collaborative economy in Europe. PwC, United Kingdom, p. 9. Available from https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjm-

 $[\]frac{uDO3sTaAhWFuRQKHXgCA8IQFggoMAA\&url=http\%3A\%2F\%2Fec.europa.eu\%2FDocsRoom\%2Fdocuments\%2F16952\%2Fattachments\%2F1%2Ftranslations\%2Fen%2Frenditions\%2Fnative\&usg=AOvVaw3mGJ-2pMjjmaDm1MKzzFNz$

Fernández, J.G. (2017, April 19) Así compran los españoles alimentación por Internet. *Expansión*. *Economía Digital*. Retrieved from http://www.expansion.com/economia-digital/innovacion/2017/04/19/58ecf440468aeb367a8b45ac.html

¹⁵⁹ Marques, A. (2017, March 10). El *ecommerce* de alimentación en España crece pero a un ritmo más lento. Ecommercerentable.es [Web blog post]. Retrieved from http://ecommercerentable.es/ecommerce-alimentacion-espana/

Unfortunately, the safety and integrity of common food products is not always ensured when ordered online. As it happens with other consumer goods, the rates of noncompliance with food law online are high, in particular in the following three categories:

• Fresh and perishable food products from small scale operators:

Fresh foods are increasing their presence in the digital shopping basket. Fresh meat is one of the top-selling products in this category, even if data show that handling and delivery of meat does not always follow food law requirements.

For example, a control initiative carried on by the German administration in 2014¹⁶⁰ identified that almost all the fresh meat samples purchased by the authority did not comply with food hygiene requirements. Most of the offers analysed indicated that the delivery was done "at the customers risk", with no guarantee of maintaining the cold chain or manipulation by third parties. Also, most of these offers were published in platforms that allowed for comments from consumers, and that confirmed that the food delivered was unsanitary.

Also, in the United Kingdom,

The online sale of meat by small-scale or unregistered providers is repeatedly observed in available intelligence. This practice effectively removes traders from the scrutiny which comes with registering as a food business operator or having a physical business premises¹⁶¹.

This situation is similar for fresh fish and other highly perishable foods. For this kind of products, the difference in safety and quality between store-based and internet-based retailers has proven significant to the point that buying them from operators that do not usually offer these products at a traditional store may be considered in most cases a risk to human health.

• Food products placed in the market in the framework of C2C commerce:

Many digital platforms allow individuals to "share" groceries, leftovers and even a full menu with other citizens. As their popularity rise, competent authorities share the concern over the safety of the dishes and products offered.

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¹⁶⁰ And that will be discussed in depth in section 2 of Part 2 of Chapter 3.

¹⁶¹ Food Standards Agency. (2016i). *Food crime: annual strategic assessment*, p. 49. Retrieved from https://www.food.gov.uk/sites/default/files/fsa-food-crime-assessment-2016.pdf

Competent authorities are struggling when trying to assess to control home-cooked, shared or swapped food products. These food products fall within the scope of the General Food Law thus must be safe. Leaving out of the radar of controls foods cooked from home may result in unnecessary risks to consumer health. Given that food safety is a priority of the European Union, and that its achievement has justified the construction of a complex legal framework that applies to the food sector and which first goal is to protect human health, consideration must be given to this issue.

• The special case of food supplements and novel foods with health claims

Food supplements containing unauthorised novel foods or dangerous substances, as well as those advertised with misleading health claims are highly traded online and have been considered the most pressing issue by competent authorities.

Often considered by consumers to have medicinal properties, food supplements are legally considered food products according to EU law. The category is defined in article 2 of Directive 2002/46/EC, which states that:

(a) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

Therefore, food supplements fall within the scope of food law and are to be officially controlled by competent authorities.

The composition of legitimate food supplements "most frequently includes vitamins, mineral substances, as well as plant or animal-derived ingredients, which are present in food and consumed as its part". The Directive establishes mandatory maximum concentrations of most common vitamins and minerals, while Member States have the power to adopt national legislation that allows for the use of other ingredients in variable concentrations. The legal situation across

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¹⁶² Wróbel-Harmas, M., Krysińska, M., Postupolski, J., & Wysocki, MJ. (2014). Food supplement-related risks in the light of internet and RASFF data. *Przeglad epidemiologicny*, 68: p. 2. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/25848779

the EU varies significantly, as some countries such as Spain did not moved from the Directive until 2018 while others like Belgium authorised the use of most varied ingredients (such as mushrooms) to be used in food supplements briefly after the adoption of the Directive.

Before initiating trade of food supplements, the European legal framework requires that food business operators notify their competent authority that the product is going to be placed in the market ¹⁶³. Article 10 of Directive 2002/46/EC:

To facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

Member States can organize the notification process as they wish. As a result, in some countries it is a centralised process, while in others there are regional authorities. The information that needs to be submitted with the label and the composition of the product, as well as the timeline of the procedure, also vary from one Member State to another. Because food supplements are food products and not medicine, there is no need to present or perform a clinical trial which confirms "the effectiveness, quality and safety profile as it is in the case of medicinal products" Instead, the advertising and presentation of food supplements must play by the rules of food information regulations, which entails that they can only be marketed using those health and nutrition claims authorised on the basis of Regulation (EC) no 1924/2006 of the European parliament and of the council of 20 December 2006 on nutrition and health claims made on foods.

Food supplements "may be purchased not only in a grocery, which seems to correspond to its definition, but also in chemists', gym, but above all on the Internet" 165. The control of digital offers of these food products is one of the

¹⁶⁴ Wróbel-Harmas, M., Krysińska, M., Postupolski, J., & Wysocki, MJ. (2014). Food supplement-related risks in the light of internet and RASFF data. *Przeglad epidemiologicny*, 68: p. 2. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/25848779

¹⁶³ The notification process that trading food supplements entails must be carried out by food business operators in addition to the registration or approval of their food establishments, as described in Section I of Chapter 2 of this thesis.

¹⁶⁵Food and Veterinary Office. (2015a). Controls on food supplements in Member States, p.1. Retrieved from https://publications.europa.eu/en/publication-detail/-/publication/947a2355-8c2c-11e5-b8b7-01aa75ed71a1/language-en

highest priorities for public authorities when it comes to increasing the safety of the digital market of foods, as data confirms that the Internet makes easily available supplements that entail serious risk to human health and illegal offers are often easier to access that safe, compliant food supplements. These food products are most attractive to European consumers, as even when they should not be advertising medicinal properties, a significant part of consumers assume they have therapeutic properties. For example, in Poland recent research indicates that "41% of respondents consider supplements to have therapeutic properties."

Taking the above into consideration, in 2009 the European Commission conducted a desk study on food supplements that was based on all Member States' answer to a questionnaire on the food supplements market in their territory as well as on the "enforcement of legislation and controls in the field of food supplements". The desk study was followed by five fact-finding missions 167 carried out in 2013 and 2014 and that tried to obtain data about the level of compliance with food law in food supplements.

Concerned by the growing number of RASFF notifications dealing with non-compliant food supplements, from January 2013 to June 2014 the Food and Veterinary Office of the European Commission carried out five fact-finding missions on controls on food supplements. Although this initiative did not target the digital market specifically, its individual objectives referred the need to "address issues such as assessment of botanicals and the control of Internet sales" ¹⁶⁸.

One of the most significant conclusions of the Commission after the initiative was closed was that "an increasing share of the trade in food supplements is developing on internet. This trade is less transparent and more difficult to control" After an outbreak in 2013 of hepatitis caused by consumption of the food supplements

Food and Veterinary Office. (2015a). *Controls on food supplements in Member States*, p.4. Retrieved from https://publications.europa.eu/en/publication-detail/-/publication/947a2355-8c2c-11e5-b8b7-01aa75ed71a1/language-en

¹⁶⁷ This fact-finding missions are further described in Section I.1 of Chapter 4 of this thesis.

¹⁶⁸ Food and Veterinary Office. (2015a), op. cit, p. 4.

¹⁶⁹ *Ibid.* p. 10.

OxyElite Pro and VERSA-1, the Commission got fully aware of the important challenges that food e-commerce at large was going to create:

The problem lies in the availability of the products to consumers on the Internet. Even though these products may be harmful to consumer's health, they remain purchasable through the Internet. The challenge is for authorities to have a better control of the Internet sales of food products in order to ensure that the products consumers buy are safe¹⁷⁰.

The fact-finding missions suggested that the performance and efficiency of official controls varied significantly from one country to another, as did the level of specialisation of public officials undertaking controls, as well as the training available to them and their time dedication. Also, even if samples were taken frequently, "a limited proportion is analysed in laboratory", which was even worse when dealing with samples of herbal ingredients and pharmaceuticals. "The level of non-compliance in food supplement samples was reported to be relatively high compared to other foodstuffs." The results being that significant difference exist "between Member States with regard to the effectiveness of the control system on food supplements" and that agencies in charge of criminal law enforcement are still leading the way against these products.

Both EU institutions and competent authorities in Member States consider that control of food supplements must be a priority, as demonstrates the fact that the coordinated control plan on online offered food products launched in 2017 dealt exclusively with food supplements and novel foods. The results of the control plan¹⁷² show that these products can still today threaten consumers' health, but that coordinated action of competent authorities in all Member States can dramatically improve the effectiveness of official controls and thus the overall safety of the digital market.

¹⁷⁰ European Commission. (2013). *RASF. The Rapid Alert System for Food and Feed*, p. 19. Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/rasff annual report 2013.pdf

¹⁷¹ Food and Veterinary Office. (2015a). *Controls on food supplements in Member States*, p.7. Retrieved from https://publications.europa.eu/en/publication-detail/-/publication/947a2355-8c2c-11e5-b8b7-01aa75ed71a1/language-en

¹⁷² The coordinated control plan CCP efood is analysed in detail in Section 3 of Chapter 4 of this thesis.

Taking all of the above into consideration, the e-foods market has a greater non-compliance rate than the brick-and-mortar market, and the same food product entails higher risks to consumer health and interests when sold online. Those circumstances make it necessary that competent authorities design control plans that focus on e-commerce.

CHAPTER 2.

REGULATION OF OFFICIAL CONTROLS IN THE EUROPEAN UNION: THE CURRENT SITUATION

1. THE LEGAL FRAMEWORK APPLYING TO OFFICIAL CONTROLS IN THE EUROPEAN UNION WAS DESIGNED FOR THE TRADITIONAL MARKET OF FOOD PRODUCTS

The General Food Law assigns food business operators and competent authorities the responsibility of building mechanisms to ensure that food products meet European rules. Food business operators "have primary legal responsibility for ensuring food safety" and must put into place self-surveillance mechanisms to identify non-compliant products before they reach the market 174. Competent authorities must verify that operators comply with the requirements of food law and control the market so that non-compliant food products, which enter the market despite business self-surveillance mechanisms, are rapidly identified and recalled.

Member States fulfil their responsibility conducting official control, which include any form of control that the competent authority performs to assess that food products compliant with food law¹⁷⁵. Official controls are not only carried out on food products, which have been placed in the market and are available to the final consumer: controls are performed at any of the stages of production, processing and distribution. This includes checks on "food businesses, on the use of food, on the storage of food, on any

¹⁷³ Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&qid=1519664164571&from=EN

¹⁷⁴ The obligations of food business operators are analysed in Chapter 1, Section I of this thesis.

¹⁷⁵ Article 2.1 of Regulation (EC) 882/2004 of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520263140748&uri=CELEX:02004R0882-20180301

process, material, substance, activity or operation including transport applied to food required to achieve the objectives of the Regulation"¹⁷⁶.

This Chapter provides a detailed description of how official controls take place under the current legal framework. The first part of this Chapter describes the general legal framework established at the EU level, while the second analyses the decisive role that Member State's law has on the organization and actual performance of controls. Lastly, the third section analyses the shortcomings of the current framework, and systematically identifies ten challenges that bust be tackled to ensure that market surveillance, material controls and final enforcement can be carried out in the digital market of food products.

However, it is useful to already define relevant concepts:

- Controls carried out at the food business operators' establishments or during transportation are known as "controls on production." Competent authorities can only perform controls on production of those establishments that are located within their jurisdiction.
- Controls carried out at a retail store are known as "controls on distribution."
 Controls on distribution can be performed on any food product placed in the market and available to the final consumer at any retail store, regardless of its origin.

1.1. Official controls under Regulation 882/2004

At present¹⁷⁷, the piece of legislation that sets the general rules for official controls is Regulation (EC) n° 882/2004, of the European Parliament and of the Council of 29 April

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https://www.fsai.ie/legislation/food legislation/official control of foodstuffs/introduction.html

¹⁷⁶ Food Safety Authority of Ireland. (2015). Official Control of Foodstuffs. Retrieved from

¹⁷⁷ As indicated in the previous Chapter of this thesis, The legal framework established in the Compliance Regulation will be replaced from the 14th December 2019 by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (hereinafter, "Regulation 625/2017" or "Official Controls Regulation").

2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (hereinafter, "Regulation 882/2004" or the "Compliance Regulation")¹⁷⁸.

The Compliance Regulation provides harmonised framework for the organisation of official controls¹⁷⁹ in Member States. It "sets out the general approach that must be taken" by Member States when regulating the official controls system at the national level. It defines the key legal concepts, and identifies the general principles that must be respected by competent authorities organizing and performing control tasks¹⁸⁰. The particular arrangements of the official control systems are adopted in each Member State. It is them that have the decisive power, while the European Commission provides support and coordination.

While "most of substantive food law in the EU consists of uniform rules and regulations enacted at the EU level" (controls are governed by Member States' legislation.

This entails that some differences arise when looking at the organization of enforcement across the EU¹⁸². Certainly, "there is a large variety of food safety control systems throughout the Member States. In certain countries the responsibility of food control is decentralized and mandated to regions or provinces, whereas in other countries food safety control is in the hands of just one central organization" ¹⁸³.

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¹⁷⁸ Unless otherwise indicated, all articles cited in this section belong to Regulation (EC) 882/2004 of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520263140748&uri=CELEX:02004R0882-20180301

¹⁷⁹ Recital 7 of Regulation (EC) 882/2004 of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520263140748&uri=CELEX:02004R0882-20180301

¹⁸⁰ However, there are several pieces of legislation that are excluded from the scope of the Compliance Regulation. Controls on plant health and seeds and propagating material, and rules on common market organisations of agricultural products, are carried out according to their specific legislation.

¹⁸¹ Nieto Martín, A., Quackelbeen, L., & Simonato, M. (Eds.). (2016). *Food Regulation and Criminal Justice*. Maklu-Publishers, Belgium. p. 71.

¹⁸² In the case of Spain, the main piece of legislation one must take into account Royal Decree 1945/1983, from 22 June, which defines infractions and establishes sanctions that apply to food law infringements (RD 1945/1983).

¹⁸³ Ministry of Agriculture, Nature and Food Quality and the Food and Consumer Product Safety Authority of the Netherlands. (2005). *European food safety control systems: new perspectives on a harmonized legal basis*. Retrieved from http://www.fao.org/docrep/meeting/008/y5871e/y5871e0l.htm#bm21

Although the European Commission would rather have one single body responsible for food law enforcement ¹⁸⁴, the "EU law has little to say about the organisation of the public sector in the Member States [as] usually, obligations in regulations or directives are conferred on the national 'competent authority'" ¹⁸⁵. The Compliance Regulation is not an exception, as official controls are said to be carried out by "competent authorities" as defined in article 2 (4) of the Regulation:

"Competent authority" means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country.

In practice, in most Member States coexist and collaborate several competent authorities entrusted with specific responsibilities.

It is frequent that ministers of agriculture or of public health, together with national independent food safety agencies, are in the charge of organization and coordination of controls, while local or regional authorities are in charge of performance of controls tasks and of law enforcement¹⁸⁶. "It is for the national legislature to decide which state organ will be the competent authority in any given matter and to endow it with the powers necessary to fulfil its obligations under EU law"¹⁸⁷. When the regional or local level are actually in charge, ensuring the proper functioning of the system demands for successful coordination between competent authorities¹⁸⁸.

The silhouette of control systems varies across Europe, depending on the distribution of powers in each country. Nevertheless, because proper functioning of the internal market requires that the official controls is consistent across the European Union, there are

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¹⁸⁴ Lex Studio Legale Alimentaria. (2010). *Shortcomings in enforcing EU food law. What does EU food law stand for?*, p. 9. Retrieved from http://regulation.upf.edu/dublin-10-papers/2F4.pdf

¹⁸⁵ Van der Meulen, B. (2009). The System of Food Law in the European Union. *Deakin Law Rev*, 14(2):27-35, p. 7. Retrieved from https://ojs.deakin.edu.au/index.php/dlr/article/viewFile/145/144

¹⁸⁶ As will be analysed later, this is the case for Spain, Germany and the United Kingdom among other. Details on the organization and implementation of enforcement in those countries is further developed in this thesis.

¹⁸⁷ Van der Meulen, B. (2013). The Structure of European Food Law. *Laws*, 2(2), p.97 Retrieved from http://www.mdpi.com/2075-471X/2/2/69/

¹⁸⁸ Article 4.3 of Regulation (EC) 852/2004 of 29 April 2004 on the hygiene of foodstuffs. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1519664867462&uri=CELEX:02004R0852-20090420

¹⁸⁹ Article 4.4 of Regulation (EC) 852/2004 of 29 April 2004.

harmonized rules set at the European level by Regulation 882/2004¹⁹⁰ that outlines how controls must be carried out by the administrative power that has been assigned this responsibility according to its national laws. As this thesis illustrates¹⁹¹, harmonisation efforts at the EU level make that, those that carry out control tasks obey to similar rules and face similar challenges regardless of their geographical location and position within the administration.

The Compliance Regulation also assigns indirect control responsibilities to the European Commission in order to ensure that all control systems function appropriately and that they are properly coordinated. It mandates that performance of national control authorities and national control systems is assessed at the EU level by the Commission's Directorate-General for Health and Food Safety (DG SANTE). This task is currently assigned to the Health and Food Audits and Analysis Directorate (previously called "Food and Veterinary Office" – FVO), in order to assess each country's performance of official controls. Member States are required to provide the Commission with yearly reports on the impact and effectiveness of controls carried out within national jurisdiction in order to facilitate this assessment.

Given the complexity of the food chain and to the vast scope of official controls, national control systems cannot function without regular cooperation with other Member States and of third parties.

Independent third party entities from the private sector are appointed as "control bodies" in which a competent authority has delegated specific tasks. The Compliance

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¹⁹⁰ Additional rules apply to controls of particular food products, such as those of animal origin that are established in Regulation (EC) 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

¹⁹¹ The comparative study carried out in Chapter 3 of this thesis identifies the similarities and differences between Member States. The control case is Spain, and its national implementation is compared to the one in Germany and in the United Kingdom.

¹⁹² The particular on how to appoint control bodies and the tasks they can be entrusted with are established in article 5 of the Regulation: Article 5. Delegation of specific tasks related to official controls: 1) The competent authority may delegate specific tasks related to official controls to one or more control bodies in accordance with paragraphs 2 to 4. A list of tasks that may or may not be delegated may be established in accordance with the procedure referred to in Article 62(3). However, the activities referred to in Article 54 shall not be the subject of such a delegation. 2) The competent authority may delegate specific tasks to a particular control body only if: a) there is an accurate description of the tasks that the control body may carry out and of the conditions under which it may carry them out; b) there is proof that the control body: (i) has the expertise, equipment and infrastructure required to carry out the tasks delegated to it; (ii) has a sufficient number of suitably qualified and experienced staff and (iii) is impartial and free from any conflict

Regulations prevents delegation of specific tasks such as the imposition of sanctions, which must be always carried out by the authority itself.

Moreover, because it is common that non-compliance issues affect more than one country, cooperation with other Member States becomes a must. Member States can only control establishments located within their jurisdiction, but frequently compliance issues involve more than one Member State. Administrative cooperation between Member States is necessary¹⁹³ when (i) a non-compliant product being sold across more than one country, and (ii) when non-compliance of a food product has been established in the retail market of one Member State but production has taken place in another.

To face the challenges that this entails, Member States assist each other mainly through "*liaison* bodies," but that are the ones responsible for ensuring proper transmission and reception of requests for assistance. For instance, when a competent authority in a Member State identifies a non-compliant food product produced in another state, the relevant information should be forwarded to competent authorities where production takes place so checks can be performed on site. This transmission of information is carried out by the *liaison bodies*, although their participation does "not preclude direct contacts by individual authorities.¹⁹⁴

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of interest as regards the exercise of the tasks delegated to it; c) the control body works and is accredited in accordance with European Standard EN 45004 'General criteria for the operation of various types of bodies performing inspection' and/or another standard if more relevant to the delegated tasks in question; d) laboratories operate in accordance with the standards referred to in Article 12(2); e) the control body communicates the results of the controls carried out to the competent authority on a regular basis and whenever the competent authority so requests. If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the competent authority; f) there is efficient and effective coordination between the delegating competent authority and the control body. 3) Competent authorities delegating specific tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating competent authority may withdraw the delegation. It shall withdraw it without delay if the control body fails to take appropriate and timely remedial action. 4) Any Member State wishing to delegate a specific control task to a control body shall notify the Commission. This notification shall provide a detailed description of: a) the competent authority that would delegate the task; b) the task that it would delegate; and c) the control body to which it would delegate the task.

¹⁹³ Cooperation mechanisms are regulated in Title IV of the Regulation. Because this thesis focuses on what staff performing official controls can do when performing official controls, and because a competent authority can only enforce law within its jurisdiction, cooperation mechanisms are intentionally excluded of this thesis.

¹⁹⁴ Food Standards Agency. (2008). *Q&A Notes for enforcement authorities on the feed and food elements* from Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, p. 32. Retrieved from https://www.reading.ac.uk/foodlaw/pdf/uk-08009-enfrocement-q&a-notes.pdf

Regulation 882/2004 applies to EU-produced foodstuffs that are destined to the EU market, to foods that will be exported from the EU, and to those food products that are imported from third countries. European Union legislation has a global approach to official controls and therefore mandates that "official controls shall be applied, with the same care, to exports outside the Community, to the placing on the market within the Community, and to introductions from third countries.¹⁹⁵" In this context, "controls in third countries are required in order to verify compliance or equivalence with [EU] feed and food law.¹⁹⁶" Thus, cooperation is also needed with authorities in third countries. The Compliance Regulation defines harmonized procedures and standards for the control of food imports.

The European Commission is currently in the process of updating cooperation mechanisms, but little information has been disclosed to the public. Thus, the scope of this thesis is limited to the controls that competent authorities can carry out within their jurisdiction.

1.2. Principles governing official controls

The essential principle governing official controls is that they must be impartial and effective ¹⁹⁷.

Controls are considered "effective" when they are proved appropriate to achieve the goals of the Regulation. But legislation does not include specific guidelines on how to measure the effectiveness of official controls. Competent authorities, in cooperation with expert audit networks, have developed an operational framework to measure the effectiveness of control systems. It is agreed that, in the context of Regulation 882/2004, "effectiveness" means

The extent to which official controls produce an (intended) effect, or achieve an objective. In this particular context the objectives are those of Regulation (EC) No

¹⁹⁵ Paragraph 4 of article 3 of the Regulation 882/2004 of 29 April 2004.

¹⁹⁶ Ministry of Agriculture, Nature and Food Quality and the Food and Consumer Product Safety Authority of the Netherlands. (2005). European food safety control systems: new perspectives on a harmonized legal basis. Retrieved from http://www.fao.org/docrep/meeting/008/y5871e/y5871e0l.htm#bm21

¹⁹⁷ Recital 11 indicates that the competent authorities for performing official controls should meet a number of operational criteria so as to ensure their impartiality and effectiveness. They should have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.

882/2004. Effectiveness is not to be confused with efficiency, which is normally used when we want to refer to input-output ratio i.e. cost and/or resources required to produce an output 198.

Authorities need to compare the outcome of control tasks with the objectives identified in the control plan. Control measures need to prove appropriate for minimizing infringements of food law. Public resources are limited, so it is necessary to ensure that control activities taken by public authorities are best allocated in order to fulfil the general and strategic objectives of the official controls system.

Moreover, efficient official controls call for adequate resources and training available to staff performing official controls. To that end, the Compliance Regulation mandates that competent authorities mush have "an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively". 199.

Resources need to be allocated to maintain equipment and to ensure continuous training of staff. Member States need to provide those in charge of performance of official controls with

(...) an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively; and (...) appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively $(...)^{200}$.

Training should not be limited to how to better perform controls. It must also include multidisciplinary activities to improve cooperation with other authorities and understanding of new issues that may affect official controls²⁰¹. Better Training for Safer Food (also known as "BTSF") is the European Commission's training initiative that provides updated legal and technical training to controls staff in both Member States and

¹⁹⁸ National Audit Systems Network. (2014). Auditing Effectiveness of Official Control Systems. Retrieved https://www.livsmedelsverket.se/globalassets/produktion-handel-kontroll/vagledningarkontrollhandbocker/auditing-effectiveness-of-official-control-systems.pdf

¹⁹⁹ Article 4.2.c of Regulation 882/2004 of 29 April 2004.

²⁰⁰ Paragraphs c and d of article 4 of Regulation 882/2004 of 29 April 2004.

²⁰¹ The list of specific subjects that must be covered during training activities is included in Annex II, Chapter I of the Regulation. Also, article 51 on "training of control staff" is the legal base of the Commission's training courses for the staff of the competent authorities of Member States responsible for the official controls referred to in this Regulation. Known as Better Training for Safer Food (BTSF), "these training courses shall serve to develop a harmonised approach to official controls in Member States."

third countries importing food products into the European Union. Its legal base is enshrined in article 51 of Regulation 882/2004:

The Commission may organise training courses for the staff of the competent authorities of Member States responsible for the official controls referred to in this Regulation. These training courses shall serve to develop a harmonised approach to official controls in Member States.

Training curriculum includes most varied issues of food and feed law, animal health and welfare and plant health rules. However, the training designed by competent authorities and EU institutions does not always meet the needs of those in charge of controls:

Training is usually intended as just an on-the spot action (one day or more) with no activity of follow-up. On the contrary needs of staff performing official control activities are bigger and more complex. Civil servants need to be supported on their day-by-day activity as complexity of legal framework, uncertainty as regards obligations and rights have to be managed in a proper way²⁰².

Additionally, staff programming, undertaking and auditing in the framework of official controls must not have a conflict of interest that may interfere with their tasks. No specific rules are provided in the Regulation, but Member States law usually rotate inspectors to avoid formation of unhealthy relationships with the regulated public²⁰³.

In order to ensure compliance with the principles of effectiveness and impartially, the Compliance Regulation provides a set of general rules that govern the organization and the performance of official controls.

1.3. Rules for the organization of official controls

Given the complexity of the food chain and the scarce resources available to competent authorities, an adequate organization of official control tasks is necessary to contain potential risks and maintain an adequate compliance rate. With that goal in mind, the Compliance Regulation mandates that Member States establish "single integrated multi-

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²⁰² Lex Studio Legale Alimentaria. (2010). *Shortcomings in enforcing EU food law. What does EU food law stand for?* Retrieved from http://regulation.upf.edu/dublin-10-papers/2F4.pdf

²⁰³ Jacobs, S., & Córdova, C. (2005). Good Practices for Regulatory Inspections: Guidelines for Reformers, p. 45. Retrieved from http://www.fao.org/3/a-at377e.pdf

annual national control plans"²⁰⁴ reflecting the country's arrangements for the organization of control activities during a limited period of time.

Multi-Annual National Control Plans (MANCP) are considered an essential element for the performance of Member States' verification role. They present the Member State's strategy for market surveillance. These plans are normally developed by central competent authorities. However, when different competent authorities have responsibilities when it comes to official controls, as it frequently happens in decentralised Member States, the central authority that represents the country at the EU level coordinates the definition of the control plan, which is designed by all competent authorities through different coordination forums. The European guidelines are defined in the European Commission's Decision 2007/363/EC²⁰⁵.

This is essentially a strategic plan setting out the national monitoring and enforcement arrangements, objectives and priorities. It should describe roles and responsibilities of the various competent authorities, and provide details of how various requirements of the Regulation are being met. This must be a single integrated plan covering arrangements for monitoring and enforcement of not only feed and food law but also animal health and animal welfare rules, as well as plant health controls²⁰⁶.

In addition to controls based on the control plan, *ad hoc* control activities are often carried out in response to consumer complaints or to information received from another Member State through administrative cooperation mechanisms. *Ad hoc* controls can also occur even though there is no suspicion of non-compliance.

Because resources are limited, one of the main goals of the plan is to define a prioritisation of controls that need to take place. Which products, operators and establishments should be controlled? Prioritization results mainly from a risk analysis of the activities that take place in the country and of the food products that circulate in the national jurisdiction.

²⁰⁴ Article 41 of Regulation (EC) 882/2004 of 29 April 2004

²⁰⁵ Commission's Decision 2007/363/EC, of 21 May 2007, on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council (notified under document number C (2007) 2099).

²⁰⁶ Food Standards Agency. (2008). *Q&A Notes for enforcement authorities on the feed and food elements from Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules,* p. 10. Retrieved from https://www.reading.ac.uk/foodlaw/pdf/uk-08009-enfrocement-q&a-notes.pdf

1.3.1. Prioritization of controls result from risk assessment

Controls need to be carried out regularly, and the continuity of controls on a specific food product or operator must be determined using a risk-based approach²⁰⁷. Risk analysis guarantees that decisions about controlling a specific food product or establishment are impartial and that the objectives of the control system are met.

Although in some cases the continuity of controls for a specific product or activity is provided by EU regulation²⁰⁸, the general rule when it comes to prioritizing controls is risk-based programming, planning, and implementation of official controls. Indeed, "risk analysis plays as the Grundnorm role as of law-making process but it also has an increasing role in the control of verification of compliance process"²⁰⁹. As the Commission has stressed out in several occasions,

With this risk-based approach the continuity of controls will be linked to risks that a product or process presents with respect to fraud, health, safety, animal welfare or in certain cases the environment²¹⁰.

When deciding which products or businesses to include in national control plans, competent authorities must consider several factors to determine the likelihood of noncompliance to occur. There are four main criteria that need to be taken into consideration when measuring risk:

Inherent product risk:

Some raw materials, products or activities entail more risk for consumers and therefore should be monitored to a higher degree. Competent authorities are more likely to carry out "higher levels of monitoring of those businesses which are involved in the production of food from animals than those that for those which

²⁰⁷ Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate continuity, so as to achieve the objectives of this Regulation taking account of: a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare; b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules; c) the reliability of any own checks that have already been carried out; and d) any information that might indicate non-compliance.

²⁰⁸ This occurs, among others, when it comes to microbiological controls of specific foods, or when dealing with controls of non-animal foods from third countries.

²⁰⁹ Lex Studio Legale Alimentaria, op cit. p. 6.

²¹⁰ European Commission. (2017a). Enforcement of rules along the agri-food chain in the EU. Retrieved from http://europa.eu/rapid/press-release MEMO-17-611 en.htm

process non-animal-based raw materials"²¹¹. But this does not mean that low-risk areas should not be included in national control plans and in monitoring and enforcement activities, as other factors such as the scale of production, professional training or location of businesses among other may also affect risk²¹². Nevertheless, it is considered that "a risk model based solely on inherent product risk would not meet the legal requirements"²¹³ of the Compliance Regulation, so other factors should also be taken into account.

• The operator's record affects risk measurement.

When measuring risk, it is necessary to take into consideration how individual operators or specific sectors have behaved in the past regarding compliance with food law requirements. Information on non-compliance extracted from individual control reports shall also be used in order to assess risk.

• Some hazards are difficult to contain with self-surveillance mechanisms.

As indicated earlier in this chapter, food business operators have a primary legal responsibility for ensuring compliance with food law requirements. In order to fulfil this legal obligation, self-surveillance mechanisms are put into place so non-compliant foods do not reach the market. However, past experience shows that operators are more likely to fail this obligation when it comes to specific hazards. Therefore, official controls need to make up for it.

• Finally, Regulation 882/2004 settles that any "other relevant information" may be used in order to measure risk. This usually includes information such as RASFF notifications, media reports or consumer complaints.

²¹² For instance, the Finnish Food Safety Authority, points out that a risk-based approach does not, however, mean that small scale activities always would be excluded from the controls, as the production may include large risks independent of the scale of the production, and measures may always have to be taken in order to manage them. EVIRA. Finnish Food Safety Authority. (2016). *A risk-based approach and impartial controls*. Retrieved from https://www.evira.fi/en/foodstuff/manufacture-and-sales/foodestablishments/small-and-medium-sized-enterprises-and-the-prerequisites-for-their-operations/a-risk-based-approach-and-impartial-controls/">https://www.evira.fi/en/foodstuff/manufacture-and-sales/foodestablishments/small-and-medium-sized-enterprises-and-the-prerequisites-for-their-operations/a-risk-based-approach-and-impartial-controls/">https://www.evira.fi/en/foodstuff/manufacture-and-sales/foodestablishments/small-and-medium-sized-enterprises-and-the-prerequisites-for-their-operations/a-risk-based-approach-and-impartial-controls/

²¹¹ MacMaoláin, C. (2015). *Food Law: European, Domestic and International Frameworks*. Hart Publishing, United Kingdom, p. 56.

²¹³ Multi Annual National Control Programme Network (MANCP). (2014). *Risk based planning of official controls*, p. 3. Retrieved from <a href="https://www.livsmedelsverket.se/globalassets/produktion-handel-kontroll/vagledningar-kontrollhandbocker/vagledningar-och-information-fran-eukommissionen/risk-based-planning-of-official-controls-may-2014

Even though the Regulation provides with some general guidelines to measure risk, competent authorities need to build their own risk models in order to ensure that controls within their jurisdiction stay effective. For instance, in Belgium, the Federal Agency for the Safety of the Food Chain (FASFC) quantifies risk using three criteria: (i) the degree of harmful effect of the hazard (for instance, a disease), (ii) its prevalence within the population, and (iii) its contribution "to the overall food chain contamination, to the spread or the impact of the disease" 214.

As will be analysed in this thesis, the fact that a food product is offered online, or that an operator is internet-based, are factors that should be taken into account when evaluating risk and prioritizing controls.

1.3.2. Active food establishments must be registered to ensure they are included in official controls

In order to adopt a control plan that ensures that the control system fosters appropriate levels of compliance with food law, a control system must take into consideration the particularities of the national food sector. Thus, when defining control plans, competent authorities need to have detailed information on the type of activities are carried out within their jurisdiction, the location of active food establishments used to manufacture food products, and the identity of the operators responsible for the above.

Registration and approval²¹⁵ of food establishments is an essential element of the organization of official controls from farm to fork. It is enshrined in article 31²¹⁶ of

²¹⁵ It must be noted that, from now on, the thesis will use the concept of "registration" to refer also to approval.

²¹⁴ Federal Agency for the Safety of the Food Chain. (2011). *Risk-based controls & the MANCP: approach of the Belgian Federal Agency for the Safety of the Food Chain.* Retrieved from http://www.afsca.be/apropos/mancp/mancpbelge/_documents/2011_11_22_Risk_based_controls_BE_v1 1.pdf

^{...}

²¹⁶ Article 31 of the Regulation reads as follows: 1) a) Competent authorities shall establish procedures for feed and food business operators to follow when applying for the registration of their establishments in accordance with Regulation (EC) No 852/2004, Directive 95/69/EC or with the future regulation on feed hygiene; b) They shall draw up and keep up to date a list of feed and food business operators which have been registered. Where such a list already exists for other purposes, it may also be used for the purposes of this Regulation. 2) a) Competent authorities shall establish procedures for feed and food business operators to follow when applying for the approval of their establishments in accordance with Regulation (EC) No 852/2004, Regulation (EC) No 854/2004, Directive 95/69/EC or with the future regulation on feed hygiene. b) Upon receipt of an application for approval from a feed or food business operator, the competent authority shall make an on-site visit. c) It shall approve an establishment for the activities concerned only if the feed or food business operator has demonstrated that it complies with the relevant requirements of feed or food law. d) The competent authority may grant conditional approval if it appears that the

Regulation 882/2004, and determines that competent authorities must define a procedure for food businesses to fully identify the locations they operate from. Based on the information received, competent authorities must keep an updated list of active food business operators. The goal of this legal provision is to better organize official controls and the national control plan: it is easier to identify frequent risks when the type of businesses and type of products and processes carried out in a jurisdiction are clearly identified.

The concept of "establishment" is defined in Regulation 852/2004, as "any unit of a food business." This includes not only processing premises, but also warehouses, retail stores, and any other establishments that are used for the manufacture of the food product. "Catering businesses run from home and mobile or temporary premises, such as stalls and vans"²¹⁷ are considered establishments that must register before proper authorities.

The details on which establishments need to be registered and which ones need to obtain prior approval in order to operate legally are set in article 6 of the EU Food Hygiene Regulation. Regarding registration,

(...) every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment²¹⁸.

establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of feed or food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months. e) The competent authority shall keep the approval of establishments under review when carrying out official controls. If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time; f) The competent authorities shall maintain up-to--date lists of approved establishments and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 62(3).

Food Standards Agency. (n.d.). *Starting a food business*. Retrieved from https://www.food.gov.uk/business-industry/startingup

²¹⁸ Paragraph 2 of article 6 of regulation 852/2004 of 29 April 2004.

On the other hand, establishments dealing with food from animal origin (and those required by national or EU legislation because of their particularities)²¹⁹ must apply for approval, which cannot be granted without a visit from the competent authority.

Thus, Member States to adopt legislation that

- clearly identifies which competent authority (local, regional, central) is responsible for registration and approvals,
- defines a procedure for operators to apply for registration or approval of establishments within their jurisdiction (including an on-site visit of establishments seeking for approval), and
- provides legal base to create a list of establishments and operators.

However, not all food business operators are required to register or request approval of their establishments. As analysed in section – of Chapter 1 of this thesis, Regulation 852/2004 excludes from this obligation undertakings consisting on the offer of small quantities of primary products (.i.e. vegetables grown in a household), collection centres and tanneries, and those that do not have "a certain continuity of activities and a certain degree of organization." The scale of the traditional brick-and-mortar market entails that consumer-to-consumer trade of food products generally fits within that last category. Thus, they do not need to register their establishments (for example, the apartment they prepare and deliver the food from) and are left out of control plans.

Competent authorities can still control these exchanges based on the fact that the General Food Law imposes the general obligation of ensuring that food is not placed in the market if it is unsafe. But, in practice, controls on commerce-to-commerce food transactions are only carried out when incidents occur or complaints are filed. The lack of registration of the establishment is normally not a problem, as the consumer is able to identify where and from whom it got the food product.

adopted in accordance with the procedure referred to in Article 14(2). Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.

111

²¹⁹ According to paragraph 3 of article 6 of Regulation (EC) 852/2004 of 29 April 2004, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required: a) under the national law of the Member State in which the establishment is located; b) under Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin; or c) by a decision adopted in accordance with the procedure referred to in Article 14(2). Any Member State requiring the

However, when private individuals offering food products on an occasional basis use digital platforms, they reach a much larger base of potential consumers. Offers are placed to strangers that may not be able to properly identify the other party, to the extent that they may not know that the food product is responsibility of a peer instead of a professional operator. Hence, if problems arise, it may be difficult for competent authorities to act.

Digital platforms are making it increasingly popular to offer homemade foods, which results in a greater number of peer-to-peer transactions completed. Moreover, research²²⁰ demonstrates that it is frequent that the food products offered are unsafe because they have not been properly handled or delivered. But, even though staff in charge of official controls can identify non-compliant offers online, there is not much they can do to control it because they cannot properly identify the person responsible for that food. It is frequent that those engaging in C2C through digital platforms open their account with a user name that is different to their personal identity, and that the platform itself does not require users to submit their personal details.

1.4. Rules governing the performance of official controls

In order to protect the effectiveness of control tasks, Regulation 882/2004 mandates that official controls are carried out without prior warning to the operator and that Member States' law must impose on operator the obligation to collaborate with control tasks performing controls.

• Food business operators must not be given advanced notice of controls²²¹ in order to protect the outcome of control activities. If an operator knows beforehand that its premises or products are going to be controlled, it is likely that measures in order to minimize or to hide non-compliance will be taken. However, even though no prior warning is the "golden rule"²²², the Regulation still allows for prior warning in the case of audits and also when the specific circumstances require (for

²²⁰ See section 2 of Part 1 of Chapter 3, on the German control plan of 2014.

²²¹ Paragraph 2 of article 3 of the Regulation (EC) 882/2004 indicates that Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis.

²²² Lex Studio Legale Alimentaria. (2010). *Shortcomings in enforcing EU food law. What does EU food law stand for?* p. 7. Retrieved from http://regulation.upf.edu/dublin-10-papers/2F4.pdf

instance, when there has been an alert and competent authorities need operators to check their own controls or products even before official controls take place).

• Member States' legislation must ensure that operators are obliged to undergo any inspection carried out in accordance with the Compliance Regulation and to collaborate with control staff²²³. The extent of collaboration is not limited to providing access to premises and documents, operators must have a proactive role to ensure that staff is able to accomplish control tasks properly²²⁴.

In order to balance the scales, the Compliance Regulation also includes rules for performing controls that protect business interests and its right of defence.

To that end, it specifically identifies the right of appeal and the right of those "whose products are subject to sampling and analysis, to apply for a supplementary expert opinion"²²⁵. Although the details on how to exercise those rights are to be regulated by national law, there are common guidelines that must be respected.

The right of appeal recognized in article 54 entails that "irrespective of the remedies available to him in the event of a court sentence" ²²⁶, a food business operator can contest measures taken against him as a result of the performance of official controls, such as a destruction order or a temporary prohibition to sell. Because competent authorities can carry out ad hoc controls even when there is no suspicion of non-compliance with food law, the right of appeal does not apply to the decision to perform a control activity (such as decision to carry out an inspection of an establishment or to sample a food product for analysis).

In order to ensure right of appeal, competent authorities must have a formal procedure to process complaints about their activities and must inform defendants of how to conduct an appeal. Moreover, competent authorities must keep detailed, written records of official

²²³ Paragraph g) of article 4 of Regulation 882/2004 of 29 April 2004.

²²⁴ *Ibid* Paragraph 2 of article 8.

²²⁵ *Ibid* Article 11 (5).

²²⁶ Gérard, A. (1983). *An Outline of Food Law: Structure, Principles, Main Provisions*. Food & Agriculture Org., Rome, p. 78.

controls²²⁷. Written procedures provide food businesses with documentary evidence on the scope and results of the controls that have been performed in their premises or over their products. Thus, Regulation 882/2004 mandates that competent authorities undertaking control activities "prepare reports of individual controls and provide copies to businesses"²²⁸.

The goal of the documentary procedure is also to ensure quality and transparency²²⁹ of official control activities, as all documentary evidence will be later used by public authorities and auditors when reviewing the efficiency of control tasks.

Lastly, the Compliance Regulation identifies the right to a supplementary expert opinion as a key element protecting food business right to defence. It entails that competent authorities must adopt legislation that ensures that operators can cross-check the results of the analysis of their products that has been sampled in the framework of official controls. "In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate" 230. When sampling, control staff is required to make sure that "one or more additional specimens are taken at the same time and under identical circumstances as the original (...)" The details on how to ensure cross-examination has not been harmonised at the EU level.

²²⁷ Paragraph 1 of article 8 of the Regulation states that competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, inter alia, the areas referred to in Annex II, Chapter II.

²²⁸ Food Standards Agency. Regulation (EC) No 882/2004 on official controls: guidance in Q&A format for enforcement authorities on the feed and food elements. Retrieved from https://www.food.gov.uk/sites/default/files/multimedia/pdfs/offcqaguidancenotes.pdf

²²⁹ Other transparency requirements are set in paragraph 1 of article 7 of the Regulation, which mandates that "competent authorities in Member States must publish information on official controls that are carried out and on their effectiveness. Businesses and citizens may access a large amount of reports available through the Commission's or the competent authorities' website, but they may also request additional information following the administrative procedure established in each country. Because transparency is the rule, whenever competent authorities deny access they need to justify their decision in writing. In particular, paragraph 2 and 3 of the referred article establishes professional secrecy rules that apply to the sharing and publishing of specific information on official controls. For instance, under Regulation 882/2004, individual inspection reports are not disclosed to the public. Transparency requirements are also set for the Commission. Its obligations include making available annual reports identifying and evaluating the monitoring and enforcement arrangements implemented by Member States.

²³⁰ Article 11 (6) of Regulation 882/2004 of 29 April 2004.

²³¹ Gérard, A. (1983). *An Outline of Food Law: Structure, Principles, Main Provisions*. Food & Agriculture Org., Rome, p. 79.

1.5. Activities included in official controls

Official controls may be carried out both at the food business operator's premises and during transportation (controlling production), and at the retail stores (controlling distribution).

When controls are made on production, the object of controls can be an establishment itself, but also the food handling procedures, documentary records, or self-surveillance systems put into place by the operator to minimize non-compliance with food law requirements. Controlling production is considered by competent authorities to be the most effective way to minimize risks for consumers, because it allows for assessing non-compliance situations that may affect several batches of production. However, in order to control production, competent authorities must have detailed information on the location of active food establishments and on the activities that take place there. If food business operators have not fulfilled their registration obligation, it is most likely that controls on production will not take place.

On the other hand, while controlling distribution is useful to check products as they are purchased by the final consumer, the scope of product that is going to be affected by control is much shorter.

In both situations, staff performing official controls can perform documentary, identity or physical checks²³². Identity checks consist on visual examination that documents accompanying the food product and consignment tally with its actual content and labelling. Documentary checks focus on assessing compliance through any commercial or accompanying documents required by traceability obligations. Lastly, physical checks go one step further and may include sampling for analysis and laboratory testing of raw materials, ingredients, and of the foodstuff as is sold to the final consumer.

Control activities include both regular monitoring activities and more intensive forms of controls such as inspections, verifications, audits, monitoring, surveillance and sampling

the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law.

115

²³² According to article 2 of the Regulation, 17. "Documentary check" means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment; 18. "Identity check" means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of the consignment; 19. "physical check" means a check on the feed or food itself which may include checks on

for analysis²³³. Article 2 of Regulation 882/2004 includes legal definition of these concepts:

- "Inspection" is "the examination of any aspect of feed, food, animal health
 and animal welfare in order to verify that such aspect(s) comply with the legal
 requirements of feed and food law and animal health and animal welfare
 rules."
- "Verification" corresponds to "checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled."
- An "audit" is "a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives." The purpose of audits is to "verify that the food operator has designed, applies and maintains procedures based on the HACCP system in accordance with the established requirements and that these are effective for the production of safe food" When engaging in audits, competent authorities lessen the odds of non-compliant food reaching the market by ensuring that operators know how to better control their products.
- "Monitoring" is defined as "conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules."
- Conducting "surveillance" entails "a careful observation of one or more feed or food businesses, feed or food business operators or their activities."
- "Sampling for analysis" is defined as "taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order

²³³ As indicated in Recital 12 of Regulation 882/2004 of 29 April 2004 on the official controls should be carried out using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples.

²³⁴ Río del, A. (2014). *Aspectos jurídicos del control sanitario oficial de los alimentos*. Paper presented at Máster en Ciencias Jurídicas. Facultad de Derecho, Universidad de Lleida, p. 57. Retrieved from https://repositori.udl.cat/bitstream/handle/10459.1/49252/ariom.pdf?sequence=1

to verify through analysis compliance with feed or food law or animal health rules."

The Compliance Regulation does not define the procedure that staff performing official controls must follow when conducting any of those control activities, as it rests within the power of Member States. But, as will be illustrated later in this thesis, national legislation in most countries has neglected the task. Only when it comes to sampling have Member States provided a legal framework to competent authorities.

The decision to regulate the sampling process is based on the fact that,

En muchos casos [la muestra] será la única prueba para que la Administración dicte una resolución que puede tener consecuencias tan gravosas para el operador alimentario como rechazar la entrada de un determinado alimento en un país, la retirada de un producto del mercado o para la imposición de una sanción²³⁵.

Thus, the procedure for taking and analysing a sample must ensure that business' right of defence is safeguarded while providing legal certainty as to what constitutes a valid sample for enforcement.

1.6. Sampling for analysis

Among physical checks, sampling for analysis is particularly important because, in most cases, the result of the analysis is the only evidence that competent authorities have to prove that a food product, raw material or packaging does not comply with food law requirements. However, for the result of the analysis to be considered valid for enforcement purposes, "samples must be handled in such a way as to guarantee both their legal and analytical validity"²³⁶.

The only samples that are legal and analytically valid are considered a "fair sample" representative of the lot they come from. Member State's laws define the legal procedure to obtain fair samples "that accurately reflects the constituent of the bulk material" ²³⁷.

²³⁵ Río del, A. (2014). *Aspectos jurídicos del control sanitario oficial de los alimentos*. Paper presented at Máster en Ciencias Jurídicas. Facultad de Derecho, Universidad de Lleida, p. 57. Retrieved from https://repositori.udl.cat/bitstream/handle/10459.1/49252/ariom.pdf?sequence=1

²³⁶ Article 16 (3) of Regulation 882/2004 of 29 April 2004.

²³⁷ Food Standards Agency. (2004). *Practical sampling guidance for food standards and feeding stuffs. Part 2: Food Standards Sampling*, p. 3. Retrieved from https://www.food.gov.uk/sites/default/files/multimedia/pdfs/samplingguidancepart2.pdf

It is up to national law to determine how to obtain a fair sample. However, some principles and operational criteria can be identified in the EU food law:

- Samples may be taken at the production stage (i.e. at the operators' premises or during transportation) or at the distribution stage (i.e. at the retail store). When dealing with imported foodstuffs, samples may also be taken at the designated Border Inspection Post. Official controls must take place "from farm to fork," and compliance should be assessed at any stage of production or distribution.
- Sampling shall be undertaken without prior warning, in the framework of a specific control plan or *ad hoc* controls. There is no need for suspicion of noncompliance to exist. Therefore, the operator has no right to appeal the decision of taking a sample.
- The sampling process must recorded in an inspection report, as the Compliance Regulation mandates that control activities must be documented by writing.

In addition, article 11 of Regulation 882/2004 (together with Annex III of the same piece of legislation) provides competent authorities with additional rules on how to establish specific methods of sampling and analysis of foodstuffs subject to official controls:

- Samples can only be analysed by laboratories that have been previously appointed by competent authorities after verification that they meet requirements set in article 12. This includes private laboratories that are accredited against EN ISO/IEC 17025 for the tests being carried out. This provision seeks to ensure that those handling the sample and performing the analysis are properly trained on the technical and legal requirements, and that the equipment used to undertake the tests is appropriate.
- When EU legislation on methods of analysis exists (as is the case, for example, regarding microbiological hazard testing)²³⁸, procurement of a fair sample must comply with the regulated method. When no valid method has been established at the European level, competent authorities must follow internationally recognized protocols. If none of the above applies to a particular case, then national protocols

²³⁸ European Commission. Commission Regulation (EC) 2073/2005 of 15 November 2005 on, on microbiological criteria for foodstuffs provides relevant information on the methods for sampling and analysis to check compliance with microbiological targets.

can be established. Lastly, "in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols"²³⁹. This requirement does not only aim at ensuring the validity of the sample, but also at encouraging the use of the methods that are considered more reliable from a scientific perspective. Given that those products that enter the EU market will be tested under those specific methods, third-countries' stakeholders are likely to decide to use these same methods in their home countries in order to ensure compliance under EU standards.

Also, based on several²⁴⁰ EU Commission guidance documents on this issue, sampling must be done in accordance with internationally recognized standards such as the Codex Alimentarius' General Guidance on Sampling²⁴¹. A basic requirement is that a fair sample valid for enforcement it should be representative of the batch²⁴² it has been selected from.

Sampling is usually carried out according to sampling plans that provide competent authorities with detailed instructions on how to select the specimen object of sampling, the minimum size of the lot to be sampled and of the sample itself, and how to perform the analysis. Sampling plans are necessary to ensure "that fair and valid procedures are used when food is being controlled for compliance"²⁴³. It can occur that "for certain analyses/parameters in foodstuffs, there are regulations, instructions and directives on the sampling method and number of samples, and these should be used where applicable"²⁴⁴.

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²³⁹ As indicated in paragraphs 1 to 4 of Regulation (EC) 882/2004 of 29 April 2004.

²⁴⁰ Among other, its Guidance Document on official controls, under European Commission. (2006). Guidance document on official controls, under Regulation (EC) 882/2004, concerning microbiological sampling and testing of foodstuffs. Health & Consumer Protection Directorate-General. Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/oc_leg_guidance_sampling_testing_en.pdf

²⁴¹ Codex Food Standards. (2004). *General Guidelines on Sampling CAC/GL 50-2004*. Retrieved from http://www.fao.org/uploads/media/Codex_2004_sampling_CAC_GL_50.pdf

²⁴² A batch (also known as "lot") does not refer to the lot number included in a food label for traceability purposes, but to "a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period" as defined in article 2 paragraph (e) of Regulation n° 2073/2005, of 15 November 2005 on microbiological criteria for foodstuffs.

²⁴³ Codex Food Standards. (2004). *General Guidelines on Sampling CAC/GL 50-2004*, p. 5. Retrieved from http://www.fao.org/uploads/media/Codex_2004_sampling_CAC_GL_50.pdf

²⁴⁴ Nordic Committee on Food Analysis. (2014). *Guide on sampling for analysis of foods*, p. 15. Retrieved from http://www.nmkl.org/dokumenter/prosedyrer/en/PROC12 ENG.pdf

For example, Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs, states the following criteria to be followed by competent authorities when sampling cereals:

B.4. Method of sampling for cereals and cereal products for lots < 50 tones

For lots of cereals and cereal products less than 50 tones, the sampling plan shall be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10 kg. For very small lots (\leq 0,5 tones) a lower number of incremental samples may be taken, but the aggregate sample combining all incremental samples shall be also in that case at least 1 kg.

B.5. Sampling at retail stage

Sampling of foodstuffs at the retail stage must be done where possible in accordance with the provisions set out in this part B of Annex I.

Where that is not possible, an alternative method of sampling at retail stage may be applied provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg.

When such instructions exist (in the law or in official controls sampling plans defined according to internationally recognized standards), competent authorities must ensure that sampling meet these terms in order to ensure that the sample is valid for enforcement.

Paragraphs 5, 6 and 7 of article 11 of Regulation 882/2004 discuss the specific challenge of ensuring the operators' capacity to request cross-examination of analytical results. In particular, the EU Regulation establishes that when the result of an analysis establishes non-compliance with food law, food business operators responsible for the product that has been sampled have the right to request "supplementary expert opinion²⁴⁵." Cross-examination does not imply the exercise of right of appeal: it is an independent prerogative of the operator that is exercised before non-compliance has been established and therefore before completion of the administrative procedure.

7. Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.

120

²⁴⁵ As states in article 11 of Regulation 882/2004, (...) 5. The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency. 6. In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.

Competent authorities in Member States are to regulate how operators can exercise the right to a supplementary expert opinion. Nevertheless, the Regulation does demand that national laws "ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable²⁴⁶ products or very low quantity of available substrate" 247

In practice, Member States' laws mandate that the sample is large enough to be divided in sample portions that may be subject to testing separately. As will be discussed in the next sections, some countries such as Spain or the United Kingdom, even go one step further, and require for the sample to be large enough for three different tests.

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²⁴⁶ It may be noted that there is no legal definition of what a "highly perishable food" is nor of what is considered a "very low quantity of available substrate."

²⁴⁷ For instance, as recalls the guidance document on official controls, under Regulation (EC) 882/2004 of 29 April 2004, concerning microbiological sampling and testing of foodstuffs, published by the Directorate General for Health & Consumers in 2006, the competent authority should inform the food business operator about the limitations of supplementary sampling for microbiological analysis. For microbiological analysis the results obtained from samples for a supplementary opinion may be of limited value as the distribution of micro-organisms within a food is often not homogenous. No two samples of the food will be the same and it is not uncommon that the results of samples for official controls and for supplementary opinion will differ. Also, bacteria may not survive or may even multiply during storage of the sample again affecting results of samples for supplementary opinion. Retrieved from: the a http://www.fve.org/veterinary/pdf/food/guidance_doc_882-2004_en.pdf

2. MEMBER STATE'S LAW PLAYS A DECISIVE ROLE IN OFFICIAL CONTROLS. SPAIN AS A CASE-CONTROL STUDY

The Compliance Regulation gives Member States a certain margin of discretion to design a legal framework for the organization and performance of official controls. Among other, Member States' legislation covers a wide range of issues:

- it assigns responsibilities to specific branches and levels of government,
- it appoints a *liaison body* that channels administrative cooperation between Member States,
- it regulates the procedure that operators must comply with to register its establishments before proper authorities,
- it sets rules to identify the competent authority in charge of performance of controls,
- it defines the procedure that staff performing official controls must follow when carrying out control activities, and, among many other,
- it establishes the list of infractions and the corresponding sanctions to be applied by competent authorities when food business operators fail to comply with food law.

Given that the Compliance Regulation leaves so many aspects to Member States' discretion, the official control system cannot be properly analysed without describing state laws. The following sections illustrate the role of Member States' law using the Spain as a case-control study²⁴⁸.

²⁴⁸ Chapter 3 provides a similar description of the legislation in Germany and the United Kingdom. Section 3 of that Chapter compares the differences between the three Member States.

2.1. The administrative organization of official controls in Spain

Spain is a decentralized state²⁴⁹. The Constitution establishes a distribution of competences among the three public administrations: national, regional and local²⁵⁰. "Autonomous Communities" is the name given to the seventeen regional public administrations, and "Provinces" and "municipalities" constitute the local public administration. All three levels of government have a significant role when it comes to official controls.

The Spanish Constitution states that the responsibilities of the national public administration²⁵¹ include international relations, criminal law and customs among other, while Autonomous Communities are responsible for relevant areas for this thesis such as consumer protection, agriculture and farming, and health²⁵². Responsibilities of the local public administration are those determined by law or by delegation²⁵³.

The Ley 17/2011, de 5 de julio, de seguridad alimentaria y nutrición (hereinafter, "Law 17/2011") is the national piece of legislation that governs food law and policy in Spain. Law 17/2011 echoes the goals and principles of the General Food Law and of European Food Law: food must be safe²⁵⁴ and food business operators have the primary responsibility to ensure compliance with food law requirements²⁵⁵.

Regarding official controls, this law merely states that food official controls shall be carried out by whichever public administration has the responsibility in that area of

²⁴⁹ As stated in article 137 of the Spanish Constitution of 1978, "el Estado se organiza territorialmente en municipios, en provincias y en las Comunidades Autónomas que se constituyan. Todas estas entidades gozan de autonomía para la gestión de sus respectivos intereses."

²⁵⁰ Indeed, article 149 of the Constitution states the responsibilities of the national public administration (that include international relations, criminal law and customs among other), while article 148 indicates what the responsibilities of Autonomous Communities are (most of them relevant to our research, as they include consumer protection, agriculture and farming, and health among others). Finally, article 140 of the Spanish Constitution indicates that responsibilities of the local public administration are those determined by law or by delegation.

²⁵¹ In particular, article 149 of Constitución Española. Boletín Oficial del Estado, 29 de diciembre de 1978, núm 311, pp. 29313 a 29424. Retrieved from https://www.boe.es/buscar/doc.php?id=BOE-A-1978-31229

²⁵² In particular, article 148 of the Spanish Constitution of 1978.

²⁵³ Article 140 of the Spanish Constitution 1978.

Article 8 of Law 17/2011, de 5 de julio, de seguridad alimentaria y nutrición. Boletín Oficial del Estado, 6 de julio de 2011, núm. 160, pp. 71283 a 71319. Retrieved from https://www.boe.es/diario_boe/txt.php?id=BOE-A-2011-11604

²⁵⁵ Article 9 of Law 17/2011, de 5 de julio, *op. cit.*

governing issue according to the Constitution²⁵⁶. The general rule is that the national government is in charge of policy setting (and therefore retaining most legislative powers) while the regional and local authorities are implementing most of the food control tasks.

Even though surveillance, monitoring and enforcement in the framework of official controls is generally is in hands of regional authorities, the role of the national government is also vital. In order to make sure that food safety policies and control decisions are harmonized with national interest, horizontal policy decisions are adopted by either the Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente (MAGRAMA) or by the Ministerio de Sanidad, Servicios Sociales e Igualdad (MSSSI).

- MAGRAMA deals with primary production, feed safety and food quality. The
 ministry is "national contact point and user of the Administrative Assistance and
 Cooperation System (ACC System)"²⁵⁷.
- MSSSI holds most of the food-safety-related responsibilities, and is in charge of health policies. Most of its responsibilities regarding food safety and nutrition have been delegated to the Agencia Española de Consumo, Seguridad Alimentaria y Nutrición (AECOSAN), which is "a subordinate specialist authority within the MSSSI." AECOSAN constitutes the national independent food safety agency providing risk assessment in Spain. It is also in charge of submitting the Spanish multi-annual control plan for official controls to the European Commission. AECOSAN is also responsible for discussing most food legislation initiatives²⁵⁸ as well as for ensuring coordination between competent authorities in Spain.

Law 17/2011 also provides the general framework for coordination among competent authorities in Spain. It is the legal base for the creation of coordination different bodies

124

²⁵⁶ As stated in paragraph 1 of article 14 of law 17/2011, Corresponde a las distintas Administraciones públicas, en el ámbito de sus respectivas competencias, la realización de los controles oficiales necesarios para asegurar el cumplimiento de lo previsto en esta ley y las disposiciones de las comunidades autónomas aplicables en la materia. A estos efectos, el punto de contacto con la Comisión Europea y con los restantes Estados miembros de la Unión Europea será la Agencia Española de Seguridad Alimentaria y Nutrición.

²⁵⁷ Herges, L., Kaus, S., Böl, G.F., & Gollnick, N. (2017). *EU Food Safety Almanac* (4th ed.). German Federal Institute for Risk Assessment (BfR). Berlin, p. 91.

²⁵⁸ In this regard, Law 17/2011 states that AECOSAN, a través de sus órganos encargados de establecer mecanismos eficaces de coordinación y cooperación entre las Administración públicas con competencias en materia de seguridad alimentaria, y teniendo en cuenta las directrices que por la Comisión europea se establezcan al respecto, adoptará los objetivos, los contenidos y periodicidades correspondientes al Plan nacional integral de carácter plurianual.

(permanent bodies or *ad hoc* forums that deal with specific issues.) that deal with the organization and implementation of the official controls system. Design and implementation of "procedures, control programs, guidelines and homogeneous criteria for regulatory interpretation"²⁵⁹, are discussed in coordination forums. Their composition includes representatives of the three levels of government.

As mandated by the Compliance Regulation, Spain has adopted legislation regarding the organization and implementation of official controls. Relevant Spanish laws are considered framework legislation that autonomous communities may transpose into regional legislation. However, these regional laws are "merely executive" of the national guidelines, "establishing the general principles of this intervention as well as the regime of infractions and sanctions"²⁶⁰ that mirrors national provisions. Regional legislation is not analysed in this thesis because all essential elements of official controls regulation are already present in national law.

2.2. Regulating the organization of official controls

Adequate organizing and prioritizing of control tasks is essential for the official controls system to function effectively and attain its objectives. In application of EU law, each Member State needs to design a multi-annual national control plan that helps individual competent authorities make control decisions that guarantee appropriate levels of compliance with food law requirements.

The legal base for the Spanish national control plan is enshrined in article 15 of Law 17/2011. Known as Plan Nacional de Control Oficial de la Cadena Alimentaria (hereinafter, "PNCOCA"), the current plan was approved in December 2015 and covers the period 2016-2020. The Plan puts especial care in delimiting the responsibilities of each level of the public administration, and provides competent authorities with guidelines on what controls to perform the most based on a risk-based approach. It defines 28 programs grouped into three thematic sections: control programs on foreign trade;

²⁵⁹ Agencia Española de Consumo, Seguridad Alimentaria y Nutrición. (2017). *Plan Nacional de Control Oficial de la Cadena Alimentaria 2016-2020*, p. 11. Retrieved from http://www.aecosan.msssi.gob.es/AECOSAN/docs/documentos/seguridad alimentaria/pncoca/PNCOCA20162020Espaa.pdf

²⁶⁰ Río del, A. (2014). *Aspectos jurídicos del control sanitario oficial de los alimentos*. Paper presented at Máster en Ciencias Jurídicas. Facultad de Derecho, Universidad de Lleida. Retrieved from https://repositori.udl.cat/bitstream/handle/10459.1/49252/ariom.pdf?sequence=1

official control programs in agriculture, livestock, fisheries and food; and official control programs in food establishments²⁶¹. The plan does not refer to e-commerce at all.

The Spanish national control plan does not refer to e-commerce. There are no specific actions focussing on e-foods. There are no sampling plans to control e-foods available in the digital market. Food establishments used for e-commerce are controlled, if known to the authorities, based on a risk analysis that does not take into account if the operator responsible is internet or store-based.

PNCOCA was designed and is regularly updated taking into consideration the activities carried out in food establishments in the national territory, and the food products that reach the brick-and-mortar market. This information is extracted primary from the database of registered food establishments and of the resulting list of active food business operators.

The obligations of Member States set in Regulation 882/2004 and Regulation 852/2004 regarding registration and approval of food establishments are transposed into the national legal framework in article 24 of Law 17/2011, which creates the Registro General Sanitario de Empresas Alimentarias y Alimentos (hereinafter, "RGSEAA"). Law 17/2011 describes the general framework for registration. It identifies that food business operators must apply for registration before the competent authority where the food establishment is located. The national government is responsible for ensuring that all regional registers

²⁶¹ *Ibid.*, p. 52.

are "connected and coordinated" ²⁶² and for creating a public website that allows for centralized access to the full list of operators inscribed ²⁶³.

Real Decreto 191/2011, de 18 de febrero, sobre Registro General Sanitario de Empresas Alimentarias y Alimentos ("RD 191/2011"), provides additional rules on registration.²⁶⁴ This piece of legislation specifies that all food establishments must be properly registered. Also, those food businesses that do not have establishments in the Spanish territory but

²⁶² Ley 17/2011 de seguridad alimentaria, CAPÍTULO IV. Instrumentos de seguridad alimentaria. Artículo 24. Registros. 1) Para la consecución de los objetivos de esta ley, las Administraciones públicas, en el ejercicio de sus competencias, crearán o mantendrán los registros necesarios para el conocimiento de las distintas situaciones de las que puedan derivarse acciones de intervención en materia de seguridad alimentaria. La solicitud de inscripción en los registros no comportará actuaciones adicionales por parte de los interesados, salvo las derivadas de la actualización de la información declarada y la solicitud de cancelación de inscripción al causar baja. 2) La exigencia de autorizaciones sanitarias, así como la obligación de someter a registro por razones de seguridad alimentaria a las empresas o productos, serán establecidas reglamentariamente, tomando como base lo dispuesto en la presente ley, la normativa europea y el artículo 25 de la Ley General de Sanidad. 3) La Administración General del Estado, sin menoscabo de las competencias de las comunidades autónomas, desarrollará los registros de alimentos y piensos, de carácter nacional, de las empresas, establecimientos o instalaciones que los producen o importan, transforman o comercializan, que recogerá las autorizaciones o comunicaciones que las comunidades autónomas lleven a cabo de acuerdo con sus competencias. 4) Los distintos registros existentes estarán conectados y se coordinarán entre si a fin de asegurar la unidad de datos, economía de actuaciones y eficacia administrativa. 5) Además, a tenor de lo dispuesto en el anexo V, capítulo I, del Reglamento 2074/2005 de la Comisión, de 5 de diciembre de 2005, por el que se establecen medidas de aplicación para determinados productos con arreglo a lo dispuesto en el Reglamento (CE) n.º 853/2004 del Parlamento Europeo y del Consejo y para la organización de controles oficiales con arreglo a lo dispuesto en los Reglamentos (CE) n.º 854/2004 del Parlamento Europeo y del Consejo y (CE) n.º 882/2004 del Parlamento Europeo y del Consejo, se introducen excepciones a lo dispuesto en el Reglamento (CE) n.º 852/2004 del Parlamento Europeo y del Consejo y se modifican los Reglamentos (CE) n.º 853/2004 y (CE) n.º 854/2004, la Agencia Española de Seguridad Alimentaria y Nutrición será la responsable de establecer el sitio web nacional para facilitar su coordinación con el sitio web de la Comisión Europea.

²⁶³ Agencia Española de Consumo, Seguridad Alimentaria y Nutrición. (n.d.) Buscadores AECOSAN. Retrieved from http://www.aecosan.msssi.gob.es/AECOSAN/web/seguridad_alimentaria/subseccion/buscadores.htm

Artículo 1. Objeto, ámbito y naturaleza del Registro General Sanitario de Empresas Alimentarias y Alimentos: 1) El Registro General Sanitario de Empresas Alimentarias y Alimentos, en lo sucesivo Registro, adscrito a la Agencia Española de Consumo, Seguridad Alimentaria y Nutrición del Ministerio de Sanidad, Servicios Sociales e Igualdad, tiene como finalidad la protección de la salud pública y de los intereses de los consumidores, facilitando el control oficial de las empresas y establecimientos sometidos a inscripción según lo dispuesto en el artículo 2. 2) El Registro tendrá carácter nacional y se considerará un registro unificado de ámbito estatal, en el que se incluirán los datos obrantes en los registros gestionados por los órganos competentes de las comunidades autónomas. Además, todas las Administraciones públicas prestarán su colaboración para conseguir la mayor eficacia y exactitud del Registro, así como para dar publicidad adecuada a los datos del mismo, sin perjuicio de los límites establecidos por la normativa de aplicación al tratamiento de los datos de carácter personal. 3) El Registro tendrá carácter público e informativo y se constituirá como base de datos informatizada. 4) La inscripción en el Registro no excluye la plena responsabilidad del operador económico respecto del cumplimiento de la legislación alimentaria.

that place food products in the Spanish market should apply for registration of the company itself²⁶⁵.

It also provides information on when the obligation to register first appears (when activities in the establishment begin), as well as on relevant modification or cancellation of business activities that must be submitted to the competent authority for inscription²⁶⁶. Moreover, the Royal Decree defines the procedure²⁶⁷ that food business operators need to follow in order to apply for registration. However, the specific documents that need to be submitted to authorities are determined by regional law.

²⁶⁵ Article 2 of Real Decreto-ley 191/2011, de 18 de febrero, sobre Registro General Sanitario de Empresas Alimentarias y Alimentos. Boletín Oficial del Estado, 8 de marzo de 2011, núm. 57, pp. 26012 a 26019. Retrieved from https://www.boe.es/diario_boe/txt.php?id=BOE-A-2011-4293

²⁶⁶ Under article 5 of the Royal Decree, Serán objeto de asiento en el Registro: a) El inicio de las actividades de las empresas y establecimientos relacionados en el artículo 2.1, a cuyo efecto se practicará la correspondiente inscripción de acuerdo con el procedimiento establecido en el artículo 6. No obstante, el establecimiento que se dedique, exclusivamente, al almacenamiento o depósito de productos envasados, perteneciente a una empresa que posee en el territorio de la misma comunidad autónoma un establecimiento de producción, transformación, elaboración o envasado, no será objeto de inscripción independiente sino que figurará anotado en la de este último establecimiento. b) La modificación de cualquiera de los datos de la información obligatoria necesaria para la inscripción de las empresas y establecimientos alimentarios, contemplados en el artículo 6.

²⁶⁷ Artículo 6. Procedimiento para la inscripción, modificación y cancelación registral de las empresas y establecimientos alimentarios. 1) La presentación de una comunicación previa a las autoridades competentes será condición única y suficiente para que se tramite la inscripción de las empresas y establecimientos en el Registro y simultáneamente se pueda iniciar la actividad, sin perjuicio de los controles que posteriormente puedan llevarse a cabo. La información que el operador de la empresa debe aportar será la siguiente: su nombre o razón social, el NIF, NIE o CIF, el objeto de todas sus actividades y la sede del establecimiento o, en el caso de empresas que no posean ningún establecimiento, el domicilio social. En el caso de los establecimientos a que hace referencia el artículo 4.2 del Reglamento (CE) n.º 853/2004 del Parlamento Europeo y del Consejo, de 29 de abril de 2004, por el que se establecen normas específicas de higiene de los alimentos de origen animal, el operador deberá presentar una solicitud de inscripción para que las autoridades competentes de la comunidad autónoma procedan a su autorización. En este caso, la información que deberá suministrar la autoridad sanitaria competente a la Agencia Española de Seguridad Alimentaria y Nutrición para la inscripción, será la prevista en el párrafo anterior. 2) La comunicación previa o solicitud de inscripción, así como la comunicación de modificación de cualquiera de los datos de información obligatoria señalados en el apartado anterior o del cese definitivo de actividad económica de los establecimientos, se presentarán ante la autoridad competente de la comunidad autónoma por razón del lugar de su ubicación, en la forma que ésta disponga. En el caso de las empresas que no posean ningún establecimiento, se dirigirán a la autoridad competente de la comunidad autónoma en que se encuentre su domicilio social. 3) Una vez recibida la comunicación previa o, en su caso, autorizada la inscripción solicitada, las comunidades autónomas lo comunicarán a la Agencia Española de Seguridad Alimentaria y Nutrición, que procederá a su inscripción en el Registro y a la asignación del número de identificación de carácter nacional. El Registro comunicará a la comunidad autónoma correspondiente el número de identificación, dentro de los quince días hábiles siguientes a la recepción de la documentación. 4) Asimismo, la comunicación de modificación de los datos de la información obligatoria necesaria para la inscripción o de la resolución de cancelación de la inscripción por cese definitivo de la actividad económica, serán remitidas a la Agencia Española de Seguridad Alimentaria y Nutrición a los efectos del correspondiente asiento registral.

When it comes to the actual information that must be submitted by food business operators, as reads paragraph 1 of article 6,

"la información que el operador de la empresa debe aportar será la siguiente: su nombre o razón social, el NIF, NIE o CIF, el objeto de todas sus actividades y la sede del establecimiento o, en el caso de empresas que no posean ningún establecimiento, el domicilio social."

All regional registers request that activities are identified from a list that has been agreed upon in coordination with all relevant competent authorities. The establishment must be registered in a specific key that identifies the type of foods it handles (for instance, key 10 refers to establishments dealing meat and meat products and key 15 to those dealing with milk and milky products).

The activities carried out in the food establishment must be identified by selection one of the following six categories: manufacturing/processing/transformation, packaging, distribution, storage, import or "other specific phases of the production chain"²⁶⁸.

The Spanish registration system entails that establishments are registered under the activity that is more likely to entail higher food safety risks:

- Si un establecimiento fabrica, transforma o elabora un producto o en su cadena de producción realiza una o varias fases específicas, no se anota como envasador, almacenista o distribuidor del mismo.
- Si un establecimiento envasa un producto, no se anota como almacenista o distribuidor del mismo.
- Si un establecimiento almacena un producto, no se anota como distribuidor del mismo.
- La distribución se asigna a las empresas dedicadas a la comercialización de productos que no entran físicamente en las instalaciones de la empresa²⁶⁹.

²⁶⁸ Agencia Española de Consumo, Seguridad Alimentaria y Nutrición, Subdirección General de Promoción de la Seguridad Alimentaria. (2017) Guía para la clasificación e identificación de las empresas y establecimientos alimentarios. 3-4. Retrieved p. http://www.aecosan.msssi.gob.es/AECOSAN/docs/documentos/seguridad alimentaria/registro/guia oper adores.pdf

²⁶⁹ Agencia Española de Consumo, Seguridad Alimentaria y Nutrición. Subdirección General de Promoción de la Seguridad Alimentaria, op. cit., p. 5.

For example, a food operator which both produces and sells its products to the final consumer in the same food establishment should register said establishment in category 1 ("manufacturing/processing/transformation"). Thus, the register entre for this establishment does not provide information on the fact that retail sales are carried out there. The justification of this system is that manufacturing entails greater compliance and safety risks than distribution, thus if an establishment is controlled as a manufacturer, the type and continuity of controls are carried out on the premises should ensure safe distribution.

The Spanish registration system does not provide competent authorities with information on the fact that the establishment engages in e-commerce. Thus, if a control plan aims at controlling production of e-foods, the necessary information is not available in the RGSEAA database.

Lastly, Royal Decree 191/2011 also determines that food establishments that "exclusively manipulate, transform, package, store or serve food for sale or delivery on site to the final consumer, with or without home delivery, or to collectivities" are not registered in the national register RGSEAA²⁷⁰. Instead, retail establishments must be registered in the "register of minor food establishments"²⁷¹. It must be noted that this distinction is based on a decision of the Spanish authorities. EU law does not require such distinction.

There are 17 special registries of minor establishments²⁷², one for *each Comunidad* Autónoma²⁷³ When applying for registration of minor establishments, food business

²⁷⁰ So, the list of retail food stores in Spain cannot be accessed through the RGSEAA's website, but is available to the public at the regional governments'.

²⁷¹ It must be noted that retail stores that sell meat or meat-by-products need to register in a third different registry before regional authorities. In order to ensure food safety, operators will provide additional information to public authorities on the nature of the meat products they handle.

²⁷² Although citizens are legitimated to ask for information about the content of the registry, there is no digital public database making this information accessible to the general public or centralised access to the information of the data collected by each region.

²⁷³ Article 2 of the Royal Decree indicates that: Quedan excluidos de la obligación de inscripción en el Registro, sin perjuicio de los controles oficiales correspondientes, los establecimientos y sus empresas titulares en el supuesto de que exclusivamente manipulen, transformen, envasen, almacenen o sirvan alimentos para su venta o entrega in situ al consumidor final, con o sin reparto a domicilio, o a colectividades, así como cuando éstos suministren a otros establecimientos de estas mismas características, y se trate de una actividad marginal en términos tanto económicos como de producción, respecto de la realizada por aquéllos, que se lleve a cabo en el ámbito de la unidad sanitaria local, zona de salud o territorio de iguales características o finalidad que defina la autoridad competente correspondiente. Estos

operators must provide basic information of the activities that are carried out at the store. However, even though each region has created its own general register and registry of retail stores, and each has adopted legislation detailing the procedure and information that stores need to provide the administration with in order to operate, they all require operators to submit the same information. Also, the classification of retail activities that operators must choose from is almost identical.

For example, the legal Framework for registration of minor establishments in the Comunidad Autónoma of Valencia is the Decreto 20/2012, de 27 de enero, del Consell, por el que se crea el Registro Sanitario de Establecimientos Alimentarios Menores. The information that needs to be submitted for register in Valencia is, according to that piece of legislation, the following:

- Legal name of the food business, its address and the contact information of the person in charge of with public notifications
- The list of activities carried out at the store, from the following:
 - a. Manufacture of bread and special breads
 - b. Manufacture of bakery products-confectionery-bakery-confectionery
 - c. Cooking of semi-processed bread products and special breads
 - d. Cooking of semi-finished products of pastry-confectionery
 - e. Preparation of fried dough
 - f. Ice cream making
 - g. Manufacture of horchata
 - h. Takeaway food processor
 - i. Establishment of sale of takeaways
 - j. Establishment of food service
 - k. Food processing establishment that also sells to the final consumer and has dedicated space for food consumption.
 - 1. Establishment of food consumption
 - m. Fishmongers
 - n. Polyvalent retailer
 - o. Specialized retailer:
 - Dispatch of bread and / or pastry products.
 - Retailer of fruits and vegetables.
 - Alcoholic beverages retailer.
 - Retailer of snack products, nuts, pickles, and similar food products.
 - Retailer of food preparations for dietary and / or special regimens.
 - Retailer of condiments and spices.
 - Candy retailer.

establecimientos deberán inscribirse en los registros autonómicos establecidos al efecto, previa comunicación del operador de la empresa alimentaria a las autoridades competentes en razón del lugar de ubicación del establecimiento. No obstante, cuando se trate de establecimientos en los que se sirven alimentos in situ a colectividades, la comunicación será hecha por el titular de las instalaciones.

Other food products. ²⁷⁴

The operator must select all the options that apply to him. For instance, if a store makes ice creams and also allows for consumers to eat them on site, categories f and k should be selected. There is no specific category to identify that ice creams are also offered online. As described for the RGSEAA, the form does not refer to the fact that the establishment is used to offer food products online.

The information that competent authorities have about the activities carried out in the retail food establishment is therefore not useful when planning official controls on e-foods.

The e-foods market has a greater non-compliance rate than the brick-and-mortar market, and the same food product entails higher risks to consumer health and interests when sold online. Those circumstances make it necessary that competent authorities design control plans that focus on e-commerce.

Given that the most effective way to improve compliance is by controlling the production stage, competent authorities must have detailed information on which food establishments engage in e-commerce.

This is currently not the case in Spain. However, it is my opinion that the specificities of the digital market make advisable a change. Because the system of keys used for registration in the RGSEAA is not established in the law, competent authorities could agree to modify it without having to amend legislation. On the other hand, the classification of activities in the registration forms for minor establishments is approved as an annex of regional decrees. Updating the information on those forms does require that the government of the *Comunidades Autónomas* modify the current legal instruments (no parliamentary procedure is necessary).

²⁷⁴ The form has been translation by me.

The information that food business operators submit to competent authorities in Spain in order to register their food establishments can be modified to include e-commerce without having to modify Member State law.

The comparative analysis in Chapter 3 of this thesis analyses how legislation in Germany and the United Kingdom.

2.3. Regulating de performance of official controls

National arrangements for the implementation of official controls in Spain are not defined in Law 17/2011. That piece of legislation only declares that there should be a regulation of the inspection procedure specific to food controls and that, while this legislation is not adopted, the relevant legal Framework will be the one of Real Decreto 1945/1983, de 22 de junio, por el que se regula las infracciones y sanciones en materia de defensa del consumidor y de la producción agroalimentaria (hereinafter, "RD 1945/1983" or the "Royal Decree").²⁷⁵

Royal Decree 1945/1983 has been amended various times since it was first approved in 1983, to accommodate its content to EU law. Together with a list of detailed infractions and sanctions that arise when noncompliance of food law has been established, it specifies that control activities must be carried out in accordance with the general principles of Spanish administrative law and with European food law. In particular, it underlines that:

- During inspection, staff performing official controls can access not only the premises but all documentation that is relevant to assess compliance.
- Competent authorities in charge of official controls can request receive assistance from other branches of the administration.

competencias de las comunidades autónomas.

²⁷⁵ Disposición transitoria única, Ley 17/2011: Procedimientos en materia de inspección. Hasta tanto se establezcan procedimientos específicos en materia de inspecciones, será de aplicación lo dispuesto al efecto en el Real Decreto 1945/1983, de 22 de junio, por el que se regulan las infracciones y sanciones en materia de defensa del consumidor y de la producción agroalimentaria, en todo aquello que no se oponga a lo dispuesto en la Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común, y sus reglamentos de desarrollo, sin perjuicio de las

- They must comply with confidentiality requirements set in EU law.
- Checks must be recorded in writing in an inspection report.

Although Law 17/2011 mandated that the inspection process was to be legally described, the Royal Decree does not provide details on how the steps that staff must follow when performing an inspection or an audit. To date

Un análisis de la normativa en vigor pone en evidencia la carencia de tal procedimiento formalizado [en España], no solo en el ámbito alimentario sino en la mayoría de los campos de actuación de la administración pública, con la notable excepción del sector tributario²⁷⁶

Articles 15 and 16 of the Royal Decree define the administrative procedure for sampling for analysis²⁷⁷. The goal of these articles is to make sure that staffs carrying out controls follow a procedure that safeguards the operators' right to cross-examination by procuring a fair sample valid for enforcement.

Article 15²⁷⁸ of Royal Decree 1945/1983 specifies that sampling procedures must be documented in a report, which must be written in the presence of the operator in charge

²⁷⁶ Río del, A. (2014). Aspectos jurídicos del control sanitario oficial de los alimentos. Paper presented at Máster en Ciencias Jurídicas. Facultad de Derecho, Universidad de Lleida, p. 58. Retrieved from https://repositori.udl.cat/bitstream/handle/10459.1/49252/ariom.pdf?sequence=1

²⁷⁷ The spanish legal framework of sampling for oficial controls also includes Real Decreto 1749/1998, de 31 de Julio, por el que se establecen las medidas de control aplicables a determinadas sustancias y sus residuos en los animales vivos y sus productos (hereinafter, "RD 1749/1998").

²⁷⁸ RD 1945/1983. Art. 15. Toma de muestras. 15.1) La toma de muestras se realizará mediante acta formalizada, al menos por triplicado, ante el titular de la Empresa o establecimiento sujeto a inspección, o ante su representante legal o persona responsable, y en defecto de los mismos, ante cualquier dependiente. Cuando las personas anteriormente citadas se negasen a intervenir en el acta, ésta será autorizada con la firma de un testigo, si fuere posible, sin perjuicio de exigir las responsabilidades contraídas por tal negativa. El acta será autorizada por el Inspector en todo caso. En el acta se transcribirán íntegramente cuantos datos y circunstancias sean necesarios para la identificación de las muestras. 15.2) Cada muestra constará de tres ejemplares homogéneos, que serán acondicionados, precintados, lacrados y etiquetados de manera que con estas formalidades y con las firmas de los intervinientes estampadas sobre cada ejemplar, se garantice la identidad de las muestras con su contenido, durante el tiempo de la conservación de las mismas. Y en cuanto al depósito de los ejemplares se hará de la siguiente forma: 15.2.1) Si la Empresa o titular del establecimiento donde se levante el acta fueren fabricantes, envasadores o marquistas de las muestras recogidas y acondicionadas en la forma antes dicha, uno de los ejemplares quedará en su poder, bajo depósito en unión de una copia del acta, con la obligación de conservarla en perfecto estado para su posterior utilización en prueba contradictoria si fuese necesario. Por ello, la desaparición, destrucción o deterioro de dicho ejemplar de la muestra se presumirá maliciosa, salvo prueba en contrario. Los otros dos ejemplares de la muestra quedarán en poder de la inspección, remitiéndose uno al Laboratorio que haya de realizar el análisis inicial. 15.2.2) Por el contrario, si el dueño del establecimiento o la Empresa inspeccionada actuasen como meros distribuidores del producto investigado, quedará en su poder una copia del acta, pero los tres ejemplares de la muestra serán retirados por la inspección, en cuyo caso, uno de los ejemplares se Pondrá a disposición del fabricante, envasador o marquista interesado o persona debidamente autorizada que le represente -para que la retire si desea practicar la prueba contradictoria-, remitiéndose otro ejemplar al Laboratorio que haya de realizar el análisis inicial. 15.2.3) Las cantidades que habrán de ser retiradas de

of the establishment where the sample is taken, its representative or a store clerk that also must sign the minute. When the aforementioned persons refuse to witness sampling and signing the report, it is necessary to make sure that another person witnesses sampling and signs the report.

The food business responsible for a food product or the establishment where sampling takes place must witness the sampling and sign the sampling report. Its representative or a store clerk can also intervene. However, it is only acceptable to have a different witness if those persons refuse to be present.

Without the intervention of a witness, sampling is not legal. Judgement of the Tribunal Superior de Justicia of La Rioja, of the 11th December 1997 (case 581/1997) declared null and void an administrative decision establishing non-compliance because sampling had not completed with no appropriate witnesses²⁷⁹.

Paragraph 2 of article 15 mandates that a valid sample consists of three homogenous specimens (also referred to as "sample portions"), has to be conveniently labelled, packaged and signed by the competent authority and the person witnessing sampling. The amount of material necessary to obtain a fair sample, and the details on how to store it, is determined by the law, a sampling plan, or based on internationally recognised standards²⁸⁰.

Once the sample has been procured, one of the three sample portions is kept by the operator, the second one is stored by the inspection body, and the third is sent to the laboratory that will undertake its initial analysis. If sampling has taken place at the distributor's premises (and thus without the presence of an operator representative), the

²⁷⁹ Río del, A. (2014). *Aspectos jurídicos del control sanitario oficial de los alimentos*. Paper presented at Máster en Ciencias Jurídicas. Facultad de Derecho, Universidad de Lleida, p. 77. Retrieved from https://repositori.udl.cat/bitstream/handle/10459.1/49252/ariom.pdf?sequence=1

cada ejemplar de la muestra serán suficientes en función de las determinaciones analíticas que se pretendan realizar y, en todo caso, se ajustarán a las normas reglamentarias que se establezcan y, en su defecto, a las instrucciones dictadas por los órganos competentes.

²⁸⁰ EU Commission guidance documents and international standards provide details on how to label and handle a sample for analysis based on the particularities of the food product and the tests that is going to be conducted.

first sample portion must be "made available" to the operator so he can withdraw it and store it. The provision does not provide details on how to make the sample available. In practice, the operator is generally informed in writing manner of the sampling taking place and on the procedure to be followed in order to obtain its specimen.

The fact that Spanish legislation requires three "homogenous sample portions" aims at ensuring supplementary expert opinion rights. The first portion of the sample is used by the appointed laboratory that performs the initial analysis. The second one is used to perform the contradictory analysis when the initial analysis results in non-compliance but the operator does not agree with this result. The final and third is used only when contradictory results arise from the analysis of the two first portions.

Only samples that are taken with full respect to this provision may be considered "fair samples" appropriate to initiate a procedure to sanction the food operator. The relevance of this procedure has been repeatedly underlined by Spanish courts that render void those administrative decisions where non-compliance has been established based on samples that did not comply with article 15 of the Royal Decree. Among others, the Judgement of the Andalusian Tribunal Superior de Justicia, of the 21st October 2013:

Esta sentencia resuelve un recurso contencioso administrativo relativo a una sanción administrativa impuesta por la Junta de Andalucía como consecuencia de la presencia de un plaguicida en unos pimientos. El Tribunal aprecia que se ha incumplido por parte de la Administración el procedimiento de toma de muestras establecido reglamentariamente, al tomar menos cantidad del alimento que el dispuesto en la norma, por lo que no puede asegurase la fiabilidad del análisis realizado, hecho que conduce a la privación de valor inculpatorio a los análisis derivados de las muestras ilegalmente recogidas, anulando la sanción de 240.000 euros que había sido impuesta a la parte recurrente²⁸¹.

Sampling must be witnessed by any of the persons identified in the law. The sample must be divided in three homogeneous sample-portions, and one of them must be made available to the operator. If this procedure is not followed, sampling is not legal.

²⁸¹ Río del, A. (2014). *Aspectos jurídicos del control sanitario oficial de los alimentos*. Paper presented at Máster en Ciencias Jurídicas. Facultad de Derecho, Universidad de Lleida, p. 69. Retrieved from https://repositori.udl.cat/bitstream/handle/10459.1/49252/ariom.pdf?sequence=1

3. PROBLEMS ARISE WHEN APPLYING CURRENT LEGAL FRAMEWORK OF OFFICIAL CONTROLS TO FOOD E-COMMERCE

In order to perform official controls, competent authorities must know what type of activities, foods and operators are present within their territory. To make this process easier, EU regulations require Member States to establish a system that imposes on food business operators the obligation of registering their food establishments and to identify the type of activities carried out there. The goal of the registration system is to ensure proper mapping of the food chain in a Member State.

Once a control plan has been established, competent authorities can actually perform controls tasks. Controls are undertaking on production (at the operators' premises or during transportation) and at the distribution stage (at the establishment that makes the food available to the final consumer).

Planning and performing of official controls is carried out according to EU and Member State law, which has proven adequate to ensure that food products placed on the EU brick-and-mortar market comply with food law. However, competent authorities are struggling to apply this legal framework to the digital market. Together with legal issues, the staff performing control tasks has to face practical problems they have been not trained for.

This section identifies the legal and practical issues that hinder competent authorities' capacity to perform effective official controls on the digital market of food products. The goal is to assess if current EU or Member State legislation should be modified to provide a suitable framework for controls, and to provide recommendations to overcome the challenges that dealing with the particularities of the digital market entail.

3.1. Issues regarding the organization of official controls on e-foods

Competent authorities have the responsibility to ensure that the digital market of foods is under the same level of control as the traditional store-based market. But mapping the digital market for the purpose of official controls is proving to be a challenging task.

Competent authorities use the information of registered food establishments to identify operators and their activities in order to assess potential risks. In this thesis, the process that leads to that identification is referred to as "mapping." Once competent authorities

have mapped the market, they can organize official controls and adopt a Multi-annual Control Plan, which is complemented with *ad hoc* control plans as needed.

a. Most internet-based operators are not registered and therefore remain outside the scope of official controls.

Anyone who places food in the market must ensure it is safe, and those food business operators whose activity has a certain degree of organisation and continuity must also comply with food hygiene regulations. Official controls must verify both circumstances, thus those offers posted in digital platforms fall within the scope of official controls regardless of the nature of the operator that placed it. However, consumer-to-consumer trade, which has increased thanks to the popularity of digital platforms, is exempt from the registration requirement. Private individuals offering food products on an occasional basis do not have to register. Given that competent authorities have identified that C2C offers are often manifestly unsafe, it is necessary to provide a recommendation about how to include these offers in the organization of official controls.

CHALLENGE 1: INCLUDING C2C E-FOODS IN CONTROL PLANS

Furthermore, competent authorities need guidance on when to consider that an undertaking responsibility of a consumer has reached a degree of organization and continuity that it becomes relevant to food hygiene law. However, the European Commission has not tackled this issue yet.

CHALLENGE 2: EVALUATING IF AN UNDERTAKING HAS REACHED A DEGREE OF ORGANIZATION AND CONTINUITY THAT IS RELEVANT TO FOOD HYGIENE LAW

Moreover, a significant number of food business operators that should register their establishments are not fulfilling this obligation. It is urgent to consider how competent authorities can redress this situation.

CHALLENGE 3: MAKING SURE THAT ALL OPERATORS COMPLETE REGISTRATION

b. Competent authorities do not have information about which food establishments are used for e-commerce.

The Compliance Regulation mandates that Member State must define a procedure for operators to register their food establishments and that registration should request information about the activities carried out in that establishment. However, in Spain, the application forms operators must submit when registering their establishments do not include information on whether or not food products offered online are distributed from the establishment. This hinders the competent authorities' capacity to map the digital market and plan controls accordingly, because even if the establishment is known to the authority, the registration database does not include information on which establishments engage in e-commerce.

CHALLENGE 4: OBTAINING ACCURATE INFORMATION ABOUT OPERATORS AND ESTABLISHMENTS THAT ENGAGE IN FOOD E-COMMERCE

Lack of information about e-commerce related activities in the register of food establishments, together with the fact that some digital operators do not register at all leads to a significant conclusion: competent authorities do not have enough information in order to appropriately map the digital market of foods and define control plans accordingly.

Taking into consideration the challenges identified above, registration of food establishments plays an essential role in the organization of official controls. Addressing registration issues is necessary to effectively control the digital market of foods.

c. Adequate control planning requires for prioritization of control activities.

According to the Compliance Regulation, competent authorities must follow a risk-based approach to prioritize controls. Prioritization is essential to ensure the effectiveness and impartiality of the official control system. Competent authorities have limited economic resources and staff, so it is not possible to control everything and all the time. Additionally, a risk-based approach should guarantee that there is no discrimination between food business operators, food products or activities. However, given the infinite number of e-food offers, their variety, and the lack of accurate information about operators, what market surveillance should competent authorities be prioritizing?

CHALLENGE 5: PRIORITIZING CONTROLS

However, the challenges that arise when it comes to planning entail technical difficulties possible to overcome if competent authorities are provided with appropriate information, equipment and training.

Spanish authorities reported at the beginning of the research phase of this thesis that they had no resources devoted to e-food official controls as they were uncertain of how to answer these questions. The next Chapter of this thesis analyses the initiatives that Germany and the United Kingdom have put into to identify operators selling food online and to foster registration. Both Member States have devoted economic and human resources to navigate the Internet in order to identify active operators whose establishments are located within their jurisdiction. This is not an easy task, and entails that staff performing official controls must engage in time-consuming internet searches to track active food operators selling food online, instead of simply withdrawing that information from the registries.

3.2. Issues concerning the performance of official controls

The current legal framework for official controls does not only pose challenges to the organization of official controls, but also when it comes to actually performing control activities. Issues arise when it comes to ensuring that competent authorities are in a position to control the digital market of foods.

It is not possible to control production of e-foods if the establishment is not properly registered. Production checks focus on the hygiene and safety conditions of the establishment, performance of the staff handling the food, inspection of documentary records or of the self-surveillance systems put into place by the operator to minimize non-compliance with food law requirements. Thus, in order to control production it is necessary to have information about the location of a food establishment. However, if the food business operator has not registered its establishment, it is most likely that controls on production will not take place.

Moreover, the registration process does not provide competent authorities with information about which establishments are used for e-commerce. Thus, competent authorities are not in a position to design control plans focusing on e-foods controlling production stage. Controlling distribution becomes of upmost importance.

a. Controls must go unnoticed by operators in order to guarantee their effectiveness.

Competent authorities do not know how to order a food product available online without infringing article 3(2) of the Compliance Regulation, which mandates that official controls should be carried out without prior warning to the operator. The goal is to make sure that surveillance of the market goes unnoticed, and that the food being sampled has not been purposely selected by the food business operator. Ensuring no prior warning is problematic, because when controlling food products offered online, some elements like the IP of the computer, can give away the identity of the surfer. Additionally, competent authorities must place an order of the food product, a procedure that requires identification of the person placing the order and of a delivery address. Special equipment and training is necessary to avoid giving away the identity of the authority.

CHALLENGE 6: CONTROLING WHILE ENSURING NO PRIOR WARNING

b. Public authorities face both significant technical and legal challenges when it comes to performing official controls on the distribution of foods sold though e-commerce.

Controlling the distribution stage is an obligation under the current official control systems, as both article 17 (2) of General Food Law and article 3 of the Compliance Regulation clearly state that official controls shall be carried out at any of the stages of production, including distribution. Member States must control food products that are distributed in their territory, regardless of their origin. This way, it is possible to assess compliance of food products as obtained by the final consumer.

When staff performs control tasks on distribution of foods sold in the brick-and-mortar market, the official visits a traditional retail store. Once there, he must identify him to a representative of the operator or to the store clerk, and then proceed with the control activities planned. Sampling must be carried out according to the procedure described in section 2.3 of Chapter 2, which in Spain entails that the representative of the operator or the clerk must witness sampling and sign the sampling report, and that the sample must be divided into three sample-portions. If the representative of the operator and the clerk refuse to intervene in sampling, the presence of another witness (such as a customer present at the store) saves the validity of sampling.

In the digital market, with no physical store to go to, controls on distributions translate in placing an order of the food product as any consumer would, receiving the parcel and then performing controls on the food product as received. However, staff performing official controls in several Member States and academia acknowledge that there is uncertainty about how to perform "test purchases" while respecting the current legal framework. The following issues have been identified as problematic:

• It is not clear whether ordering e-foods anonymously is legal, in Spain and in other Member States. The Compliance Regulation states that sampling must safeguard the operator's rights to defence, including to a supplementary expert opinion. The details on how to do that are specified in Member States' law. In Spain, staff performing official controls interpret that the Spanish legal framework does not allow mystery shopping because Royal Decree 1945/1983 requires that the operator, its representative or a store clerk is present when the sample is procured. Other witnesses can only intervene if these persons have refused to do so. It is my belief that this is not what the provision implies. I believe there is no infringement of article 15 if the operator is warned once the parcel is in hands of the competent authority, that does not open the package until the operator or its representative is present. However, given that this fear is shared by staff in other Member States that deal with similar provisions, this issue must be analysed further in the comparative analysis.

CHALLENGE 7: PROVIDING AN INTERPRETATION OF THE LEGAL FRAMEWORK THAT ALLOWS COMPETENT AUTHORITIES TO USE MYSTERY SHOPPING TECHNIQUES

• Additionally, competent authorities raise doubt about the possibility of obtaining a "fair sample" from test purchases. When sampling for analysis in the framework of official controls, the sample must be obtained following the methods of sample procurement and analysis established in legal instruments or in sample plans, and if none of those apply, according to internationally recognised standards. These instruments include instructions for sampling procurement (for example, the sample must be taken from a specific part of the consignment, and a specific amount of food product from the same batch is necessary). When placing an order online, officials must make sure that the food product that will be delivered is going to meet the requirements for that food or for that analysis. Competent authorities fear that

this might not always be possible, as large amounts of products may be needed and ordering large parcels may raise suspicion about the true identity of the buyer. I believe that obtaining a fair sample should be possible because, in most cases, the rules that apply to sampling include provisions that make possible sampling of small number of items. For example, back to the rule that requires sampling for analysis of mycotoxins in cereal products to be at least of 1kg, the footnote of passage B.5 states that "in case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg." However, given that this issue has been raised by staff in several Member States, the comparative study includes Germany and the United Kingdom's position on the subject.

CHALLENGE 8: OBTAINING A SAMPLE CONSIDERED "FAIR" FOR ENFORCEMENT

• Furthermore, it is unclear which activities should be recorder to comply with Regulation 882/2004, which mandates that should take place on the basis of documented procedures. The staff performing official controls does not know if this provision requires that inspection or sampling report includes evidence of the searches and surveillance performed online. Settling this issue is important, because failing to keep appropriate record of controls undermines the operator's capacity to cross-check public action and contest administrative decisions.

CHALLENGE 9: RECORDING CONTROL ACTIVITIES TO SAFEGUARD THE OPERATOR'S RIGHT OF DEFENCE

Taking into consideration the three challenges identified above, sampling of e-foods at the distribution stage plays an essential role in the performance of official controls. Addressing sampling issues is necessary to effectively control the digital market of foods.

3.3. Issues concerning enforcement of food law

a. Competent authorities struggle with the task to ensure that food law is enforced online.

In the traditional market, once competent authorities have identified a food product that does not comply with food law, control staff must adopt measures to ensure that the operator corrects the situation, and to contain or eliminate risks. The Compliance Regulation provides a varied list of actions, which are further developed in Member States' law. Measures generally include the proposal to initiate sanctioning proceedings, a requirement to correct specific issues of non-compliance, and the suspension of the activity in a specific food establishment, among others. All of those measures can be applied to those establishments and food business operators that engage in e-commerce. The business may be sanctioned, and the establishment may be closed. But, given that competent authorities cannot always identify any of those two in the digital market, control staff may find necessary to turn to the digital world to ensure enforcement. When no measures can be taken in the traditional brick-and-mortar food chain because authorities do not know who to address a notification or what establishment to close, competent authorities look for alternatives to make non-compliant offers stop. How can they enforce food law online?

CHALLENGE 10: ENFORCING FOOD LAW ONLINE

It is urgent to provide authorities with recommendations on how to tackle these challenges. Competent authorities must be able to officially control the digital market of foods.

Both legal challenges and technical issues are relevant from a legal perspective. Article 4 of the Compliance Regulation mandates that competent authorities

Have, or have access to (...) a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively; [and] that they have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively²⁸².

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²⁸² Article 4, paragraphs c) and d) of Regulation (EC) 882/2004 of 29 April 2004.

But currently, at least in some Member States such as Spain, competent authorities do not have appropriate training and equipment to tackle the technical challenges that performing controls on distribution of e-foods entail.

Member States must redress this situation. As was analysed by the Court of Justice of the European Union in case C-331/07 Commission v Greece (judgment of 23 April 2009), the European Commission could consider that lack of controls on e-foods entail a failure to fulfil obligations under EU law. The case discussed the European Commission's assessment that, during the period 2001-2006, Greece had consistently failed to provide competent authorities in charge of veterinary checks with sufficient staff to ensure efficient official controls. The Court interpreted the following:

Il découle des termes mêmes de cette disposition [paragraph 2 of article 4 of teh Compliance Regulation] que, pour qu'un manquement à celle-ci puisse être constaté, il est suffisant qu'une partie des contrôles ne puisse pas être effectuée de manière efficace et effective en raison du manque de personnel affecté à la réalisation de ceux-ci²⁸³.

Chapter 3 of this thesis analyses the policy for e-food control built by Germany and the United Kingdom, and identifies how authorities in those Member States are dealing with the eight challenges previously identified.

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CHAPTER 3.

APPROACH TO E-FOOD CONTROL IN GERMANY AND THE UNITED KINGDOM

Uncertainties over the legal framework, coupled with limited human, training and equipment resources during the economic crisis, have prevented competent authorities from monitoring the market and enforcing food law online.

Until fall 2017, the European Union has not considered taking coordinated actions in this field, so national authorities have had to face the issue alone. Competent authorities in several Member States have tried to establish their own initiatives for the control of e-foods, but the absence of coordination among national authorities has resulted in good practices going undetected by other Member States. Spanish competent authorities, as those in many EU Member States, have not been able to face the challenges alone.

This Chapter analyses Germany and the United Kingdom's strategies to include the digital market in official controls. For both case studies, this thesis first analyses the administrative organization for official controls (in order to identify the competent authorities with responsibilities in this field), and the pieces of legislation that have been adopted by the Member State to implement the rules of the Compliance Regulation. Given that the challenges identified in the last section of Chapter 2 relate to issues related to registration of food establishments and to sampling, the regulation of both elements in each selected Member State is described in detail. The second part of each case study describes the Member States' approach to food law enforcement in the digital market: while Germany focuses on organizing effective surveillance of the market, the United Kingdom provides advice on how to perform control tasks that can lead to effective enforcement of the law. Finally, the third part of each case study recapitulates how they tackle the challenges previously identified.

Part 3 of this Chapter compares both cases, as to the legal framework they operate in and as to how their approach faces the challenges identified in this thesis. This comparison includes also reference to the similarities and differences in Spain. Section 3 includes a Table 1 that summarises how Spain, Germany and the United Kingdom deal with those challenges.

PART 1.

G@ZIELT, A PIONEER IN E-FOOD CONTROL

1. GERMANY'S POLITICAL AND ADMINISTRATIVE STRUCTURE AND ITS ARRANGEMENTS WHEN IT COMES TO OFFICIAL CONTROLS

The first case that is analysed in this thesis is the German strategy. Fostered by the success of a pilot project on retailers' compliance with registration obligations, which was undertaken from 2011 to 2013 by the Federal Office of Consumer Protection and Food Safety (BVL), Germany created a special unit "G@ziel" that monitors e-foods available to German consumers. Germany has been a pioneer in the control of food on the Internet, to the extent that part of the German team moved on to the European Commission years later and is currently leading EU Commission's activity in this field.

1.1. Political structure of Germany and distribution of powers when it comes to official controls

Germany is a federal parliamentary republic composed of sixteen federal states, which are called *Bundesland länder* (hereinafter, "*länder*"). It operates under the Basic Law for the Federal Republic of Germany²⁸⁴. Its public administration is highly decentralised²⁸⁵, which means that different levels of government participate in the achievement of food safety. Indeed, both the national government and the *länder* have important responsibilities when it comes to planning and implementing official controls of foodstuffs. Enacting food legislation is a responsibility of the national government, while "implementation and control at the regional level is the responsibility of the 16 federal states"²⁸⁶.

²⁸⁴ Basic Law for the Federal Republic of Germany in the revised version published in the Federal Law Gazette Part III, classification number 100-1, as last amended by Article 1 of the Act of 23 December 2014 (Federal Law Gazette I p. 2438). Retrieved from https://www.gesetze-im-internet.de/englisch_gg/englisch_gg.html

²⁸⁵ The general distribution of powers between the Federal government and the 16 *länder* is established in article 30 of the Basic Law for the Federal Republic of Germany.

²⁸⁶ Herges, L., Kaus, S., Böl, G.F., & Gollnick, N. (2017). *EU Food Safety Almanac* (4th ed.). German Federal Institute for Risk Assessment (BfR). Berlin, p. 42.

The Bundesministerium für Ernährung und Landwirtschaft (Federal Ministry of Food and Agriculture in English, hereinafter BMEL) is the ministry responsible for agricultural policy and food safety at the national level, and therefore drafts legislation in those fields. There are two special authorities within BMEL that are relevant to food official controls, which are the Bundesinstitut für Risikobewertung (German Federal Institute for Risk Assesment in English, hereinafter BfR) and the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety in english, hereinafter "BVL"). While the first one "contributes to the enforcement of legislation by undertaking risk assessments and advises political circles²⁸⁷" and also risk communication, the BVL is responsible for risk management issues.

- BfR has fifteen scientific committees and is responsible for undertaking risk assessments in the framework of marketing authorisations for plant protection. Also, it "has the task of assessing risks, identifying new health risks and drawing up risk minimisation recommendations." BfR is EFSA's contact point in Germany, acting "as an interface between EFSA and national food safety authorities, research institutes and other stakeholders". Additionally, it provides scientific advisory service to the BVL, which include complete risk assessments reports and updated scientific data relevant to BVL's activities.
- BVL is in charge of risk management and is RASFF's national contact point²⁸⁹ in Germany. It is in charge of coordination on food control tasks at the national level: "together with the federal states, the BVL coordinates programmes for inspection and control of food to ensure comparable results and procedures in all sixteen" *länder*. Its risk management and regulatory decisions are based

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²⁸⁷ Herges, L., Kaus, S., Böl, G.F., & Gollnick, N. (2017). *EU Food Safety Almanac* (4th ed.). German Federal Institute for Risk Assessment (BfR). Berlin, p. 3.

²⁸⁸ European Food Safety Authority. (n.d.). *EU Member States. EU Member State scientific support is critical for the normal functioning of the EU food safety system.* Retrieved from https://www.efsa.europa.eu/en/partnersnetworks/eumembers

²⁸⁹ As stated in recital 7 of Regulation (EU) 16/2011, of 10 January 2011, laying down implementing measures for the Rapid alert system for food and feed, In accordance with Regulation (EC) No 178/2002, the Commission, the Member States and EFSA have designated contact points, which represent the members of the network in order to benefit from a correct and fast communication. In application of Article 50 of that Regulation and in order to avoid possible mistakes in the transmission of the notifications, only one designated contact point should exist for each member of the network. This contact point should facilitate the rapid transmission to a competent authority inside a member country.

²⁹⁰ Herges, et al, *op. cit*, p. 44.

on prior risk assessment reports from BfR. It plays a significant role in regulatory issues related to genetically modified organisms (GMOs) in food and feed. BVL extends its scope not only to food products but also to cosmetics and tobacco products.

Länder have competency over the definition of the official control system within their territory: "implementation of food and feed safety is therefore the responsibility of the federal states". and no supervision from the national administration is required nor accepted in this field. Coordination of activities and procedures among *länder* is ensured through working groups, which unite competent authorities in all the federal states with the presence of the national government represented by the BVL.

As a result of this distribution of responsibilities, the German multiannual control plan (Mehrjährigen Nationalen Kontrollplan, hereinafter "MNKP") required by Regulation 882/2004 consists of individual integrated multiannual control plans of the *länder*, and a transnational plan²⁹². Together with this instrument, there are several other control programmes "on a nationwide scale such as food monitoring, the National Monitoring Plan (BÜP)"²⁹³.

MNKP is valid for the period 2017-2021, and does refer to the fact that official controls must include those food products offered online. However, as is analysed in section 2 of Part 3 of Chapter 3, organization of controls on the digital market are included in G@zielt's control plan, which is adopted yearly by $l\ddot{a}nder$ and the BVL. Thus, MNKP does not provide additional information on this issue.

²⁹¹ Herges, L., Kaus, S., Böl, G.F., & Gollnick, N. (2017). *EU Food Safety Almanac* (4th ed.). German Federal Institute for Risk Assessment (BfR). Berlin, p. 45.

²⁹² Bundesministerium für Ernährung und Landwirtschaft. (2017). Integrierter mehrjähriger Kontrollplan der Bundesrepublik Deutschland. Retrieved from https://www.bvl.bund.de/SharedDocs/Downloads/01 Lebensmittel/06 mnkp dokumente/lm mnkp Rah menplan.pdf? blob=publicationFile&v=3

²⁹³ Federal Ministry of Food and Agriculture. (2014). *Food control and inspection in Germany*. Retrieved from https://www.bmel.de/EN/Food/Safe-Food/ Texte/Lebensmittelueberwachung.html

Instruments for the organization of official controls in Germany do refer to the digital market. MNKP acknowledges that e-foods fall within the scope of control activities, and there is a specific annual control plan that deals with food products offered online.

1.2. Legislation relevant to the organization and performance of official controls

As a member of the European Union, Germany's legal framework for official controls is based on EU regulations, which rules are developed in specific pieces of legislation adopted by the Member State.

The Lebensmittel un Futtermittelgesetzbuch²⁹⁴ ("Food and Feed Code" in English, hereinafter "LFGB") is the basic rule on food law in Germany. In 2005, the LFGB adapted the German food law system to the requirements of the European General Food Law. The code, as it is today²⁹⁵, provides rules regarding food, feed, cosmetic products and other consumer products. It aims at preventing danger to human health and any action that may be misleading to the final consumer²⁹⁶. Sections 2 and 3 of LFGB describe the general rules applying to food, which mirror the requirements of Regulation 178/2002. Section 7

²⁹⁴ Bundesministerium für Ernährung und Landwirtschaft (n.d). *Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch*. Retrieved from https://www.gesetze-im-internet.de/lfgb/

²⁹⁵ In 2013, the LFGB was amended to include in its scope other consumer goods such as cosmetic products, changing its name to "Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch" (abbreviation still remains "LFGB").

²⁹⁶ Article 1 of LFGB as amended: Zweck des Gesetzes ist es, 1) vorbehaltlich der Absätze 2 und 4 bei Lebensmitteln, Futtermitteln, kosmetischen Mitteln und Bedarfsgegenständen den Schutz der Verbraucherinnen und Verbraucher durch Vorbeugung gegen eine oder Abwehr einer Gefahr für die menschliche Gesundheit sicherzustellen, 2) beim Verkehr mit Lebensmitteln, Futtermitteln, kosmetischen Mitteln und Bedarfsgegenständen vor Täuschung zu schützen, 3) die Unterrichtung der Wirtschaftsbeteiligten und a) der Verbraucherinnen und Verbraucher beim Verkehr mit Lebensmitteln, kosmetischen Mitteln und Bedarfsgegenständen, b) der Verwenderinnen und Verwender beim Verkehr mit Futtermitteln sicherzustellen, 4) a) bei Futtermitteln aa) den Schutz von Tieren durch Vorbeugung gegen eine oder Abwehr einer Gefahr für die tierische Gesundheit sicherzustellen, bb) vor einer Gefahr für den Naturhaushalt durch in tierischen Ausscheidungen vorhandene unerwünschte Stoffe, die ihrerseits bereits in Futtermitteln vorhanden gewesen sind, zu schützen, b) durch Futtermittel die tierische Erzeugung so zu fördern, dass aa) die Leistungsfähigkeit der Nutztiere erhalten und verbessert wird und bb) die von Nutztieren gewonnenen Lebensmittel und sonstigen Produkte den an sie gestellten qualitativen Anforderungen, auch im Hinblick auf ihre Unbedenklichkeit für die menschliche Gesundheit, entsprechen.

of LFGB provides a harmonized framework for the organization and implementation of the German official controls system.

Together with the LFGB, there are two main German regulations relevant to this thesis, which set general principles for the registration of food business operators and for the execution of sampling:

- German General Administrative Provision on Food Hygiene (AVV-LmH) of September 2007 (Allgemeine Verwaltungsvorschrift über die Durchführung der amtlichen Überwachung der Einhaltung von Hygienevorschriften für Lebensmittel und zum Verfahren zur Prüfung von Leitlinien für eine gute Verfahrenspraxis), and
- German General Administrative Provision on Framework Controls (AVV-RÜb) of 21 December 2004 as amended on 15 March 2007 (Allgemeinen Verwaltungsvorschrift Rahmen-Überwachung).

It must be noted that each land has its own legislation for the organization and undertaking controls in its own territory. As it happens in Spain, these pieces of legislation are mostly executive and must comply with the above-mentioned administrative provisions. A working group ensures that the administrative procedures, rights and obligations amongst the *länder* are comparable. Thus, this thesis does not analyse regional legislation.

1.2.1. Regulating the organization of official controls

Member States adopt multi-annual control plans to make sure that the organization and prioritization of control tasks is appropriate to maintain adequate levels of compliance with food law and that unsafe products do not reach (or are rapidly recalled from) the market. Ensuring that all food operators have registered their establishments is essential to organizing official controls. Registration allows competent authorities to map the market and carry out controls on production. It is key to establish a proper strategy for market surveillance.

Registration is regulated in the German General Administrative Provision on Food Hygiene (AVV-LmH) of September 2007, which adapts the rules of Regulation 852/2004 to the German legal system. As indicated in its first article, this piece of legislation is addressed to competent authorities and laboratories participating in official controls. It defines national arrangements for official controls when it comes to hygiene regulations,

including criteria for registration and approval of food business operators under Regulation 852/2004.

Although article 2(7)²⁹⁷ of the AVV-Lmh establishes that competent authorities must notify BVL of any new approval of establishment, this legal framework does not create a central registration system or register of establishments at federal level²⁹⁸. In most *länder*, registration is made before trade and commerce offices of local authorities, physically or online.

Unlike in Spain, retail stores in the German territory are included in the same register than any other food establishment. There is no register of minor food establishments.

Each *länder* has its own application form for registration but, in all of them, the information that the operator must submit is scarce. Forms require information for the identification the business itself (the name and identification number of the business, its address, the name of a representative responsible for the application procedure), the location of the establishment, and nature of the activities it carries out.

The German administration adopted a guidance paper for a nationwide framework for the registration of businesses²⁹⁹, which states that application forms should include the type of products handled in the establishment (for example, beverages), and the general

²⁹⁷ Paragraph 7 of article 2 AVV-Lmh states the following: (7) Die zuständige Behörde teilt dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Bundesamt) unverzüglich die Zulassung sowie den Widerruf und die Rücknahme der Zulassung unter Angabe des Betriebes und soweit vergeben der Zulassungsnummer, im Falle eines Betriebes in einem Großmarkt unter Angabe des Betriebes oder der Gruppe von Betrieben und soweit vergeben unter Angabe der Zulassungsnummer und der entsprechenden Unternummer zum Zwecke der Veröffentlichung nach Artikel 5 in Verbindung mit Anhang V der Verordnung (EG) Nr. 2074/2005 der Kommission vom 5. Dezember 2005 zur Festlegung von Durchführungsvorschriften für bestimmte unter die Verordnung (EG) Nr. 853/2004 des Europäischen Parlaments und des Rates fallende Erzeugnisse und für die in den Verordnungen (EG) Nr. 854/2004 des Europäischen Parlaments und des Rates und (EG) Nr. 882/2004 des Europäischen Parlaments und des Rates und zur Änderung der Verordnungen (EG) Nr. 852/2004 und (EG) Nr. 854/2004 (ABl. L 338 vom 22.12.2005, S. 27) mit.

²⁹⁸ While BMEL has a search tool that helps FBOs identify the competent local authority to register its establishments, there is no public access to the registry as it happens in Spain. Also, unlike in Spain, there is no special registry for retail stores.

²⁹⁹ Federal Ministry of Food and Agriculture. (2012). Leitfaden zur Registrierung von Betrieben nach der Verordnung (EG) Nr. 852/2004 über Lebensmittelhygiene, p. 7

activity carried out (for example, processing or packing, among other). This guidance document provides *länder* authorities with an example form, copied below:

-				
Art der Meldung	C Anmeldung	Aktualisierung	C Abmeldung	
Bezeichnung und Adresse der	Betriebsstätte	·		
Name:				
PLZ:	C	rt:		
Straße:				
Vornutzung der Betriebsstätte				
Mantalitation deal about an international	least and burners			
Kontaktdaten des Lebensmitte				
Name:	V	Vorname:		
PLZ:	C	rt:		
Straße:				
Telefon:	Fax:			
Handy:	E-Mail:			
Betriebsart / Tätigkeit (allgemeine Beschreibung, z.B. Getränkehersteller, Hofladen, Pizza-Service)				
Angaben zum Produktsortiment				
Untoro obvift				
Unterschrift				
Ich bestätige die Angaben der Meldung mit meiner Unterschrift.				
Ort / Datum		Unterschrift Lebensmittelunternehmer		

Image 1

Currently, none of the *länder* takes the opportunity to use the registration form to ask about e-commerce activities. Just like in Spain, the relevant forms when applying for registration or approval are not suitable if we want to obtain information about e-commerce activities³⁰⁰.

³⁰⁰ Büchter, B., Kuhr, C., & Schreiber, G.A. (2011). Pilotprojekt zur amtlichen Kontrolle des Handels mit Lebensmitteln im Internet. *Journal of Consumer Protection and Food Safety*, (6):375. P. 3. Retrieved from https://doi.org/10.1007/s00003-011-0700-9

The lack of information about e-commerce activities, together with the lack of centralised access to the register of food establishments, makes it very difficult for competent authorities in Germany to use registry information to identify operators that are engaging in food e-commerce and the establishments they operate from, and then organize controls on production.

Competent authorities in Germany have decided to be proactive and search for operators that may be responsible for establishments located within the authority's territory in order to obtain relevant information to control production. Their methods are analysed in section 2.3 of Part 2 of this Chapter.

When it comes to the issue of controlling consumer-to-consumer trade of food products online, German legislation and guidance document do not provide any additional insight. They simply reproduce the statement of article 2 of Regulation 852/2004, which excludes those undertakings that do not entail a certain degree or organization or continuity from the scope of hygiene rules and thus of obligation to register³⁰¹.

Länder also fail to provide additional guidance. For example, the administrative provision regulating registration in the land of Bayern, Registrierung von Betrieben gemäß Artikel 6 Abs. 2 der Verordnung (EG) Nr. 852/2004und Erfassung von Betrieben gemäß § 7 Abs. 1 AVV Rüb³⁰², merely states that assessing if an undertaking is exempt from hygiene rules must be made on a case-by-case basis. No further guidance is provided.

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³⁰¹ BVL's guidance on how to apply for registration of establishments states the following: Nicht registrierungspflichtig sind Lebensmittelunternehmer, die vom Geltungsbereich der Verordnung (EG) Nr. 852/2004 (Art. 1 Abs. 2) ausgenommen sind, also insbesondere die Primärproduktion, wie z. B. der Anbau von Nutzpflanzen oder die Haltung von Lebensmittel liefernden Tieren, für den privaten häuslichen Bereich, der private häusliche Bereich und die Abgabe von Primärerzeugnissen in kleinen Mengen an bestimmte Abnehmer, reine Tierhaltungsbetriebe ohne Lebensmittelerzeugung und Lebensmitteltätigkeiten ohne eine gewisse Kontinuität und einen gewissen Organisationsgrad, wie es z. B. bei Vereinsfesten der Fall sein kann (Einzelfallentscheidung). Im Zusammenhang mit dem Inverkehrbringen tierischer Lebensmittel muss im Einzelfall geprüft wer-den, ob ggf. eine Zulassungspflicht im Sinne des Artikels 4 der Verordnung (EG) Nr. 853/2004 besteht. (FAQ zur Registrierung und zu Pflichten von Lebensmittelunternehmenn sowie den wichtigsten Gesetzesregelungen), p. 3. Retrieved from: https://www.bvl.bund.de/SharedDocs/Downloads/01 Lebensmittel/Internethandel/FAQ Registrierung L ebensmittelunternehmen.pdf? blob=publicationFile&v=10

³⁰² Mühlbauer, B. (2015). Registrierung von Betrieben gemäß Artikel 6 Abs. 2 der Verordnung (EG) Nr. 852/2004 und Erfassung von Betrieben gemäß § 7 Abs. 1 AVV RÜb, p. 2. Retrieved from

German authorities face the same challenges that their Spanish peers. There are no recommendations about how to control e-foods placed in the market in the framework of peer-to-peer e-commerce.

1.2.2. Regulating de performance of official controls

The German General Administrative Provision on Framework Controls (AVV-RÜb) of 21 December 2004 as amended on 15 March 2007³⁰³ lays down the rules for the performance of official controls. This piece of legislation sets down general principles for national monitoring. Additionally, it regulates other aspects relevant to control activities, such as the continuity of inspection on food establishments, and distribution on the basis of risk-based assessment.

However, the law does not define a procedure to be followed when undertaking an inspection. AVV-Rüb provides much more information about sampling activities. It underlines that, in accordance with the distribution of responsibilities among the national government and the *länder* established in the German Basic Law, each land is responsible for defining a sampling plan that will be executed by the local authorities. Based on this sampling plan, competent authorities should get at least 5 official food samples per 1000 inhabitants, 80% of them in the framework of coordinated risk-based programmes.

As it happens in Spain, German law does not define the steps to carry out an inspection but identifies rules that govern sampling.

The general guidelines that apply to the procurement of samples for analysis in the framework of official controls are not defined in AVV-Rúb but instead in the LFGB. Article 43 of this piece of legislation states the following:

(1) Die mit der Überwachung beauftragten Personen und, bei Gefahr im Verzug, die Beamten der Polizei sind befugt, gegen Empfangsbescheinigung Proben nach ihrer Auswahl zum Zweck der Untersuchung zu fordern oder zu entnehmen. Soweit in unmittelbar geltenden Rechtsakten der Europäischen Gemeinschaft oder der Europäischen Union oder in Rechtsverordnungen nach diesem Gesetz

 $\underline{https://www.stmuv.bayern.de/themen/lebensmittel/allg_lebensmittel/betriebe/doc/hinweise_registrierung_erfassung_betriebe.pdf}$

³⁰³ Last updated by the Admistrative order of 15 February 2017 (BAnz At 17.02.2017 B3).

nichts anderes bestimmt ist, ist ein Teil der Probe oder, sofern die Probe nicht oder ohne Gefährdung des Untersuchungszwecks nicht in Teile von gleicher Beschaffenheit teilbar ist, ein zweites Stück der gleichen Art und, soweit vorhanden aus demselben Los, und von demselben Hersteller wie das als Probe entnommene, zurückzulassen; der Hersteller kann auf die Zurücklassung einer Probe verzichten.

- (2) Zurückzulassende Proben sind amtlich zu verschließen oder zu versiegeln. Sie sind mit dem Datum der Probenahme und dem Datum des Tages zu versehen, nach dessen Ablauf der Verschluss oder die Versiegelung als aufgehoben gilt.
- (3) Derjenige, bei dem die Probe zurückgelassen worden ist und der nicht der Hersteller ist, hat die Probe sachgerecht zu lagern und aufzubewahren und sie auf Verlangen des Herstellers auf dessen Kosten und Gefahr einem vom Hersteller bestimmten, nach lebensmittelrechtlichen Vorschriften zugelassenen privaten Sachverständigen zur Untersuchung auszuhändigen.
- (4) Für Proben, die im Rahmen der amtlichen Überwachung nach diesem Gesetz entnommen werden, wird grundsätzlich keine Entschädigung geleistet. Im Einzelfall ist eine Entschädigung bis zur Höhe des Verkaufspreises zu leisten, wenn andernfalls eine unbillige Härte eintreten würde.
- (5) Absatz 1 Satz 2 und die Absätze 2 und 3 gelten nicht für Proben von Futtermitteln.

In order to ensure cross-examination, the LFGB mandates that officials take a sample large enough to obtain two homogeneous portion samples. The result of the analysis of the second sample portion (the defence sample) will determine compliance.

While in Spain the law requires that sampling produces three homogeneous sample-portions, German law only requires two sample-portions.

Both sample portions must be sealed by the public official undertaking the control, indicating on the package both the date it has been taken and the date the sample's validity expires. Then, the first portion is sent to the laboratory for analysis, while the second remains in the hands of the food business operator so –if needed- the second sample portion can be used for a supplementary expert opinion³⁰⁴.

AVV-Rüb determines that main focus of competent authorities should be on taking samples at the food business operator's food establishments and at import border control

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³⁰⁴ Other specific aspects of the sample process -such as the time for which the operator needs to keep the sample- are set in Länder legislation (f.i. in the land of Berlin, it is 8 weeks).

posts. Thus, having detailed information about the location and activities of active establishments is a must. However, bugs in registration entail that competent authorities do not have appropriate information to identify and control food establishments that engage in food e-commerce.

The lack of information about the location of those food establishments that are used for e-commerce makes extremely difficult to perform official controls on production.

Controlling distribution is considered secondary but still necessary, as it keeps operators vigilant and working to ensure compliance.

But article 43 LFGB poses specific problems to official controls of e-foods at the distribution stage. In particular, the German administration understands that article 43 LFGB does not provide legal basis to take samples anonymously:

Article 43 of the food and animal feed regulations (LFGB) does not contemplate electronic commerce and only allows conventional sampling in the establishments of online stores if they store the products there. For official online sampling, there is a lack of a legal basis to purchase without the need to indicate the identity of the buyer (the authority)³⁰⁵.

It is G@zielt's team interpretation that paragraph 1 of the referred article entails that public officials must identify themselves when willing to take a sample and then inform the operator or its representative that the sample is going to be taken so someone can witness the process. This does not contradict the Compliance Regulation's mandate that control activities are carried out without prior warning, as public officials only inform the operator once they are on their premises.

According to the German administration, national law prevents competent authorities from using mystery shopping in the framework of official controls. A sample obtained from a test purchase cannot be considered a fair sample because it infringes article 43 LFGB.

³⁰⁵ Schreiber, G.A., & Liebscher, B., & Kranz, P. (2015). *Der online-handel mit Lebensmitteln – herausforderung für die Überachung*, ZLR 3/2015, p. 291. It must be noted that the authors of the paper were at the time part of the German central unit. The translation is mine.

A second major issue for German authorities is that, as stated in paragraph 4 of article 43 LFGB, competent authorities do not pay the selling price for a sample that is going to be used for enforcement. This entails a very particular problem when it comes to e-foods, as if the previous challenge was somehow overcome, the staff doing mystery shopping would still need to purchase the product to complete the order. Thus, a system to reimburse the authority should be put in place in order to comply with LFGB³⁰⁶.

LFBG poses an additional challenge for German competent authorities: controlling distribution could only take place if a system to reimburse the authority of the cost of a test-purchase.

Undertaking official controls on distribution of e-foods is currently not possible under German legislation.

Given that bugs in registration make it very complicated to locate establishments distributing e-foods, and therefore to perform control tasks on production, German authorities are facing the challenge of controlling the market using new surveillance methods that are described in the next section.

³⁰⁶ Schreiber, G.A., & Liebscher, B., & Kranz, P. (2015). *Der online-handel mit Lebensmitteln – herausforderung für die Überachung*, ZLR 3/2015, p. 291.

2. THE GERMAN APPROACH TO OFFICIAL CONTROLS OF E-FOODS

2.1. The construction of a central unit for food e-commerce control

Under the premise that consumers in Germany are increasingly buying food on the Internet but that the number of harmful or deceiving offers of e-foods is also increasing³⁰⁷, the central unit for food e-commerce monitoring has become the first and most ambitious initiative to improve e-food compliance with food law in the world.

G@zielt (short for "Zentralstelle Kontrolle der im Internet gehandelten Erzeugnisse des LFGB und Tabakerzeugnisse" or "Control of e-commerce of food, feed, cosmetics, commodities and tobacco" in English) is the German body monitoring the market of e-foods accessible to German consumers. Since the definition of its concept by the German administration in 2009, both its legal status, responsibilities and tasks have evolved. What started as a temporary unit undertaking a pilot project focusing exclusively on e-foods within the BVL (2011-2013) is currently a permanent independent agency under the authority of the BVL that seeks to ensure that the digital market of consumer products at large is as safe as the traditional market.

The initial pilot project³⁰⁸ was launched by the BVL in January 2011 in collaboration with the German tax office, and aimed at monitoring the international trade of foodstuffs in the digital market. To that purpose, a specific group in the BVL was to search the Internet for offers addressed to the German consumer, and to coordinate any activity related to food e-commerce control in the country. First efforts were put on identifying e-foods that could be harmful to the final consumer and on identifying active food business operators that were not registered before proper authorities and therefore remained outside the radar of competent authorities. The necessity of such a national unit was clear to the German authorities:

Conducted on behalf of the German Federal States as a central body, the Common Central Unit is in a better position to face the internet trade, which transgresses

³⁰⁸ Because official controls are a responsibility of the *länder*, the decision to launch the pilot project was taken by the German Working Group on consumer protection (LAV).

³⁰⁷ Büchter, B., Kuhr, C., & Schreiber, G.A. (2011). Pilotprojekt zur amtlichen Kontrolle des Handels mit Lebensmitteln im Internet. *Journal of Consumer Protection and Food Safety*, (6):375, p. 1. Retrieved from https://doi.org/10.1007/s00003-011-0700-9

Länder and national borders. Duplicate search work is avoided, resources are preserved and work processes can be organized efficiently. With G@ZIELT, the German food control authorities take the lead in the enforcement of consumer protection in the e-commerce of food³⁰⁹.

The initial project ran until June 2013, and gradually incorporated the collaboration of other administrative bodies such as the Federal Criminal Police Office, the *Länder* Police Offices, the Customs Authority and the Central Authority for Medical Devices. By the end of the project, "more than 3,000 online food establishments and 1,200 online offers of 450 suppliers were reported to the competent authorities."

Today, G@zielt works under the Administrative agreement between the German Federal Republic and länder, for the control of the operation of a central unit for the control of Internet-traded LFGB products and tobacco products³¹⁰ signed in 2013 after the favourable report by the German working group on consumer protection (also known as "LAV-ALB"). The central unit is in charge of conducting "preparatory tasks"³¹¹ that will help competent authorities in each land perform the corresponding official controls. As will be analysed later in this section, these preparatory tasks include internet searches that lead to identifying unsafe products and of food business operators that are present in the digital market of foods among other.

The central unit is financed³¹² by the *länder* based on the *Königstein Agreement* that states that the quota that each land must bare is calculated based on its fiscal income (2/3) and its population $(1/3)^{313}$. Regarding the composition of the unit, article 2 of the agreement

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³⁰⁹ Federal Office of Consumer Protection and Food Safety. (2018). *G@ZIELT: Safe Shopping on the Internet*. Retrieved from https://www.bvl.bund.de/EN/01 Food/ 01 tasks/06 E-Commerce/lm E-Commerce_node.html;jsessionid=8D157ED87113A3193C5C7A2C5DC1B9ED.2_cid350

³¹⁰ Remmel, J. (2013). Bericht des MKULNV zu einem Entwurf einer Verwaltungsverein- barung zur Regelung des Betriebes einer gemeinsamen Projekt- zentralstelle "Kontrolle der im Internet gehandelten Erzeugnisse des LFGB und Tabakerzeugnisse". Ministerium für Klimaschutz, Umwelt, Landwirtschaft Natur- und Verbaucherschutz des Landes Nordrhein-Westfalen. Retrieved from https://www.landtag.nrw.de/portal/WWW/dokumentenarchiv/Dokument/MMV16-934.pdf

³¹¹ Paragraph 3 of the agreement's preamble.

³¹² Further details on the financing of the cost of the unit are provided in article 2 of the agreement.

³¹³ The agreement also explicitly indicates that the cost of ordering food products for sampling via mystery shopping will be covered by the BVL but that the länder ordering the taking of the sample will be later billed for the total cost of obtaining the product. This does not contradict 43 LFGB, as will be analysed later, as the samples are order only to get additional information on operators and are not used as evidence in the framework of enforcement procedures.

specifies that it must be directed by a professional food chemist, veterinary o equivalent and provides details on the training and tasks of the rest of the team.

To ensure that the unit is accountable to the *länder*, article 4 of the agreement requires for an annual activity report that G@zielt will submit to each state. Also, any fundamental change on the units' functioning or its budget needs to be agreed by all the *länder* and the BVL³¹⁴. The agreement also identifies the BVL as its representative before third parties (EU Institutions, Member States and third countries).

Finally, in order to ensure coordination and cooperation among *länder*, BVL and the central unit, each state needs to identify a contact point within its administration that will be in charge of communicating with G@zielt.

2.2. Tasks developed by G@zielt

G@zielt executes its tasks each year according to a specific annual plan of activities that needs to be agreed upon with the *länder* and the BVL at least on the 30th November of the prior year. The plan includes a list of specific product groups which compliance with food law needs to be analysed, the identification of the food business operators that are offering those products in the digital market and addressing them to German consumers, and specific proposals for sampling (article 5.1).

For instance, the 2014 annual plan for food products focused on perishable refrigerated food products that could entail risks for consumers because of potential breaks of the cold chain during delivery³¹⁵. During the execution of the program, G@zielt identified 173 online retailers that offered perishable refrigerated e-foods. Eight of these retailers were not registered before the competent authorities and where therefore subject to a premises inspection for the first time. Also, the central unit conducted 8 test purchases, while other 7 were conducted by the *länder*. Seven of those 15 test purchases showed the temperature of the received food product was warmer than required by food legislation, and their packaging did not meet legal requirements³¹⁶.

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³¹⁴ Paragraph 3 of article 3 of the agreement.

³¹⁵ Under EU food hygiene legislation, meat products must be kept bellow 4° or 7° (depending on the animal) while fish temperature must remain under 2° during transportation and until delivery.

³¹⁶ Bundesamt für Verbraucherschutz und Lebensmittelsicherheit. (2014). FAQ zur Registrierung und zu Pflichten von Lebensmittelunternehmern sowie den wichtigsten Gesetzesregelungen. Retrieved from

While executing its annual plan, the activities that the agreement assigns to G@zielt may be grouped into the two following categories:

- Surveillance activities seeking to:
- Identify risky products available to the final German consumer
- Identify online traders operating in the digital market

The particulars on how this surveillance takes place are explained in the next section of this Chapter. In both cases, the results of the searches

Are passed on to the competent authorities of the Länder, of other EU Member States or of third countries, so that they can take the necessary steps within their field of competence, for example, to delete the offer from the Internet or to enforce registration³¹⁷.

• International Cooperation, both with European Institutions, Member States and third countries.

Given that e-commerce is a transnational phenomenon, e-foods addressed to the German consumer may come from operators based outside the country and even outside the European Union. Taking that into consideration and as will be described later in this section; it is part of G@zielt's activities to contact competent authorities around the globe in order to improve the safety of the foods that can be bought from Germany³¹⁸.

Both types of activities are undertaken in accordance with article 3 of its creation agreement, which lists the duties assigned to the central unit:

- a. Übermittlung von Daten über den Internethandel gemäß § 38 a Abs. 1 Satz 3 LFGB,
- b. Durchführung von Recherchen nach Erzeugnissen und Anbietern von Erzeugnissen im Sinne des LFGB und von Tabakerzeugnissen im Sinne des vorläufigen Tabakgesetzes
- c. Weiterleitung der Rechercheergebnisse an die Länder,

 $\underline{https://www.bvl.bund.de/SharedDocs/Downloads/01\ Lebensmittel/Internethandel/FAQ\ Registrierung\ L}\\ ebensmittelunternehmen.pdf?__blob=publicationFile\&v=10\%0A$

³¹⁷ Federal Office of Consumer Protection and Food Safety. (2018). *G@ZIELT: Safe Shopping on the Internet*. Retrieved from https://www.bvl.bund.de/EN/01 Food/ 01 tasks/06 E-Commerce/Im E-Commerce_node.html;jsessionid=8D157ED87113A3193C5C7A2C5DC1B9ED.2_cid350

³¹⁸ Cooperation is governed by the Administrative Cooperation mechanism established in article 25.2 of Regulation (EC) 882/2004 of 29 April 2004.

- d. Überprüfung des Internets auf Erzeugnisse, die Gegenstand von RASFF-Meldungen sind, sowie von RAPEX-Meldungen, soweit es sich um Erzeugnisse des LFGB oder des VTabakG handelt,
- e. Probenbeschaffung im Auftrag der zuständigen Behörden der Länder,
- f. Kontakt zu Recherche führenden Behörden im Inland sowie in EU-Mitgliedstaaten und Drittländern,
- g. Erstellung von Jahresberichten über die Arbeit der Projektzentralstelle,
- h. Beratung der zuständigen Behörden (inkl. Fortbildungsveranstaltungen),
- i. Weiterentwicklung der Suchstrategien und des Konzepts zur Überwachung des Internethandels³¹⁹.

But in practice, as part of the BVL G@zielt also has significant activity when it comes to the following tasks that seek to improve consumer protection:

• Improving consumer awareness

 Collaborating with trust mark organisations to help consumers identify safer options:

Taking into account the great amount and variety of offers addressed to the German consumer and the fact that consumers may have difficulty to identify safer products, the Federal Ministry of Justice together with the central unit and German consumer associations put in place the "D21" initiative, which recognises trademarks that ensure companies that use the trust mark must comply with quality standards that include, among other, having fulfilled its registration obligations³²⁰. Even if the fact that companies have registered their establishments does not guarantee the safety of the e-food, it is an

165

Traducción al español del punto 2 del artículo 3 del acuerdo: (2) En el marco del control del comercio electrónico la unidad central de control asume las siguientes tareas: a) transmisión de datos sobre el comercio electrónico según el art. 38, apartado 1, párrafo 3 de la normativa alimentaria y de comida para animales (LFGB), b) realización de controles sobre productos y proveedores de productos en base a la LFGB y de productos de tabaco en base al borrador de Ley del tabaco, c) transferencia de los resultados de las investigaciones a los estados federales, d) control en internet de productos que sean objeto de avisos del sistema de alerta rápida RASFF y RAPEX, siempre y cuando se trate de productos de la LFGB o del borrador de Ley del tabaco, e) muestreos encargados por las agencias responsables de los estados federales, f) contacto con las agencias que realizan las investigaciones y controles nacionales, así como de países miembros de la UE y países terceros, g) realización de informes anuales sobre el trabajo de la unidad central de control, h) asesoramiento a las agencias responsables (incl. formación continua), i) desarrollo de estrategias de investigación y nuevos conceptos para el control del comercio electrónico.

³²⁰ To the date, in Germany 4 trademarks are part of this initiative: EHI Geprüfter Online-Shop, Datenschutz cert Gmbh, Trusted Shops and TüV Süd s@fer shopping.

important step forward because it means that the establishments fall within the radar of competent authorities and, as such, will be included in official control programs.

 Creating information campaigns and written materials to educate consumers:

The central unit has coordinated education campaigns that focus on helping consumers to avoid risky offers and identify safe web shops (among others, through the above-mentioned trust seals). The history of most campaigns and flyers are available through G@zielt's official website. These activities have been most varied. In late 2017 the unit has incorporated an original education proposal to its website called the "BVL-Mustershop"³²¹, a web shop that tests consumer knowledge of the risk of e-food grocery shopping.

• Improving available offers online by educating food business operators on their responsibilities and obligations, through direct contact and by publishing written materials and tutorials.

Indeed, evidence suggests that a significant part of operators that operate exclusively online is not aware of their responsibilities and obligations. In order to fix this problem, the central unit has carried out workshops addressed to these retailers, published guidelines available at several of the *länder* and federal websites, and collaborated with internet marketplaces on automatically providing updated information to operators posting e-food offers.

• Institutional cooperation:

G@zielt participates in several working groups treating the issue of e-commerce. The unit plays a significant role in the European Working Group on e-Commerce of the Food Law Enforcement Practitioners (FLEP) network, which first sit in November 2010 and has been witness of the evolution of the

Korrigieren Sie die Fehler in unserem Online-Shop! (n.d.). Retrieved from http://download.gsb.bund.de/BVL/bvl-demoshop/index.html

workings of the German central unit since the initial pilot project was first put into place.

Given that the scope of this thesis is limited to control tasks, further detail is provided only on how the central unit monitors the digital food market.

2.3. G@ziel's surveillance activities

Only in 2014, the German central unit conducted surveillance activities focusing on 220 different e-food products. Surveillance consisted on searching offers of those products online in order to assess product compliance as well as to identify food operators trading these products and the establishments they operate from.

According to information provided by G@zielt's team, surveillance on those products led to the identification of 1100 offers addressed to the German consumer. Of those, 570 were issued by a food business operator based in Germany, 350 from a operator based in another Member States and finally 180 from operators in a third country³²². These numbers prove that, although there is a pressing concern over the role that food business operators in third countries (and even in other Member States) are playing when it comes to putting unsafe foods in the market via the Internet, by focusing on operators at home, competent authorities could take legal action against the majority of non-compliant efood offers.

The information obtained from surveillance activities resulted in specific information about food business operators active in the German market as well as detailed evidence of the type of unsafe foods that can be bought online. The activities carried out to obtain relevant results, which have evolved every year since the beginning of this research, are described next.

The German strategy aims at controlling foods distributed from establishments located within its national borders, and with food offers that are "directed" to the German consumer via the Internet. The criteria used by the central unit to determine if an offer is directed to the German consumer is the one first adopted by the German Federal Court of

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³²² These numbers prove that, although there is a pressing concern over the role that FOBs in third countries (and even in other Member States) are playing when it comes to putting unsafe foods in the market via the Internet, the German data suggest that focussing on operators at home, competent authorities could take legal action against the majority of non-compliant offers of e-foods.

Justice on it Judgement I ZR 24/2003 from 30 march 2006. The Court ruled that competent authorities should consider that a product was being offered to German consumers if it was written in German and "contains no clear and well-defined disclaimer."

The criteria chosen by the German Federal Court of Justice has been later developed by the Court of Justice of the European Union, which in Judgement of 7 December 2010 ruled that:

In order to determine whether a trader whose activity is presented on its website or on that of an intermediary can be considered to be 'directing' its activity to the Member State of the consumer's domicile, within the meaning of Article 15(1)(c) of Regulation N° 44/2001³²³, it should be ascertained whether, before the conclusion of any contract with the consumer, it is apparent from those websites and the trader's overall activity that the trader was envisaging doing business with consumers domiciled in one or more Member States, including the Member State of that consumer's domicile, in the sense that it was minded to conclude a contract with them.

The following matters, the list of which is not exhaustive, are capable of constituting evidence from which it may be concluded that the trader's activity is directed to the Member State of the consumer's domicile, namely

- the international nature of the activity,
- mention of itineraries from other Member States for going to the place where the trader is established,
- use of a language or a currency other than the language or currency generally used in the Member State in which the trader is established with the possibility of making and confirming the reservation in that other language,
- mention of telephone numbers with an international code,
- outlay of expenditure on an internet referencing service in order to facilitate access to the trader's site or that of its intermediary by consumers domiciled in other Member States,
- use of a top-level domain name other than that of the Member State in which the trader is established, and mention of an international clientele composed of customers domiciled in various Member States.

The mere accessibility to the website or platform where the offer is stored is therefore not enough to consider that it is addressed to the national consumer. It must be that the purchase can be completed and the product actually shipped while any other of those circumstances (i.e. use of language and currency of the country of residence of the buyer)

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³²³ Council Regulation (EC) 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1519930037157&uri=CELEX%3A02001R0044-20150110

also is checked. This understanding of what constitutes an offer directed to a specific Member State is not only valid for e-foods but for consumer goods sold online in general.

Limiting the scope of activities to food products placed in the German market aims at ensuring that the investigation tasks are most useful for later enforcement by competent authorities in the Member State.

2.3.1. Mapping the German market of e-foods through food business identification

As indicated by Büchter, Kuhr & Schreiber, "if you are known to the competent control authority, you are just as controlled as any conventional food business in the framework of the national control plan"³²⁴.

Therefore, one of the most pressing challenges for competent authorities dealing with e-foods is to be able to map the digital market of food. The data obtained by the central unit suggests that a significant amount of internet retailers (almost 40%)³²⁵ do not comply with registration obligations and so remain outside the administration's radar when planning controls³²⁶, a fact that is difficult to counteract given that current German legislation does not include a sanction applicable to the omission of registration duty³²⁷.

G@zielt's team identified that, in 2014, while only 13% of traditional retailers that also operated in the digital market were not properly registered, when it comes to operators dealing exclusively online this number increased up to 40% of non-registered operators³²⁸. That is to say that close to half of Internet-based food business operators is not registered before proper authorities.

169

³²⁴ Büchter, B., Kuhr, C., & Schreiber, G.A. (2011). Pilotprojekt zur amtlichen Kontrolle des Handels mit Lebensmitteln im Internet. *Journal of Consumer Protection and Food Safety*, (6):375, p. 2. Retrieved from https://doi.org/10.1007/s00003-011-0700-9

³²⁵ Schreiber, G.A., & Liebscher, B., & Kranz, P. (2015). Der online-handel mit Lebensmitteln – herausforderung für die Überachung, ZLR 3/2015, p. 297.

³²⁶ Büchter, B., Kuhr, C., & Schreiber, G.A, op. cit., p. 1.

³²⁷ Schreiber, G.A., & Liebscher, B., & Kranz, P, op. cit.

³²⁸ Schreiber, G.A., & Liebscher, B., & Kranz, P, *op. cit.*, p. 298.

The central unit contacted a significant amount of those unknown operators, and concluded that omission of registration is often due to lack of knowledge or understanding of food regulations and not to a deliberate willingness to remain unregistered³²⁹. Small and medium-sizes enterprises tend to have a reactive approach in dealing with food safety requirements³³⁰, a reality that increases in the digital market.

But also, lack of knowledge is based on the fact that a significant part of e-food offers are placed by individuals who do not consider themselves operators because they offer products "on the side" of their primary professional activity and therefore do not get informed about the responsibilities of food law. However, even if C2C does not fall within the scope of hygiene regulations, still foods must be safe.

The German administration considers that non-compliance is often due to the fact that Internet-based operators are not fully aware of their legal obligations. Educating operators individually has proven an effective way to improve compliance.

In order to increase the rate of registration of establishments that engage in e-commerce, G@zielt's activities are divided between coordination of cooperation requests and actual investigation of the operator's identity.

• Ensuring administrative cooperation:

Tax authorities have reached the conclusion that tracking information online is a useful way to identify non-declared income from individuals but also to identify operators who are not declaring their activity for tax purposes. In order to find out who is trading products or generating income, tax authorities are monitoring public information that people share on websites, platforms and social networks. In Germany, the Federal Tax Office uses software to locate relevant information in an automated manner and therefore reduce the time and resources needed to carry out useful investigations online.

³²⁹ Schreiber, G.A., & Liebscher, B., & Kranz, P, op. cit., p. 299.

Yapp, C., & Fairman, R. (2006). Factors affecting food safety compliance within small and mediumsized enterprises: implications for regulatory and enforcement strategies. *Food Control*, 71(1): p. 50. Retrieved from https://doi.org/10.1016/j.foodcont.2004.08.007

Its software Xpider³³¹ was developed by Deutsche Börse Systems as software that allows automated search and storage of information available on the Internet. It is normally used by the German tax authorities to look for tax evaders or operators that are unknown to the authorities by crawling information from digital platforms such as eBay or Facebook, retail advertising and other web shops. Although the exact workings of this software are unknown, as any other web crawler it creates a copy of all the visited pages by a search engine, which will later index and process the pages in a format that is manageable by a public official.

In order to help competent authorities track unknown food business operators, article 38 (a) 1.3rd of LFGB³³² on the transmission of data on internet trading was amended to allow the tax authorities to share information relevant to food law enforcement authorities. It today states that

The Federal Tax Office shall provide the competent authorities of the Länder, at their request, with data relevant to ensure the supervision of compliance with EU legislation on electronic communication networks and services³³³.

In application of this legal provision, when a *land* wants information on specific operators or offers it must addressed its request to the Federal Tax Office via the BVL. It is the BVL who will receive the data in return and

³³¹ Xpider was developed by Deutsche Börse Systems as software that allows automated search and storage of information available on the Internet. It is normally used by the German tax authorities to look for tax evaders by crawling information from digital platforms such as *eBay* or *Facebook*, retail advertising and other web shops. Although the exact workings of this software are unknown, as any other web crawler it creates a copy of all the visited pages by a search engine, which will later index and process the pages in a format that is manageable by a public official.

³³² Art.38.a.1.3rd of LFGB reads as follows: § 38a Übermittlung von Daten über den Internethandel (1) Das Bundeszentralamt für Steuern übermittelt nach Maßgabe des Satzes 2 oder 3 zur Unterstützung der den Ländern obliegenden Überwachung der Einhaltung der Vorschriften (...) 3. der unmittelbar geltenden Rechtsakte der Europäischen Gemeinschaft oder der Europäischen Union im Anwendungsbereich dieses Gesetzes den zuständigen Behörden der Länder auf deren Anforderung die ihm aus der Beobachtung elektronisch angebotener Dienstleistungen nach § 5 Absatz 1 Nummer 17 des Finanzverwaltungsgesetzes vorliegenden Daten über Unternehmen, die diesem Gesetz unterliegende Erzeugnisse oder mit Lebensmitteln verwechselbare Produkte im Internet anbieten. Die Anforderungen sind über das Bundesamt für Verbraucherschutz und Lebensmittelsicherheit an das Bundeszentralamt für Steuern zu richten; das Bundeszentralamt für Steuern übermittelt die Daten an das Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, das die Daten den anfordernden Behörden weiterleitet. Soweit die Länder für den Zweck des Satzes 1 eine gemeinsame Stelle einrichten, ergeht die Anforderung durch diese Stelle und sind die in Satz 1 bezeichneten Daten dieser Stelle zu übermitteln; diese Stelle leitet die übermittelten Daten den zuständigen Behörden weiter.

³³³ Translation is mine.

forward it to the land authorities. The goal of this transfer of information is to reduce the number of degree of investigations that need to be carried out by public officials in charge of official controls by automatically tracking down the identity of the operators and the location of establishments that are actively offering food online.

This combination of Internet search crawler and content analysis software³³⁴ of Xpider helps identify offers of food on the Internet in an automated manner. It focuses on those offers matching the specifications (product, location, information on website...) that the central unit or the *länder* have decided upon. The data obtained by Xpider is then sent to G@zielt for it to later be forwarded to the corresponding *land*'s contact point to be later distributed to the precise competent authority that will check if the operator is properly registered. The central unit does not access the data; instead it is filtered by the *land* and directly sent to each contact point.

Being that Xpider produces very large amount of data, local authorities decide which information to check with a risk-based approach and following the guidelines and control programmes that may be implemented that year. But this system has a significant weakness that needs to be addressed in order ensure efficiency: up to 2015, almost 20% of the data sets forwarded to the competent authorities had already been forwarded at least one other time. Thus, competent authorities receive the same unfiltered information over and over again, which discourages proper use of this resource.

Automated software can help competent authorities track down food business operators. However, it is necessary to make sure that the data generated by this software can be filtered so that staff is not flooded with unmanageable information.

³³⁴ Büchter, B., Kuhr, C., & Schreiber, G.A. (2011). Pilotprojekt zur amtlichen Kontrolle des Handels mit Lebensmitteln im Internet. *Journal of Consumer Protection and Food Safety*, (6):375, p. 3. Retrieved from https://doi.org/10.1007/s00003-011-0700-9

Investigating the identity of operators and the location of their establishments Mapping activities also include actual investigation by the members of the central unit: when in the framework of a specific e-food offer the team notices that relevant information such as the food business operators' legal name or address is missing, G@zielt tries to obtain the missing data by placing information requests to the site administrator, the information service provider, *Paypal* or other relevant stakeholders such as DENIC (the manager of the domain ".de")³³⁵. Thanks to these investigations, up to 2015 G@zielt had sent *länder* over 2.500 references of internet food business operators properly identified.

However, investigating is not an easy task. It stars with an initial selection of a website or page where an offer of a food product has been published. It must be analysed in order to obtain information that allows for complete identification of the business. According to both the e-commerce Directive and Regulation 1169/2011 on food information, the website should include the name and address of the company. But those do not always match the address of the registered establishment which actually participates in the production of the food. The legal name and address listed on the website are used to browse the competent authority's register of establishments and to try to identify those establishments where production of e-foods of that specific company may be taking place. If the business has properly registered its establishments, and those are located within the jurisdiction of the controlling competent authority, the legal name should match a list of establishments in the register. With that information, competent authorities are able to perform official controls on production.

But it can also be that the information included in the offer of an e-food does not match any registered establishment:

o If the address is the one of a business located in another land, it may entail that its establishment is located there and consequently has been

³³⁵ Schreiber, G.A., & Liebscher, B., & Kranz, P. (2015). Der online-handel mit Lebensmitteln – herausforderung für die Úberachung, ZLR 3/2015.

registered there. Therefore, the establishment is not to be controlled by the investigating authority. The same applies to offers and establishments located in another country³³⁶.

O If on the other hand the address is the one of a business located in that land, it suggests that the operator responsible has not fulfilled its legal obligation to register before proper authorities. Authorities shall contact the operator and demand registration to ensure that the establishment falls within the radar of official controls.

Competent authorities can undertake manual online investigations to identify operators and their establishments. However, these investigations are time consuming.

2.3.2. Performing official controls

The most important task (both in terms of magnitude and impact in food safety) that G@zielt develops is watching over unsafe e-foods distributed online.

The central unit performs searches of potentially unsafe products made available to the German consumer through the Internet. It analyses the content of offers and orders products to check their compliance with food law when noncompliance with food law is suspected. Also, the unit takes a variety of actions that aim at removing the product from the digital market of foods without actually opening the administrative procedure for law enforcement. All of those tasks are described in this section.

But, since there is an immense amount of offers online, the central unit must prioritize control of specific food products. In compliance with Regulation 882/2004, prioritization of what products to control is done using a risk-based approach and under the guidelines of the annual plan agreed upon with the *länder*. In accordance with its creation agreement, G@zielt team also performs *ad hoc* searches at the request of the *länder*. In this case, a local authority may address the land's contact point who will later forward the specific

³³⁶ It must be underlined at this point that this thesis deals with the control tasks that can be carried out by competent authorities within their jurisdiction, therefore issues arising on administrative coordination are not covered.

search request to the central unit. Those requests are usually triggered by consumer or business complaints.

The central unit controls e-foods that may entail a health risk for the consumer and are manifestly unsafe.

In particular:

• Foods with forbidden ingredients

The central unit observes that a significant amount of the foods offered online are manifestly non-compliant with food law because the list of ingredients in the offer refers to the presence of ingredients or substances which are not permitted under EU food law. It can be that an unauthorised substance is present (i.e., food supplements with extract of the plant epimedium grandiflorum), but also that the product lists an ingredient not authorised in that particular food product (i.e., an olive oil whose list of ingredients includes food additives different than those accepted by EU law). In these situations, through the mere examination of the information posted with the offer, the officers can be certain that the product does not comply with food law.

According to the team, it is common that part of those products is offered via a web shop where most of the products are manifestly failing to comply with food law requirements. In some of them, it happens that the website includes a banner on the top of the page states that the shop does not have commercial activity and is only a "demo shop;" but a test purchase proves otherwise. In other cases, the operator is not identified in the offer and relevant data such as an offshore mailbox, an anonymous domain, or packages being sent without a return address are an intuitive indication that the operator may not be legal ³³⁷. In both situations, the information and evidences gathered by the team should be transferred to the authorities in charge of criminal investigations, as it

When this happens, officials may contact the official body responsible for domain registration in Germany ("DENIC"), who will request the missing information directly to owner of the domain. If the owner does not provide the missing information, DENIC may block the website without the need of any further procedure.

exceeds the scope of administrative control of Food Law requirements. The central unit can then assist criminal law enforcement agencies if so required.

• Foods that have been subject to notification in the framework of alert systems:

G@zielt also gives priority to monitoring e-foods that have been subject to RASFF notifications because they entail a potential risk to human health and should not be available to consumers. Using the information in the RASFF portal, officials of the central unit review the notification database regularly in order to identify products that are frequently offered in the digital market but that should no longer be available online. Also, G@zielt takes into account notifications received via the International Food Safety Authorities Network (INFOSAN)³³⁸. This alert system includes warning from third countries, including those of the United States' Food and Drug Administration.

It must be noted that these notifications refer to a specific batch of food product that is not compliant with food law and may entail risk for human health. Because the batch number is not available on online offers, G@zielt's team focuses on identifying similar batches that they suspect may entail the same risk as the notified batch.

• Food products that may infringe EU food hygiene regulations:

Finally, the central unit also closely monitors offers of fresh food products highly suspected of not respecting EU food hygiene regulations. G@zielt's annual plan in 2014 had targeted these food products and concluded that, when sold by internet-based operators, non-compliance was the rule. Thus, this category of e-foods has since stays within the radar of the central authority.

Offers include fresh meat, eggs, cereals or vegetables. They may be placed in digital platforms such as eBay or Facebook but also in tailor-made websites. The offers that raise more suspicion are those offers which indicate that purchases may only be made certain days of the week in order to ensure fresh delivery. Other similar statements appear, for example, "delivery is done at

³³⁸ "The International Food Safety Authorities Network (INFOSAN) is a global network of national food safety authorities, managed jointly by FAO and WHO with the secretariat in WHO. National authorities of 186 Member States are part of the network."

the customers' risk." This statement reflects that operators responsible for these offers are not aware of (or do not comply with) their obligations when it comes to ensuring the safety and hygiene of the foods they place on the market.

• Food products handled and distributed by private individuals from their home:

Online platforms have fostered peer-to-peer food trade. Offers include homemade dishes, bakery products, or meat and fish from hunting trips. In this case, the team analyses not only the images included in the offer but also the reviews and opinions posted by purchasers in order to assess the level of risk the foods may entail to consumers. Those published statements often confirm that hygiene and safety rules are not being followed, as the users of the platform that have previously purchased the food product report received deteriorated foods and may have even fallen sick.

Article 14 of the e-commerce Directive states that intermediaries have no general obligation to monitor that their users are not carrying out illegal activities through or depending on the service provided. Thus, platforms do not have mechanisms the obligation of monitoring the compliance of the offers that their users publish. In absence of the private monitoring, manifestly non-compliant offers are frequently identified by G@zielt.

The combination of ignorance of food law on the part of operators, together with lack of monitoring from platforms and competent authorities' uncertainty regarding how to handle these offers in the framework of official controls, has turn home-cooked and fresh e-foods into a matter of major concern. They fall therefore within the radar of G@zielt's monitoring activities.

G@zielt gives priority to watching over e-foods that:

- include ingredients or substances forbidden by EU food law,
- have been subject to notification in the framework of alert systems such as RASFF,
- are marketed manifestly breaching food hygiene regulations, or
- are placed by private individuals in the framework of peer-topeer trade.

2.3.2.1. Undertaking searches

G@zielt's team surfs the Internet searching for offers addressed to the German consumer that may be considered unsafe or non-compliant with food law. Although the specific protocol followed by the team has not made available to the public to ensure its effectiveness, the essential elements of the procedure are indicated below.

First of all, the team must ensure that its activity goes unnoticed by operators: if the operator could track the surfer to a competent authority, chances are that access to the website or to specific offers would be blocked by the operator³³⁹. To that end, the central unit's hardware and software has been selected and programmed so it does not reflect that it is a public authority who is surfing.

When it comes to hardware, it is necessary to ensure that the PC that is used to carry out surveillance does not share the usual internet network connection of the competent authority. This is useful not only to avoid identification, but also to protect the authority in case any virus was to attack the PC. Also when it comes to software, the central unit makes sure that it prevents tracking. Specialized software tools are also used to store information as well as to make searches faster.

To the date, the search for e-food offers is performed manually by the central unit's team and following a well-defined methodology to navigate and store the information gathered. This search starts with the introduction of keywords on popular search tool engines such as *Google* or *Yahoo*, so that the first results of the search that the public official gets are the same that a German consumer would. A similar approach is taken when it comes to carrying out searches in market places such as *Amazon*, *Alibaba* or *eBay*.

But, in order to obtain relevant results, the manual search needs to be tailored-made and must take into account the different workings of the engines and platforms. Different keywords are used depending on the type of results that the official is looking for: is monitoring focusing on a product of a specific brand or batch that has been object of a RASFF notification or is it focusing on a wider category of products?

³³⁹ Schreiber, G.A., & Liebscher, B., & Kranz, P. (2015). Der online-handel mit Lebensmitteln – herausforderung für die Úberachung, ZLR 3/2015, p. 297.

Once the initial query on the search engine is complete, a huge number of results appear. Among the hundreds or even thousands of results, the team focuses on those offers addressed to the German consumer.

Given the great number of offers in the digital market of food, limited human resources capacity as well as the time-consuming reality of manual searches, only a very small fraction of the offers of e-foods addressed to German consumers are being monitored.

Performing manual searches with limited personnel and technical resources has been proved of low efficiency. It is the position of the German administration that "an efficient search can only be achieved through the use of automated software systems"³⁴⁰. Their recommendation is clear:

Zum Auffinden risikobehafteter Lebensmittel sollen automatisierte Recherchen mit einer Kombination aus Crawlern und Textanalyse durchgeführt werden. Anlassbezogene Recherchen könnten beispielsweise von den Untersuchungsämtern der Länder aufgrund von eigenen Verdachtsfällen oder Hinweisen von Verbrauchern oder Verbraucherorganisationen bei der Zentralstelle in Auftrag gegeben werden. Denn liegen Erkenntnisse in Untersuchungsämtern über die Nicht Verkehrsfähigkeit eines Produktes vor, ist eine zentralisierte Recherche nach weiteren Angeboten dieses Produktes im Internet sinnvoll. Neben dem Auffinden solcher Produktangebote soll auch die Vorgangsbearbeitung bis zur Abgabe an die zuständigen Behörden weitgehend standardisiert und automatisiert abgewickelt werden.

But to date there is no IT structure available to control authorities that would ensure the automated analysis of the virtual food market³⁴¹. Consequently, the German administration decided to develop computer software that would perform searches automatically. To this goal, a partnership was established between EDV Gesellschaft für Projektmanagement & Informationssysteme (computer association for project management and information systems) and the BVL, which has resulted in the creation

³⁴⁰ Translation is mine. Büchter, B., Kuhr, C., & Schreiber, G.A. (2011). Pilotprojekt zur amtlichen Kontrolle des Handels mit Lebensmitteln im Internet. *Journal of Consumer Protection and Food Safety*, (6):375. 1-6. Retrieved from https://doi.org/10.1007/s00003-011-0700-9

³⁴¹ Krewinkel, A., Tolg, B., & Fritsche, J. (2001). Online-Lebensmittelhandel und Strategien zur Kontrolle des virtuellen Lebensmittelmarktes. Verbraucherschutz und Leb. *Journal of Consumer Protection and Food Safety*. (6):375, p. 1. Retrieved from https://doi.org/10.1007/s00003-011-0701-8

of the Arbeitsgruppe der Hochschule für Angewandte Wissenschaften Hamburg and is currently working on software that will make searches easier.

The specific aim of this collaboration is to develop software that is able to carry out an automated search and analysis of online food offers while also automatically identifying non-registered food operators. The working group is analysing information available on the relevant internet domains on which non-compliant food products are frequently offered. The selection of relevant data is done by the application of a new tool that allows for more than one search to be done at the same time. The system should thus be able to carry out a differentiated analysis of the previously identified relevant web pages in order to finally store the selected data in a database so it can be further processed any time³⁴². The project is still ongoing and no information is available about its development.

2.3.2.2. Product analysis

Once a search has identified e-foods that appear to be unsafe, G@zielt's team carries out checks to try to determine noncompliance. However, because central unit has not overtaken the responsibility for the performance of official control activities, thus its activity should only be considered a preliminary analysis that cannot be used as evidence for enforcement purposes.

Controls carried out by G@zielt are considered preliminary. Their outcome cannot result in enforcement.

- Formal monitoring: the central unit performs a formal analysis by analysing the product information on the website³⁴³. If by examining the information on the website it is suspected that the e-food may not comply with food law, screenshots are then taken and safely stored for further analysis.
- Material controls: G@zielt may decide to perform analysis of the food products that are suspected to be non-compliant. When this happens, the

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³⁴² *Ibid*.

³⁴³ The team does not only check the rigor of the food information – as defined in Regulation 1169/2011-, but also looks for mandatory particulars established under general consumer law such as the identification of the food business operator and its address, a link on their websites to the European Online Dispute Resolution platform, or the provision of a contact e-mail address, among other.

central unit will purchase the product using mystery shopping techniques. Anonymity is required to ensure that the product that is actually delivered has not been purposely chosen by the food business operator and that it is a good example of the food it is actually offering to German consumers.

In order to perform mystery shopping, the central unit needs specific equipment that will not reveal the buyer's identity or location. This does not only include especial software to ensure anonymity, but also payment methods that are suited to this task: it is not fair nor legal to make a public official purchase the product at their expense, so other payment options have been established. Detailed information about those is not available to the public.

German authorities have established a protocol to place test purchases without giving away their identity, in order to ensure no prior warning. However, no details have been disclosed to the public.

Once the product is in hands of the central unit, the team proceeds to check the parcel, the individual packaging of the items purchased, the documents that may have been delivered, and any other aspects relevant to food law (such as the temperature of the food when dealing with fresh, perishable or refrigerated food products). During this examination, photographs and video are taken in order to keep appropriate record for further inspection.

Sample for analysis may also be taken and forwarded to a laboratory to check product identity, adulteration, or the presence of microbiological or chemical hazards. The results of sampling are not used for enforcement purposes because all controls carried out by G@zielt are considered mere preliminary checks³⁴⁴.

The results of formal and material controls are only used as a source of information to identify risky products or retailers.

³⁴⁴ It must be noted that even when these purchases were made my competent authorities in the *länder*, they would still not be considered fair for enforcement because German authorities consider that the current legal framework does not allow for legal sampling. No fair sample can come from these purchases under current German legislation.

2.3.2.3. Enforcing food law

Because G@zielt has not assumed regional and local competent authorities' responsibilities in official controls, once formal and material checks have been completed the unit may follow three different courses of action:

- Forwarding the information resulting from the preliminary tasks to the competent authority, so it can perform controls on production.
- Contacting the operator that posted the offer and requesting that it removes or corrects the non-compliant offer.
- Initiating a notice-and-take down procedure to have the intermediary remove or block the offer "expeditiously."

Several or all of those options may be used, depending on the degree of non-compliance and the risks the non-compliant food product may entail to potential consumers.

• Forwarding the information resulting from the preliminary tasks to the competent authority, so it can perform controls on production.

Once G@zielt's controls suggest that an e-food is not compliant with food law, the central unit may forward the information that has been collected to the competent authority in the land or country the food establishment that shipped the food product is located in. The information is transmitted to the authority that has jurisdiction over that establishment to make sure that controls at the production stage can be carried out. Therefore, even if the legal framework entails that currently no direct enforcement can come from controlling distribution of e-foods in Germany; competent authorities can have a significant impact when it comes to improving food law compliance in the digital market based on the preliminary work of G@zielt.

The information can also be shared with competent authorities in other Member States or with third-countries. G@zielt's officials may forward the information and evidence gathered to the national contact point the Member States through the Administrative Assistance and Cooperation "AAC" mechanism established in Regulation 882/2004. Although the particular of how many requests for assistance have been submitted or the products affected by it or its outcome have not been published, competent authorities in Member

States such as Spain acknowledge that G@zielt has issued several assistance requests.

Lastly, when operators or the establishment are located in third countries, G@zielt initiates contacts with competent authorities of the concerned country to communicate that there are e-foods that are not compliant with EU food law are being offered within its territory³⁴⁵.

Even though the results of its investigations are not suited for enforcement, the preliminary investigations and controls carried out by G@zielt facilitate that competent authorities carry out controls at the production stage.

 Contacting the operator that posted the offer and requesting that it removes or corrects the non-compliant offer.

When the offer of an e-food heavily suggests that the food does not comply with food law (for instance, because the list of ingredients lists forbidden substances, because it has been object of a recall order from proper authorities, or because it is clear that its handling does not follow food safety and hygiene rules), the central unit may decide to contact the operator and request him to remove the offer of an e-food as fast as possible from the market. In the experience of G@zielt's team, in many cases the author of a non-compliant offer is not aware of this circumstance or does not want to challenge the public administration's view on the issue. Therefore, once summoned to eliminate the offer, in a significant amount of cases it is duly eliminated.

The specificities of the e-foods market make it frequent that internet-based operators are not fully aware of their responsibilities and obligations according to the General Food Law nor of the specifications established in food regulations (such as labelling, use of additives or food contact materials). They are also not keeping track of relevant RASFF notifications. This is an informal manner to try to improve compliance while educating operators. The goal is

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³⁴⁵ Again, currently there is no official information of how these contacts have been carried out or their outcome.

to have an impact on the digital market of e-foods using all available tools and not only enforcement.

Given that the response of legitimate operators is generally positive, competent authorities can make a difference when it comes to improving the overall safety and compliance rate of the digital market of foods.

Initiating a notice-and-take down procedure to have the intermediary remove
or block the offer "expeditiously" is one of the most successful activities of
the central unit in order to eliminate non-compliant offers from the German
digital market.

Collaboration between <u>G@zielt</u> and digital marketplaces relies essentially on direct contact between the central unit's team and the platform. When dealing with large platforms such as *Amazon*, *eBay* and *Alibaba*, the removal or blocking request is carried out through a specific form available to public enforcement agencies on the platform's website. The central authority fills the form with information of the preliminary tasks performed, and requests the removal of the offer. This communication channel does not preclude additional informal contacts when considered appropriate.

Notice-and-take down procedures are frequently used to remove from the market offers of food products that are manifestly not compliant with food law.

3. RECAPITULATION

G@zielt does not perform official controls on e-foods. It performs preliminary investigations and material checks that are later used by competent authorities in each *länder* to initiate official control tasks within their territory. They are a source of information, not evidence suitable for enforcement.

The creation of a central unit has increased the efficiency of investigatory tasks for the identification of operators based in Germany and offers addressed to the German consumer. Its team have developed specific investigation skills that are adapted to this particular activity. Their (undisclosed) protocol prevents operators from noticing that they are being monitored, which ensures compliance with the rule that controls must take place without prior warning.

Based on risk-analysis, G@zielt's activities focus on e-foods that:

- include ingredients or substances forbidden by EU food law,
- have been subject to notification in the framework of alert systems such as RASFF.
- are marketed manifestly breaching food hygiene regulations, or
- are placed by private individuals in the framework of peer-to-peer trade.

Consumers engaging in C2C and making non-compliant e-foods available, are directly contacted and requested to address non-compliance. When operators refuse or ignore this request, the central unit submits a NTDs to the platform hosting the offer.

Controls on production of food establishments that are not registered is possible thanks to its coordination of information flows between *länder* and the tax authority, as well as to the manual investigations carried out by its staff. Investigation methods have been developed in order to track down operators and request the registration of their establishments.

However, German authorities are not actively requesting information about e-commerce engagement. The application forms used for registration do not refer to internet trade, thus there is no systemized information to define control plans focusing on controlling e-foods at the production stage.

Additionally, official controls on distribution of e-foods are not carried out. G@zielt uses mystery shopping techniques to perform material checks on e-foods, such as analysing the conditions of the parcel, the packaging of food items, and compliance of the food product with food law. No purchases are made for the purpose of official controls because, according to the interpretation of the German authorities, controlling distribution is not legally feasible. The obstacles are enshrined in article 43 LFBG, and are the following:

- There is no legal base to order a food product anonymously, and the operator must witness sampling.
- Competent authorities must no pay for the food products they sample.

Once an offer is suspected to be non-compliant, the central authority may contact the operator and request that it corrects or removes the offer. It is the experience of the German team that most operators collaborate. When the operator does not collaborate, G@zielt initiates a notice-and-take down procedure. It is the platform (intermediary) that should then block or remove the non-compliant offer.

G@zielt is an example of how cooperation between authorities can increase effectiveness and efficiency, minimizing costs³⁴⁶. Given its success, the scope of its activities has been extended to the control of cosmetic products, consumer products, animal feed and tobacco.

The German authorities propose to create one central investigation unit for the European territory financed by all Member States, which would deal with offers in all EU languages, performing searches of online offers for EU consumers, and distributing results to competent authorities in each Member State:

The German model of central internet control by the responsible agencies in the 16 federal states could be transferred in the same way to the EU with its 28 member states. Many stores have their offers in several languages and could be controlled by an agency instead of by parallel controls of several affected member countries. A central unit covering all the EU languages and having extensive experience in relation to food law and online controls would be, as in the case of Germany, the most effective, efficient and economic solution to face the challenge of control in the European scope. In combination with quality seals, the result would be a European market in the EU "Safer Shopping" for the more than 500 million consumers. At the same time, traders moving in this market would have

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³⁴⁶ Schreiber, G.A., & Liebscher, B., & Kranz, P. (2015). Der online-handel mit Lebensmitteln – herausforderung für die Úberachung, ZLR 3/2015, p. 297. Translation is mine.

an important competitive advantage, as their offer would not only be attractive for EU consumers, but also for consumers around the world, especially those from states that do not have enough food security³⁴⁷.

But deciding on whether a Member State should create a centralised unit should not be a decision based exclusively in economically or efficiency driven considerations. As the German experience shows, centralising entails first of all an agreement that control is going to be led by a single authority outside the regional authority. Even if enforcement powers could still be hold by the competent authority, it entails removing resources and some degree of autonomy from the regional or local authorities who did have the responsibility assigned in the first place.

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³⁴⁷ Schreiber, G.A., & Liebscher, B., & Kranz, P. (2015). Der online-handel mit Lebensmitteln – herausforderung für die Úberachung, ZLR 3/2015, p. 297.

PART 2.

THE UNITED KINGDOM IS CONTROLLING THE DIGITAL MARKET AT THE PRODUCTION AND DISTRIBUTION STAGE

The second initiative that is analysed is the United Kingdom's strategy to control e-foods. The UK has not created a centralised unit. Its approach aims at providing competent authorities and staff performing controls with advice on how to (i) search for non-registered operators, (ii) find mechanisms to carry out sampling at the distribution stage in compliance with the Compliance Regulation and state laws, and (iii) enforce food law in the digital market.

1. THE UNITED KINGDOM'S POLITICAL AND ADMINISTRATIVE STRUCTURE AND ITS ARRANGEMENTS WHEN IT COMES TO OFFICIAL CONTROLS

As is well known, the political and administrative structure and division of powers in the United Kingdom is most particular since, in 1997, the kingdom started devolving powers to Northern Ireland, Scotland and Wales³⁴⁸. Based on three agreements known as "devolution settlements", those three counties have undertaken "a process of decentralisation that puts power closer to the citizen so that local factors are better recognised in decision-making"³⁴⁹.

Since the devolution process started, the Parliament in each country has reclaimed power to legislate on a wide range of issues, known as "devolved matters." On the other hand,

³⁴⁸ On the other hand, England is the only nation in the United Kingdom that has remained un-devolved.

³⁴⁹ Cabinet Office, Northern Ireland Office, Office of the Secretary of State for Scotland and Office of the Secretary of State for Wales. (2013). *Guidance: Devolution of powers to Scotland, Wales and Northern Ireland*. Retrieved from https://www.gov.uk/guidance/devolution-of-powers-to-scotland-wales-and-northern-ireland

those issues that remain an exclusive responsibility of the UK Parliament are known as "reserved matters"350.

In this particular process of decentralisation, and different than what happens in Germany and Spain in respect to the *länder* or to the Autonomous Communities to that matter, the list of devolved matters varies from one nation to another, based on the content of the devolution settlement agreed upon with the UK.

That being said, it must be noted that "the Devolved Administrations are the competent authorities for their countries with regard to food legislation, animal health and welfare and plant (including tree) health law"³⁵¹. Thus, official controls are devolved matters in the UK.

1.1. Political structure of United Kingdom and distribution of powers when it comes to official controls

Responsibilities for official controls are assigned to each country's central authorities³⁵² "but, in practice, day to day responsibility for enforcement functions is divided between central and local government, 353. Identifying central authorities in a systematized manner in the UK is a complex task, as the distribution of administrative powers is not mirrored between nations.

There are two independent non-ministerial offices with responsibilities in food law:

nationalcontrolplan2013-2018.pdf

351 Food Standards Agency. (2017). Multi-Annual National Control Plan for the United Kingdom. April 2013 to March 2018, p. 9. Retrieved from https://www.food.gov.uk/sites/default/files/ukmulti-

³⁵⁰ Reserved matters consist mainly of the following: international relations and defence, national security, nationality & immigration, nuclear energy, broadcasting, the UK tax system (except for some taxes in Scotland) and employment and social security (except Northern Ireland).

³⁵² For instance, competent authorities for official controls, in the following areas, according to the current MANC, are: • When it comes to animal health and welfare: "With regard to animal health and animal welfare control responsibility is held centrally by: DEFRA and its agencies; and equivalent Departments in the Devolved Administrations. Day-to-day monitoring and enforcement is carried out by: the central Departments (or their agencies or contracted agencies); and local authorities (as well as DAERA in Northern Ireland). " • When it comes to plant health: "Plant health control responsibility lies with "UK Plant Health Service" which comprises a number of units from within: DEFRA, The Animal and Plant Health Agency (APHA), the Agriculture/Rural Affairs/Natural Resources Departments in the Devolved Administrations; the Forestry Commission and; Natural Resources Wales."

³⁵³ Food and Veterinary Office. (2015c). Country profile. Organization of Official Controls, p. 4. Retrieved from http://ec.europa.eu/food/audits-analysis/act_getProfile.cfm?pdf_id=384%0A

- Food Standards Agency (hereinafter, "FSA"), which has responsibilities in England, Wales and Northern Ireland according to the respective devolvement settlements, as well as some responsibilities for the whole of the UK, and
- Food Standards Scotland (hereinafter "FSS"), created in 2015 and that took over the responsibilities previously entrusted to the FSA.

Additionally, there are also ministerial bodies relevant to official controls, such as:

- Department of Health and Social Care (hereinafter, "DHSC") of the United Kingdom, which leads public health policies at large and nutrition legislation in particular in England and has parallel equivalents in the other three nations, and
- Department for Environment, Food and Rural Affairs (hereinafter, "DEFRA") that "is the UK central competent authority for animal health and welfare law in England and is responsible for policy and regulations on environmental, food and rural issues"³⁵⁴. It also has an equivalent body in the devolved administrations in Scotland, Wales and Northern Ireland.

It is the DHSC and DEFRA that "generally leads on negotiations in the EU and internationally for the UK" in their respective matters. However, the Food Standards Agency has a decisive role in the official controls system.

The FSA was created in 2001 by the Food Standards Act of 1999³⁵⁶, and based on the White Paper "The Food Standards Agency: A Force for Change" presented to the UK Parliament by the Minister of Agriculture, Fisheries and Food on the 14th January 1998. According to the white paper, the FSA is to "promote high standards throughout the food chain, from the point of production to the point of consumption."

This "non-ministerial", independent government department is "accountable to the Westminster Parliament through the UK Secretary of State for Health and to the Scottish Parliament, National Assembly for Wales and Northern Ireland Assembly via the

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³⁵⁴ Food and Veterinary Office. (2015b). Country Profile Follow-up status of FVO. p. 8.

³⁵⁵ Food and Veterinary Office, op. cit.

³⁵⁶ The Food Standards Act of 1999 is a law applicable to the whole of the United Kingdom.

Minister of Health or equivalents"³⁵⁷. Once created, the Agency took on most of the responsibilities that DEFRA and DHSC were carrying out in the field of food law.

Before 2015, the FSA was the competent authority when it comes to food safety and standards law responsible for the following in the whole of the United Kingdom:

- Development of food policy and provision of advice, etc. to public authorities (Food Standards Act, art. 6)
- Provision of advice, information and assistance to other persons (Food Standards Act, art. 7)
- Acquisition and review of information about matters connected with food safety and other interests of consumers in relation to food (Food Standards Act, art. 8)
- Also, under article 12 of the Food Standards Act, "the Agency has the function of monitoring the performance of enforcement authorities in enforcing relevant legislation. That function includes, in particular, setting standards of performance (whether for enforcement authorities generally or for particular authorities) in relation to the enforcement of any relevant legislation." Still, the FSA "consults local (...) food authorities directly during the development of policies that may impact on their (...) enforcement activities" 358.

But because since 2015 Scotland has its own authority called Food Standards Agency, the FSA is today the central competent authorities only in England, Wales and Northern Ireland³⁵⁹. The FSS is a non-ministerial government department office of the devolved administration of Scotland, which means among other that it remains directly accountable to the Scottish Parliament. First created on April 2015 by the Food (Scotland) Act 2015³⁶⁰, it is responsible for

those central Government functions previously carried out by the FSA in Scotland, including food and feed safety and standards, nutrition, food labelling, and meat inspection policy and delivery³⁶¹.

192

³⁵⁷ Multi Annual National Control Programme Network (MANCP). (2014). *Risk based planning of official controls*, p. 17. Retrieved from <a href="https://www.livsmedelsverket.se/globalassets/produktion-handel-kontroll/vagledningar-kontrollhandbocker/vagledningar-och-information-fran-eukommissionen/risk-based-planning-of-official-controls-may-2014

Food and Veterinary Office. (2015c). *Country profile. Organization of Official Controls*, p. 15. Retrieved from http://ec.europa.eu/food/audits-analysis/act_getProfile.cfm?pdf id=384%0A

³⁵⁹ Even if food safety, standards, nutrition and dietary health are considered devolved matters in Northern Ireland, they are a responsibility assigned to the "FSA in Northern Ireland."

³⁶⁰ Legislation Government United Kingdom. (2015). *Food (Scotland) Act 2015*. Retrieved from http://www.legislation.gov.uk/asp/2015/1/contents/enacted

³⁶¹ Multi Annual National Control Programme Network (MANCP). (2014). *Risk based planning of official controls*, p. 7. Retrieved from https://www.livsmedelsverket.se/globalassets/produktion-handel-

Its tasks include therefore "monitoring the performance of enforcement authorities in enforcing food and feed legislation and setting performance standards"³⁶².

So, the FSA and FSS are the central competent authorities in the UK when it comes to both food safety and standards law. But, as indicated by the Country Report, the FSA is still the central competent authority for the United Kingdom "where a single point of contact or authority is designated to represent the UK as a Member State". The relation between the two agencies is laid out in a memorandum of understanding, "which sets out the principles for the working relationship between the FSA and FSS"³⁶³.

One of the tasks that remain a responsibility of the FSA for the whole United Kingdom is the definition of the multi annual control plan required by EU food law. The UK's multi Annual national control plan (MANCP) is co-ordinated by the FSA, who is the designated contact point. Nevertheless, FSA still "works closely with FSS, DEFRA and its agencies". The current plan³⁶⁴ was first approved in 2013 for the period 2013-2016, but it was amended in 2016 and later in 2017 to extend its temporal scope to 2018.

Local authorities³⁶⁵ in the four countries carrying the weight when it comes to official controls in the UK³⁶⁶. There are over 400 of them in the United Kingdom, and each one of them acts according to a service plan that is defined under the recommendations of the Framework Agreement on official feed and food law controls by local authorities³⁶⁷.

The Framework Agreement gives detailed guidance to local authorities on how to build their own service plans describing how official food and feed controls are going to be carried out within their jurisdiction. It provides the mechanism through which the FSA

 $\underline{kontroll/vagledningar-kontrollhandbocker/vagledningar-och-information-fran-eukommissionen/risk-\underline{based-planning-of-official-controls-may-2014}$

³⁶³ *Ibid.* p. 32.

³⁶² *Ibid*.

³⁶⁴ *Ibid*.

³⁶⁵ The local authority responsible for official controls in each country differs based on its own national legislation, but in general terms, it goes as it follows: by County councils and District councils in England, by Unitary authorities in Wales, and by Unitary councils in Scotland.

³⁶⁶ DEFRA's agencies have responsibilities in very particular areas, as well as do the FSA and the FSS, who remain in charge of official controls when it comes to very specific areas as indicated in the Food Safety Act, such as licensing of irradiated food facilities.

³⁶⁷ There is an Agreement for the FSA (introduced in 2001 and amended last in 2009) and another for the FSS.

sets standards for, monitors and audits local authorities and port authorities' food law enforcement activities.

Each of those authorities appoint the officers who will carry out official control activities such as inspecting premises and foods, and taking samples whenever they consider it necessary.

In order to ensure coordination and collaboration between local authorities, there the FSA, the FSS and DEFRA, as well as the other agencies participating in official controls, have set up a number of working groups to ensure coordination and cooperation among competent authorities in the United Kingdom and within countries. The UK has gradually established therefore a "system of Regional Food Liaison Groups at which representatives of Local Authorities Food Liaison Groups can raise issues with the FSA2"³⁶⁸ and the FSS. One of them is the Enforcement Liaison Group, which focuses on enforcement of food law in the framework of official controls.

1.2. Legislation relevant to the organization and performance of official controls

As a member of the European Union, the United Kingdom's legal framework for food law is based on EU regulations, together with specific pieces of legislation that incorporate European law requirements into the UK system such as the Food Safety Act (hereinafter, "the Act") of 1990. The Act is applicable within the limits of Great Britain (so Wales, England and Scotland), and has been amended regularly in order to adapt the law to the changes in European Food Law. Northern Ireland has its own similar legislation on this matter, which is the Food Safety Order of 1991.

The Food Safety Act is a "wide-ranging legislation on food safety and consumer protection in relation to food throughout Great Britain"³⁶⁹ that suffered significant changes in the early 2000 in order to mirror the requirements of Regulation 178/2002. The Food Safety Act also sets the legal base when it comes to registration of food establishments in Great Britain (as also does the North Irish law), and the general

³⁶⁸ Food and Veterinary Office. (2015c). Country profile. Organization of Official Controls, p. 15. Retrieved from http://ec.europa.eu/food/audits-analysis/act_getProfile.cfm?pdf_id=384%0A

³⁶⁹ Food Safety Act. (2009). *The food Safety Act 1990 - A guide for food businesses*, p. 8. Retrieved from https://www.food.gov.uk/sites/default/files/multimedia/pdfs/fsactguide.pdf

principles that must guide enforcement of food law requirements such as sampling for official controls.

Together with the Food Safety Act and North Ireland's Food Safety Order, other relevant pieces of legislation govern food safety and hygiene in the four UK countries:

- The General Food Law Regulations of 2004 describe the penalties for breaches of Regulation 178/2002.
- The Food Hygiene Regulations of 2006 and 2013, which deal with EU set food hygiene requirements as well as with sampling requirements³⁷⁰.
- The Official Feed and Food Controls Regulations of 2009, which

identify the authorities in the UK that are responsible for organising and undertaking enforcement checks in respect of feed and food [and] provide the legal powers to these authorities to enable them to meet the obligations set out in 882/2004, in particular with regard to monitoring, auditing and financing of official controls and reporting on enforcement activity³⁷¹.

Under the Official Feed and Food Controls national regulations, the Food Law Codes of Practice ensure appropriate and consistent enforcement. Each country in the United Kingdom has its own Code of Practice, published together with a corresponding Guidance document. It is in these Codes that one should find "details about the enforcement actions available and when they should be applied"³⁷².

In order to make this vast legal framework manageable for staff in charge of official controls, the FSA (and from 2015 also the FSS when it comes to Scotland) has the power to issue one Food Law Code of Practice for each nation. The Code of Practice (together with a corresponding Guidance document) provides local authorities with specific advice on how to perform official controls within their jurisdiction with full respect to both EU and national law requirements.

³⁷⁰ There is one regulation in that matter for each of the nations in Great Britain, and parallel legislation for Northern Ireland. For instance, when it comes to the Food Hygiene Regulations, the national laws currently are: - In England, the Food Safety and Hygiene (England) Regulations 2013 - In Wales, the General Food Regulations 2004 No.3279 and the Food Hygiene (Wales) Regulations 2006 (as amended) - In Scotland, The Food Hygiene (Scotland) Amendment Regulations 2016 (SSI 2016 No. 260) - In Northern Ireland, Food Hygiene Regulations (Northern Ireland) 2006 (as amended).

³⁷¹ Food Standards Agency. (2004). *Official feed and food controls regulation*. Retrieved from https://www.food.gov.uk/enforcement/regulation/europeleg/feedandfood

³⁷² Food and Veterinary Office. (2015c). *Country profile. Organization of Official Controls*, p. 21. Retrieved from http://ec.europa.eu/food/audits-analysis/act_getProfile.cfm?pdf id=384%0A

All of those documents and regulations have been analysed in order to identify the requirements for registration of food establishments and for performance of official controls. The next section presents those requirements in a summarized manner, using the example of England.

1.2.1. Regulating the organization of official controls

Following the European Food Law mandate, the Food Safety Act states that central competent authorities in each nation may,

By regulations, make provision for the registration by enforcement authorities of premises used or proposed to be used for the purposes of a food business, and for prohibiting the use for those purposes of any premises which are not registered in accordance with the regulations.

Depending on the activities carried out at each establishment, local authorities, the FSS or FSA "are responsible for approvals of food establishments across the UK"³⁷³. The detailed procedure is defined across the varied legislation referred to in the previous section³⁷⁴. The law establishes a general recommendation to apply for registration or approval of establishments 28 days before the beginning of the activities.

Both the FSA and FSS keep a centralised list of approved food establishments which is available through its website, while information on registered establishments can be asked for but is not public.

The FSA has produced a model application form for approval o registration of establishments which is very similar to the one used for the same purposes by both German and Spanish competent authorities. The form requires the applicant to provide its full name and address as well as name and address of the food business and the location establishment that needs to be approved or registered. Also, it requires for very general information about the activities carried out on the premises (more than one option can be selected):

- Staff restaurant/canteen/kitchen

³⁷³ Food Standards Agency. Regulation (EC) No 882/2004 on official controls: guidance in Q&A format for enforcement authorities on the feed and food elements, p. 22. Retrieved from https://www.food.gov.uk/sites/default/files/multimedia/pdfs/offcqaguidancenotes.pdf

³⁷⁴ Detailed information may be found both in each nation's Food Code of Practice and, in general, in the Food Standards Agency. (2004). Approved Food Establishments. Retrieved from https://www.food.gov.uk/enforcement/approved-premises-official-controls/sectorrules

- Hospital/residential home/school
- Retailer (including farm shop)
- Distribution/warehousing
- Restaurant/café/snack bar
- Food manufacturing/processing
- Market/ Market stall
- Importer
- Takeaway
- Catering
- Hotel/pub/guest house
- Packer
- Private house used for a food business
- Moveable establishment e.g. ice cream van
- Wholesale/cash and carry
- Primary producer livestock
- Food Broker
- Primary producer arable
- Other. 375

When it comes to registering establishments that are used for the shipment of food online, the Guidance on the Code of Practice for England (as do the ones of the other nations) issued in November 2017 indicates the following:

3.2.6.5 Internet sales

Certain businesses offer their goods for sale via the internet. Although such trade is not specifically referred to in Regulation (EC) 852/2004, such businesses fall within the definition of a food business and the relevant requirements of food law are applicable to them. Such businesses must register with the most appropriate competent authority. This may be where they live, where their office is located or where the food stocks are stored. Food businesses such as those who set up web sites providing caterers' menus to consumers, which facilitate sale of the food and arrangement of its delivery from caterer to consumer, should also be registered as food businesses³⁷⁶.

Also, the FSA's document Selling and buying food online - Q&A states that

As a food business you will be required to register those food-related operations or activities. You can register as a food business on Gov.uk or by contacting your local authority³⁷⁷.

³⁷⁵ There is a most similar model for each nation. For instance, the model for England is included in Annex 5 of its Food Standards Agency. (2017c). *Food Law. Code of Practice (England)* Retrieved from https://www.food.gov.uk/sites/default/files/food law code of practice 2017.pdf

³⁷⁶ Food Standards Agency. (2017b). *Food Law. Practice Guidance (England)*, p. 11. Retrieved from https://www.food.gov.uk/sites/default/files/foodlawpracticeguidance2017.pdf

³⁷⁷ Food Standards Agency. (2016h) *Selling and buying food online – Q&A*. Retrieved from https://www.food.gov.uk/sites/default/files/selling-food-online-qa.pdf

Moreover, the FSA's Guidance for food business selling food online indicates the following:

If you are selling food online it is a legal requirement to register your business with your local authority 28 days before you intend to trade. If you are already trading and have not registered you need to do so as soon as possible. Registering your business is free of charge.

The registration form requires basic details of your food business activities and the address(es) where you carry out food operations. This would also include your office, even though you may not physically handle any food products. This should include all multi-site businesses where activities are carried out³⁷⁸.

Food business operators should apply for registration of the establishment where the food is stored or shipped from using the "retailer" and/or "distribution/warehousing" option. If the operator is a broker that does not have access to the foods, both the distribution and the "broker" category apply.

But, as it happens in Spain and Germany, the list of activities in the model registration form does not include any option for food e-commerce. An applicant may decide to provide this information under the "other" option, but this is currently not required or suggested in any way.

As it happens in Germany and Spain, in the United Kingdom the application forms used for registration of food establishments do not ask for detailed information on their e-commerce undertakings.

When it comes to the issue of considering if those e-foods offered in the framework of peer-to-peer commerce, the FSA acknowledges that all food offers must be safe because they fall within the scope of the General Food Law, but that only

Certain operations ('undertakings') supplying food (...) are registered as food business operators with the 'competent authorities' (in the UK these will be local authorities). An 'undertaking' must have 'a certain continuity of activities' and 'a certain degree of organisation' 379.

Food Standards Agency. (2016f). *Food sold online*, p. 1. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

³⁷⁹ Food Standards Agency. (2016c). *Guidance on the application of EU food hygiene law to community and charity food provision*, p. 10. Retrieved from https://www.food.gov.uk/sites/default/files/hall-provision-guidance.pdf

The issue is therefore again, how to include C2C offers within the radar of official controls, and how to determine that an undertaking has reached a degree of organization and continuity that makes it relevant to food hygiene regulations.

The FSA's Guidance on the application of EU food hygiene law to community and charity food provision does provide some insight on the second issue. It provides advice on how to assess if an undertaking should be registered. This document does not analyse the situation of domestic e-foods but to charity and community food provision.

The document provides its views on what 'a certain continuity of activities and a certain degree of organisation' (i.e. an 'undertaking') looks like in day-to-day terms and provides relevant examples³⁸⁰.

FSA understands that the assessments should be done on a case-by-case basis, but the general rule should be that activities consisting on the "provision of food on at least one occasion on an average monthly basis"³⁸¹ are considered as having some degree of continuity. However, in order to fall within the definition of food business of Regulation 852/2004, it is not enough that the activity that takes place more than once a month. It should also require "a certain degree of organization." Continuity alone does not determine that the undertaking is a food business.

In order to assess if that second circumstance is met, the FSA considers that both the overall nature of the organisation and the likely risks to consumer health should be considered³⁸². This idea is not developed in the document but from the list of examples it includes, two conclusions can be drawn:

- The nature of the organisation refers to both the human and economic resources that, together with equipment, may be needed to carry out the activity.
- The likely risk to consumer health is considered low when dealing with canned, packaged foods and soft drinks while those examples that deal with "hot food" (such as soup) and "hot meals", as well as with collection of

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³⁸⁰ *Ibid.* p. 6.

³⁸¹ *Ibid.* p. 11.

³⁸² Food Standards Agency. (2016c). *Guidance on the application of EU food hygiene law to community and charity food provision*, p. 11-12. Retrieved from https://www.food.gov.uk/sites/default/files/hall-provision-guidance.pdf

sandwiches and similar items, are considered to entail higher risk to the consumer.

But, must both circumstances be present for us to consider that the activity entails "a certain degree of organisation" The guidance document does not say.

An example based on the FSA's interpretation: a private individual offering hot home-made soups or fresh meat from their hunting trip, which only places offers a couple of times a year, does not fall within the scope of Regulation 852/2004. Even if the food handling entails risks to consumer health, there is no degree of continuity.

What about the same individual offering it more than once a month? The organisation needed to carry out the activity is scarce, but the risk for consumer health could be high. Does it fall within the scope of Regulation 852/2004? The guidance document does not provide additional information to answer this question.

1.2.2. Regulating de performance of official controls

As it is already the case in Spain and the United Kingdom, there are currently no regulations defining the steps to follow in order to carry out general control activities such as an inspection. This said, the Food Safety Act does deal in articles 29 to 31 with the general principles that govern sampling for analysis³⁸³.

Further details on sampling as a process, the details for procuring the samples or the testing methods are enshrined in national regulations for each nation:

• The General Food Law Regulations (2004), while repeating the procedure traced in the Act, provide competent authorities with details on which public analyst or examiner should handle the sample and on the type of certificate they should issue after their analysis or examination is done.

³⁸³ Although the Act is only applicable in Great Britain, North Ireland's Food Safety Order's articles 29 to 32, as well as the rest of the legislation from the UK nations, deal with food sampling in an almost identical way, so observations and conclusions on sampling made in this Section should be considered valid for the whole Member State.

- The Official Food and Feed Controls Regulations, also repeating the procedure traced in the Act, mirror the food operators' duties when sampling for enforcement. For instance, article 29 of the Regulation in England (amended in 2009) states the following:
 - (1) The person responsible for introducing any product into England shall permit an authorised officer of an enforcement authority to carry out checks in relation to the product pursuant to Article 16 of Regulation 882/2004.
 - (2) When an authorised officer is carrying out checks in relation to a product pursuant to Article 16 of Regulation 882/2004, the person introducing the product shall provide the facilities and assistance which the authorised officer reasonably requires to carry them out.
 - (3) When an authorised officer of an enforcement authority is carrying out an identity check or a physical check on a product in accordance with Article 16 of Regulation 882/2004 he shall be entitled to require that the check takes place at a specified place.
- Finally, the Food Safety (Sampling and Qualifications) Regulations focus, as stated in the current regulation for England, on "the qualifications necessary to be a public analyst, a food analyst or a food examiner for the purposes of the Food Safety Act 1990" and on "the procedures to be followed when a sample has been procured under that Act for analysis or examination (…)"³⁸⁴.

The Sampling and Qualification Regulations are, therefore, those which provide information relevant to this thesis. The procedure and requirements when it comes to sampling and its use for enforcement defined in each of the four national Sampling and Qualification Regulations are equivalent to one another³⁸⁵. Taking into account the scope of this thesis, the main elements of this process are described below.

An officer from the competent authority can purchase or take a sample of "any food, or any substance capable of being used in the preparation of food" which appears to be

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Food Standards Agency. (2013). *Explanatory memorandum to the food safety (sampling & qualifications)* (*England*) *Regulations* 2013, no. 264, p. 1. Retrieved from http://www.legislation.gov.uk/uksi/2013/264/pdfs/uksiem_20130264_en.pdf

³⁸⁵ The wording being even almost identical in the four regulations, mentions to the English regulation are done as examples of what all four regulations establish.

intended³⁸⁶ for human consumption. The Food Law Codes of Practice further explain this specification:

The choice is at the discretion of the authorised officer, having regard to the policy of the competent authority. Where the quantity or continuity of sampling gives rise to significant financial consequences for the owner of the food, the competent authority could offer an *exgratia* payment if samples are not purchased. The officer must give the owner a receipt for, or a record of, all samples the officer has taken. If enforcement action is anticipated following microbiological examination or chemical analysis, the sampling officer must purchase the sample³⁸⁷.

Therefore, contrary to what the legislation states in Germany, in the United Kingdom there is no legal issue at stake regarding the payment of the food bought online through mystery shopping.

Officers should carry appropriate identification³⁸⁸ if the sample is taken at the food business operator's premises, and shall produce that identification "if so required"³⁸⁹ by the person allowing them to enter those premises. This provision is interpreted in the

Obtails on how to interpret that presumption are further specified in the General Food Law Regulations of 2004, such as England's Food Safety and Hygiene Regulation (2013), that states the following: (2) Any food commonly used for human consumption shall, if placed on the market or offered, exposed or kept for placing on the market, be presumed, until the contrary is proved, to have been placed on the market or, as the case may be, to have been or to be intended for placing on the market for human consumption. (3) The following, namely: (a) any food commonly used for human consumption which is found on premises used for the preparation, storage, or placing on the market of that food; and (b) any article or substance commonly used in the manufacture of food for human consumption which is found on premises used for the preparation, storage or placing on the market of that food, shall be presumed, until the contrary is proved, to be intended for placing on the market, or for manufacturing food for placing on the market, for human consumption. (4) Any article or substance capable of being used in the composition or preparation of any food commonly used for human consumption which is found on premises on which that food is prepared shall, until the contrary is proved, be presumed to be intended for such use.

³⁸⁷ Food Standards Agency. (2017b). *Food Law. Practice Guidance (England)*, p. 11. Retrieved from https://www.food.gov.uk/sites/default/files/foodlawpracticeguidance2017.pdf

³⁸⁸ As stated in the FSA's Guidance on the Food Safety Act (page 18), "they must carry evidence of their identity" when performing their duties.

³⁸⁹ Article 32 (1) of the Food Safety Act states the following (very similar wording in the Food Safety Order for Northern Ireland reflect the same requirement): Powers of entry: (1)An authorised officer of an enforcement authority shall, on producing, if so required, some duly authenticated document showing his authority, have a right at all reasonable hours: (a)to enter any premises within the authority's area for the purpose of ascertaining whether there is or has been on the premises any contravention of the provisions of this Act, or of regulations or orders made under it; and (b)to enter any business premises, whether within or outside the authority's area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention within that area of any of such provisions; and (c)in the case of an authorised officer of a food authority, to enter any premises for the purpose of the performance by the authority of their functions under this Act; but admission to any premises used only as a private dwelling-house shall not be demanded as of right unless 24 hours' notice of the intended entry has been given to the occupier.

sense that, if competent authorities would like to control e-foods at the distribution stage, they could do so by purchasing the product anonymously.

When procuring a sample for enforcement purposes, the public official must take a specimen that can be divided into three sample parts, which must be placed in a container that is afterwards sealed and labelled. The official must "as soon as reasonably practicable give one part to the owner and give the owner notice that the sample will be analysed³⁹⁰", submitting then one of the parts for analysis and retaining the last portion sample in case supplementary expert opinion is required.

FSA's Manual for Official Controls, updated in January 2018, provides some clarification on this provision, and states that when taking a sample "for physical confirmation of the failure" to comply with legal requirements,

The authority official should inform the food business operator of their intentions. Enlist the services of a colleague to witness the collection of the sample (if available) and also to record details of what, when, where and how; recording the date and time in their pocket notebook. The samples should be bagged and labelled with all relevant details and sealed with a tamper evident seal³⁹¹.

There is no apparent challenge for sampling e-foods obtained from mystery shopping.

In the United Kingdom, the legal framework does not pose challenges to controlling food products that are offered online at the distribution stage. Mystery shopping is accepted as long as the food business operator is informed "as soon as reasonably practicable" after sampling has taken place.

³⁹⁰ Article 7.3.c) of the Secretary of State for Health. (2013). FOOD, ENGLAND. *The Food Safety* (Sampling and Qualifications) (England) Regulations 2013. Retrieved from http://www.legislation.gov.uk/uksi/2013/264/pdfs/uksi_20130264_en.pdf

³⁹¹ Food Standards Agency. (2016b). Chapter 7 Enforcement in Manual for Official Controls, p. 17. Retrieved from https://www.food.gov.uk/sites/default/files/chapter-7.pdf

2. APPROACH TO OFFICIAL CONTROLS OF E-FOODS IN THE UNITED KINGDOM

The responsibility for the organization and performance of official controls falls within different administrations depending on the nation in the United Kingdom, as well as on the type of food product that needs to be controlled. However, in general controls are usually performed by local authorities. The FSA supervises and provides advice to local authorities in Northern Ireland, Wales and England while since 2015 it is the FSS who does so in Scotland.

In that context, the FSA³⁹² has sought the best way to improve control over the digital market of foods, which is based on providing systematized advice and training to public officials who perform control tasks while producing guidance documents to improve how food businesses understand their obligations when it comes to selling food online. Also, actions have been taken to educate the public on the precautions they need to take when buying e-foods.

2.1. The Food Standards Agency's strategy to improve the safety of the digital market of foods

The Food Standards Agency considers that food e-commerce is "a high risk to food safety" and has designed a "strategy to tackle the issues, along with consumer facing communications, advice to online businesses and development of greater intelligence sharing". Although the FSA has not published any policy paper defining its strategy on food e-commerce, the Authority has enabled a specific page in their official website called "Food Sold Online", where one may find information for consumers, businesses and authorities on the subject. In particular, the information currently available consists of four guidance documents that have been updated regularly since 2015:

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³⁹² On the other hand, and in part due to the fact that the FSS has only recently started operating, there are apparently no activities coming from that authority in the field of food e-commerce control. There is currently no published guidance or reports on the subject, and no information has been obtained during this research on the activities carried out by the FSS or other departments in the Scottish administration on this matter. But, as the FSA still plays a significant role when it comes to food law in the UK as a whole, for instance as sole representative before EU institutions, this apparent lack of activity could also be understood as the fact that the FSS supports all FSA's initiatives in this area, and considers them applicable in Scotland.

³⁹³ Food Standards Agency. (2016f). *Food sold online*, p. 7. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

- Advice to businesses selling food online
- Advice for buying food online
- Selling and buying food online questions and answers
- Food sold online, guidance to local authorities³⁹⁴.

The FSA considers that informing businesses and consumers, as well as training public officials, is necessary to improve the function and safety of the market of e-foods and has planned several actions accordingly.

2.1.1. Consumer awareness

When it comes to consumers, the advice provided by the Authority focuses on "giving practical advice about how to purchase food online safely." The goal is to improve the citizens' skills when it comes to making decisions on what products to buy online. To that end, the three page document provides tips such as to check that the address of the operator is indicated, to avoid buying from websites from outside the EU or with many spelling mistakes (as it may be proof that it is not professionally run), and to check if the feedback from previous consumers is good.

The guidance also compels consumers to look for the "Food Hygiene Rating" of the business:

Food businesses selling food online may also be rated by the local authority as part of the Food Hygiene Rating Scheme. You can check if they are rated and the score at the Food Standards Agency site (some businesses are exempt from rating)³⁹⁶.

The Food Hygiene Rating is a rating scheme put into place by the FSA in partnership with local authorities, which goal is to give consumers information about a food business' performance (both retail stores and restaurants) when it comes to food hygiene and based on the results of official controls³⁹⁷:

³⁹⁶ Food Standards Agency. (2016a). *Advice for buying food online*, p. 1. Retrieved from https://www.food.gov.uk/sites/default/files/advice-for-buying-food-online_0.pdf

Food Standards Agency. (2016f). *Food sold online*, p. 7. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

³⁹⁵ There is a similar rating in Scotland, the "Food Hygiene information scheme."

³⁹⁷ More detailed information on the scheme is available at the FSA's website.

The (...) result given to a business reflects the standards of food hygiene found on the date of inspection or visit by the local authority. The food hygiene rating is not a guide to food quality.

The rating system has proven easy to understand for consumers, as it only consists of an image with the grading, where a result from 0 to 5 (zero being the poorest score and 5 the highest) is marked in bold black and there is an indication of the meaning of the number just under it, as shows the image bellow³⁹⁸:



Image 2

Nevertheless, it must be noted that when it comes to e-commerce, operators are not obliged to include this rating label on their website. It is the consumers' role to surf to the FSA's website and use the search engine, putting the name and address of the business in, and the score will then appear.

It is interesting that the authorities in the United Kingdom have decided to build their own trust mark instead of partnering with existing seals as it is done in Germany. Given the level of infancy of the Food Hygiene Rating, it is not possible for now to evaluate its success and weaknesses.

2.1.2. Improving the safety and quality of the offers y training business

When it comes to businesses, the FSA has produced the *Distance selling guidance for food businesses*, which focuses on informing businesses on what their obligations are in this field, not only based on food law requirements but with consumer legislation at large such as the information that must appear on the website before the purchase is complete, consumer's rights to cancel the contract and on the "sums paid on cancellation restoration of goods by the consumer after cancellation".

Also, the guidance document insists on the fact that food establishments must be registered:

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³⁹⁸ The Food Hygiene information scheme of Scotland has a different mark.

If you are selling food online it is a legal requirement to register your business with your local authority 28 days before you intend to trade. If you are already trading and have not registered you need to do so as soon as possible. Registering your business is free of charge.

The registration form requires basic details of your food business activities and the address(es) where you carry out food operations. This would also include your office, even though you may not physically handle any food products. This should include all multi-site businesses where activities are carried out³⁹⁹.

2.1.3. Training public officials

Finally, the FSA has produced a very detailed guideline on how to perform official control tasks in the digital market of foods while ensuring compliance with Regulation 882/2004 and national laws. This document is analysed in the next section of this Chapter.

Also, the FSA has established partnerships among different institutions to provide public officials with additional training. For instance, public officials can get access to a course of the National Trading Standards e-Crime Unit which provides basic information on "how the internet works, the make-up of web pages, what domains name are, how to capture web pages and other digital assets for evidential purposes"⁴⁰⁰. Enforcement officials from the United Kingdom also participate in BTSF initiates on the subject.

2.2. The guidance for official controls

Food sold online: Guidance for Local Authorities⁴⁰¹ was first published in early 2016 and has been since updated in September and December 2016. It has been written by public officials who usually participate in official control tasks and was subject to an open consultation through the FSA's document in late 2015.

Even if the document acknowledges that "it is a difficult task for an individual officer or local authority to tackle widespread non-compliance", it nevertheless seeks

to assist local authorities with assessing and monitoring compliance with food law of businesses operating online. It provides specific inspection and identification

Food Standards Agency. (2016f). *Food sold online*, p. 1. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

⁴⁰⁰ *Ibid.* p. 18.

⁴⁰¹ *Ibid*.

techniques, sampling guidance and a basic understanding of the capture of digital evidence⁴⁰².

By involving more and more officials and competent authorities in the responsibility of making e-foods safer, food businesses will have greater incentives to comply with food law requirements and therefore to better protect consumer. The goal of this guidance (analyzed in the next section of this Chapter) is to foster their abilities to navigate both the Internet and the law in order to include e-foods in the official controls system.

The United Kingdom's strategy focuses on providing competent authorities and staff performing official controls with an effective system to watch over the digital market of e-foods, and to define procedures that allow for enforcement action with full respect to all regulations.

These guidelines were considered urgent after the Trading Standards North West area conducted in 2015 a survey on compliance with nutrition and health claims regulation online that concluded that non-compliance was widespread: "of 213 online health claims reviewed, 162 did not comply – a failure rate of 76%"⁴⁰³. From seven samples that were purchased, none of them was found compliant with food law requirements at large and it even was established that one of them had been subject to adulteration.

This initial survey was followed by a series of smaller initiatives dealing with other food products:

- Purchasing feed samples over the internet all seven samples purchased failed due to non-compliant labelling and one was found to be adulterated.
- Purchasing sweets online from UK specialists in American sweets all seven purchased samples failed due to inadequate labelling.
- Purchasing meat and meat products online such as sausages and pies and then collecting from shops – of the seven samples purchased all but one was unsatisfactory due to meat content deficiency, presence of other species, labelling inadequate. The survey also identified two new producers of meat products that were unknown.

⁴⁰² Food Standards Agency. (2016f). *Food sold online*, p. 5. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

⁴⁰³ *Ibid.* p. 6.

⁴⁰⁴ Food Standards Agency. (2016f). *Food sold online*, p. 7. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

The conclusion of all of those actions was there was a failure rate 90% across all surveys, therefore, the "FSA and the European Union (EU) have identified e-commerce as a high risk to food safety" ⁴⁰⁵

But, as was also concluded by the German team, the results of the above-mentioned survey has lead the FSA to believe that most non-compliance are due to both lack of knowledge of the legal requirements and a sense of impunity among digital operators:

Once significant and sustained follow-up work had taken place, a further review found compliance rate to be 72%, a massive swing of 48% which demonstrates that intervention (mostly through advice) can be effective even if resource intensive. 406

The United Kingdom does not create a specific body or department to deals with e-foods.

2.2.1. Mapping the market of e-foods through food business identification

As it is the case in Germany, not only do competent authorities lack systematized information on the websites and web-based platforms through which food businesses sell their food online, but there is also a generalised problem of omission of registration or approval of the establishments intervening in food e-commerce.

Therefore, the first recommendation of the FSA to competent authorities is to take action to identify "online business operating within their local authority area" that is to say those whose establishments are located within their jurisdiction. Thus, the focus is set on ensuring that official controls activities on production can be carried out, instead of focusing on businesses offering their e-foods to consumers in that territory.

In the United Kingdom, staff is instructed to prioritize performing investigations addressed to identify operators whose establishments are located within their jurisdiction, in order to facilitate controls on production.

⁴⁰⁵ *Ibid*.

⁴⁰⁶ *Ibid.* p. 6.

⁴⁰⁷ *Ibid.* p. 7.

The goal of the Authority is to reduce risks by making sure that what can be controlled in ones' territory does not fall off the radar of competent authorities. If (while searching the Internet) a public official tracks down a food business that is in another local authority's territory, FSA's recommendation is to forward the information to the competent authority⁴⁰⁸.

When it comes to the identification of establishments that deal with e-commerce, paragraph 13 of the guidance makes the following proposal:

Local authorities' should ensure information is captured about businesses in the area that have an online sales platform and include this as a key part of their inspection protocol. This could be achieved with a premises / property use code for internet businesses on each local authority's premises management information system. This may be used as a primary usage if business sales are only online or as a subsidiary usage, for example if the business also has a physical retail premises.

What the FSA suggests in this passage is that once a public authority has knowledge that an establishment is used for e-commerce, it makes available this information to other competent authorities that may participate in controlling that establishment. That is to be done by defining a code that would appear in the establishment's fact sheet of the authorities' information system. This research has obtained no information of that code being put into place.

Thus, the FSA makes a specific proposal about how to obtain accurate information about operators and establishments engaging in food e-commerce. Competent authorities should identify those establishments assigning them a specific code number in the management information system.

Additionally, the FSA makes specific recommendations to identify operators by tracking the information available on their web shop or with their offers in marketplaces. In particular, the Authority suggests looking at the "contact us" page or at the terms and conditions on the website, where the legal address of the business is usually found. If the

Food Standards Agency. (2016f). *Food sold online*, p. 23. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

legal name appears, "a Companies House search should be carried out. 409" This search is carried out through a search engine of that generates "company information, for example registered address and date of incorporation, current and resigned officers, document images, mortgage charge data, previous company names, insolvency information" This is a new tool still under development. It provides users with the information that is available at the Companies House, the body responsible for registration of businesses that operate and are located in the UK. The search engines provide the address of the company's main office and identify its owner.

With this information, a public official can use the database of the register of food establishments to check their location and plan controls on production. If no establishments are registered, the public officer may visit the head office or contact the business and request information about the location of its establishments.

On the other hand, if there is no information on the name of the business, a public official may use the investigation techniques identified in Annex B of the guidance document which explains how to use domain name information and the IP address to track down the location of the operator. Given that, normally, it is necessary to include a complete address in order to register for a domain with the UK's body in charge of domains, known as Nominet, relevant information on location could be obtained from there⁴¹¹.

2.2.2. Identifying unsafe products and Enforcing food law to improve consumer protection

The guidance also provides information on how to monitor compliance of e-foods while in compliance with the Compliance Regulation and ensuring the operator's right of defence.

⁴¹⁰ Government United Kingdom. (2018). *Get information about a company*. Retrieved from https://www.gov.uk/get-information-about-a-company

Food Standards Agency. (2016f). *Food sold online*, p. 9. Retrieved from https://www.food.gov.uk/business-industry/guidancenotes/food-sold-online

⁴¹¹ However, as acknowledged by the Authority, these techniques have significant limitations, as in some cases a domain is registered by an individuals, who are under no obligation to include an address. Also, in other cases the information provided is false. Finally, this technique is only appropriate when tracking down the identity of a business that uses its own website to sell e-foods: if the offer is placed in a platform, there is no domain or IP information to follow.

While G@zielt's controls constituted preliminary activity not suited for enforcement, in the United Kingdom, the control authority doing the monitoring has the power to enforce food law. Therefore, the principles and operational criteria of the Compliance Regulation must be guaranteed.

In particular,

- Searches and checks must target e-foods using a risk-based approach.
- Monitoring, inspection and sampling must occur without prior warning to the food business operator.
- All control activities must be documented.
- Sampling must result in procurement of a "fair sample" appropriate for guaranteeing the operator's right to supplementary expert opinion as well as potential exercise of appealing rights.

This section, while describing the recommendations of the guidance, will identify how these requirements are satisfied.

2.2.2.1. Undertaking searches

The guidance does not provide any indication on what triggers a specific business or offer control. It is at the competent authority's discretion, but it is essential that a risk-based approach is taken in accordance with Regulation 882/2004⁴¹².

The FSA does not provide any automated software to speed up searches. The staff performing controls must manually surf the Internet to obtain relevant information. For that reason the guidance includes some "going online top tips" that seek to guarantee that

⁴¹² Competent authorities must keep in mind that, as analysed in Chapter 2 of this thesis, risk analysis does not only take into consideration inherent product risk to human and animal health or risk of fraud, but other variables such as the history of the operator or the existing notifications of similar products, as well as consumer or competition complaints must be taken into account when deciding which foods to target.

food business operators do not notice surveillance, thus improving the chances of effective controls⁴¹³.

Officials must clear cookies and avoid repeated visits to the same website in order to prevent the operator from detecting that monitoring is taking place. Moreover, although the general recommendation is to "use the advanced search on any search engine," Annex A of the guidance does provide the example of how to undertake a search with metasearchers and how to use tools to find website content that has been removed but that could be used for enforcement purposes. Also, the guidance gives specific tips to search in Amazon and eBay to try to find in the sellers' information any clue on where its premises may be located.

• Storing information from searches

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This issue, which affects investigations carried out by criminal and administrative law enforcement agencies, is indeed relevant but should be dealt with at the national level. It is not an issue that can be solved from a food law perspective.

⁴¹³ Additionally, the guidance indicates that in some cases surveillance may be subject to prior authorisation under the Regulation of Investigatory Powers Act (hereinafter, "RIPA"). This piece of legislation defines the requirements that must be respected by public agencies carrying out investigations that include the interception of communications, the acquisition and disclosure of data relating to communications, the carrying out of surveillance, the use of covert human intelligence sources and the acquisition of the means by which electronic data protected by encryption or passwords may be decrypted or accessed. The goal of RIPA is to ensure respect with human rights (in particular, the right to privacy) of those who are being investigated by public authorities, when methods such as surveillance or interception of communications are used. The law mandates that, when those activities are used as methods of investigation, an authorisation must be obtained from the relevant authority. It is a Regulation that is commonly used when investigations are carried out by security and intelligence agencies, but its scope is not limited to criminal investigations. Therefore, the FSA understands that it is still applicable to official controls in a very particular situation: when public officials investigate operators in a social network that requires the creation of a full profile in order to access the network. The FSA's guidance for local authorities on food sold online interprets that, when surveillance is conducted on general information publicly available online (with no ID, profile, password or code to access), it remains outside the scope of RIPA and therefore is not subject to authorisation. On the contrary, if the creation of a user that does not identify the authority is necessary to access the information in the social network, then RIPA does apply. The guidance's interpretation is based on the definition of "interception of communication" provided by article 2 of RIPA: a person intercepts a communication in the course of its transmission by means of a telecommunication system if, and only if, he: (...) (b) so monitors transmissions made by means of the system (...) as to make some or all of the contents of the communication available, while being transmitted, to a person other than the sender or intended recipient of the communication. In application of that definition, when an operator posts an offer in a social network there is a transmission of information whose intended recipients are the users of the platform but not the covert authority. Researches in the UK agree with FSA's interpretation and consider that surveillance by an enforcement authority through a social media network that requires a password to access the network (such as Facebook) is in fact an "interception of communication" and should therefore be authorised and executed in accordance with the requirements of that Act. The relevant fact that determines the application of RIPA is therefore the interception of communications that are not public, not the fact that the competent authority needs build a covert identity to monitor.

Storing information and results obtained from the searches is necessary in order to ensure that controls are documented, and therefore that the complete file of the investigation can be reviewed by both the competent authority and the food business operator if an administrative procedure is initiated. The records from the investigations also allow for further review by the public administration or the judge in the case that right of appeal is exercised.

FSA provides detailed information on how to store the information found online for official control purposes. Annex D of the guidance includes some tips that are extracted from the Forensic Science Regulator's Code of Practice and Conduct⁴¹⁴. As it occurs with the use of search engines, FSA does not command to use specific software to store evidence. Instead, it indicates that,

programmes such as *Hypercam*, *BB flashback* and *Snag It*, that enable you to record what you see on a computer screen, for example as you place an order for a food sample from an online retailer or look at the claims made on the website.

Software such as the ones recommended have the particularity that the data they store from a webpage includes the information on the links that appear in the page, which can be useful when the offer forwards consumers to another webpage to get part of the information on the product. Additionally, the guidance recommends using web reaper software to "capture content of websites so you may be able to see what it looked like in the past" ⁴¹⁵.

The guidance insists on the need to choose software that does not allow for editing of the data that it stores, in order to protect the integrity of information that could be considered evidence in the framework of official controls. The information in Annex D consists of recommendations for public officials. It does not establish a detailed protocol on how to record and store data or how to document the monitoring, which may have been useful to competent authorities in order to carry out investigations and ensuing documentation in a standardized manner.

⁴¹⁴ The current version of the Code of Practice and Conduct that includes detailed information on the subject is retrieved from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499850/2016_2_11_-
_The_Codes_of_Practice_and_Conduct_-_Issue_3.pdf

⁴¹⁵ Food Standards Agency. (2016g). *Food Sold Online. Guidance for local authorities*, p. 29. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf

Challenge no 8 identified in this thesis (recording control activities to safeguard the operator's right of defence) is tackled by the United Kingdom.

2.2.2.2. Product Analysis

Once monitoring has resulted in identification of an e-food that appears to be noncompliant with food law, the Guidance recommends conducting an inspection in two phases:

- a review of the website to gain an understanding of the nature of the business and any compliance issues, particularly for standards officers. Consider taking samples at this point.
- a physical visit to the address of the online food business. This may be a private dwelling, storage unit, warehouse or retail outlet 416.

Staff performing controls should review the information online "to gain an understanding" of the type of product and food business they are dealing with in order to forecast what issues could arise if they decide to perform material controls of the e-food.

The information that appears on the Internet is a tool to help competent authorities assess non-compliance. For instance, inaccurate information and the advertising of products with unauthorised substances may suggest possible risks to human health, as well as other non-compliance issues. Additionally, the information may also be used to locate unregistered establishments. However, if the monitoring precedes a test purchase, is to it is necessary to "digitally record the online purchasing process should it be required as evidence" ²⁴¹⁷.

Controlling distribution

The FSA recommends competent authorities to expand their initial scope for online investigation (food businesses operating within their territory) and target "high-risk

⁴¹⁶ Food Standards Agency. (2016g). *Food Sold Online. Guidance for local authorities*, p. 9. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf

⁴¹⁷ *Ibid*, p. 12.

products that consumers in their area can purchase over the internet" using "an intelligence led and risk based approach" ⁴¹⁸.

In order to mystery shop, the competent authority shall create "test purchase persona", with a given Google appropriate e-mail address, credit card and delivery address that hides the fact that the purchase is made by a competent authority. The Sampling and Qualification Regulations do not mandate that the food business operator witnesses the procurement of the sample. Instead, once the e-foods has been received,

The authority official should inform the food business operator of their intentions. Enlist the services of a colleague to witness the collection of the sample (if available) and also to record details of what, when, where and how; recording the date and time in their pocket notebook. The samples should be bagged and labelled with all relevant details and sealed with a tamper evident seal⁴¹⁹

On the other hand, FSA's recommendation when it comes to ensuring that the authority does not give away its identity on the delivery phase of the test purchase is most interesting:

Using a council address for delivery, for example, County Hall, may alert the business that it is a test purchase by an enforcement officer. Consider if there are local authority's premises in your location where the address does not stand out as council property or ask the local housing department if you can use the address of a vacant house⁴²⁰.

(...) Once an address has been used for some time then it may need to be changed to avoid alerting sellers that a purchase is being made by an officer.

The FSA deals with how to place test purchases without giving away the identity of the authority, in order to ensure no prior warning.

When it comes to procuring the sample, the guidance states that the purchase process must be recorded and stored as evidence. In particular, it recommends to "record the

⁴¹⁸ Food Standards Agency. (2016g). *Food Sold Online. Guidance for local authorities*, p. 11. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf

⁴¹⁹ Food Standards Agency. (2016b). *Chapter 7 Enforcement* in *Manual for Official Controls*, p. 17. Retrieved from https://www.food.gov.uk/sites/default/files/chapter-7.pdf

⁴²⁰ Food Standards Agency. (2016g). *Food Sold Online. Guidance for local authorities*, p. 11. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf

division process in officer's notebooks"⁴²¹. It also recommends keeping "packaging, as postmarks may help identify sellers if identity is disputed later"⁴²².

The Authority reminds local authorities that because there are currently no special rules for sampling food that is sold online, it must be done following the same principles as when sampling foods sold in the traditional market:

- Where it is being sent for analysis, sufficient product is obtained and where
 reasonably practicable, the sample is divided into three parts, in order that a
 supplementary second expert opinion can be sought by the owner and another
 retained as a referee sample.
- The Food Business Operator is notified that a sample has been taken after it is received.
- Evidential rules are followed.

On the issue of obtaining "sufficient product" for sampling, competent authorities must keep in mind that any existing rules on how to procure the sample (including amount, conditions and methods) apply to the sampling of e-foods. Therefore, when placing the order it is necessary to order enough items to ensure appropriateness of the sampling.

From the above it is sensible to conclude that, as opposed to what happens in Germany that the legislation in the United Kingdom's nations do not pose specific legal challenges to e-food controls on the distribution stage.

Controlling distribution is legally feasible if the process is witnessed by a second official, the operator is informed of the sampling taking place "as soon as legally feasible" and the sample is procured in accordance with general rules for fair sampling.

⁴²¹ Food Standards Agency. (2016g). *Food Sold Online. Guidance for local authorities*, p. 12. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf

⁴²² *Ibid.* p. 13.

2.2.2.3. Enforcing food law

Once checks evidence non-compliance with food law, competent authorities must "consider which action is reasonable, proportionate, risk-based and consistent with good practice, in accordance with Chapter 6 of the Food Law Code of Practice and the LA's own enforcement policy". That is to say, that general rules on how to deal with infringements of food law apply. It is the competent authority's responsibility to decide if educating food business operators, detaining and seizing food, or initiating a sanctioning procedure are the best options to address non-compliance.

When controls are carried out according to the guidance, the results can be used for enforcement. According to the FSA, competent authorities must use the administrative procedure to enforce the law as they would do regarding a food product placed in the brick-and-mortar market.

However, the guidance – which was published before the approval of the new official controls Regulation⁴²³ - acknowledges that there is no legal base in food law that gives power to competent authorities to close the website of those food business that are not compliant with food law requirements. Chapter 4 of this research it will be analysed how the new official controls regulation may change this scenario from 2019 onwards.

Therefore, if the operator does not respond to the administrative procedure, the Authority recommends contacting other actors such as webhosts or marketplaces, and other branches of government such as the National Food Crime Unit or the authority in charge of compliance with the provision of the electronic communications and services

⁴²³ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation).

Directive⁴²⁴, that can take action to delete or hide non-compliant offers in specific situations. For instance, when it comes to webhosts, which operate under "webhosting agreements [that] contain clauses that require the site to confirm it complies with the law", the FSA recommends contacting them and providing evidence that the site is in breach of the law and therefore in breach of contractual terms with the webhost who may agree to remove the site from the internet"⁴²⁵.

The guidance provides local authorities with the contact e-mail of *eBay* and *Amazon*'s enforcement department that deals with public authorities' requests and comments on apparently non-compliant offers posted on their sites. As opposed to the situation in Germany, from the guidance it may be inferred that there is no close collaboration or contact with those platforms on a regular or institutionalised manner, as its advice is formulated in the following terms:

You can contact the webhost or sales platform and outline the criminal offences and that they may be liable for if they continue to host the site / seller via applicable act or default provisions of the legislation, which is being breached.

Furthermore, in reference to the liability exemption for hosts set in the EU law, the guidance goes on:

The protection provided to webhosts by of European e-Commerce Directive 2000/31/EC Article 14 would not be effective once they have actual knowledge of the illegal activity and fail to act expeditiously to remove or to disable access to the information⁴²⁶.

Competent authorities can use notice-and-take down procedures to remove or block non-compliant offers of e-foods. If the intermediary that was contacted does not process the authority's request, the liability exemption should be considered lifted.

⁴²⁴ Directive (EC) 2002/21 of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive). Retrieved from http://eurlex.europa.eu/legal-content/EN/TXT/?qid=1520010491234&uri=CELEX:02002L0021-20091219

⁴²⁶ Food Standards Agency. (2016g). *Food Sold Online. Guidance for local authorities*, p. 16. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf

3. RECAPITULATION

The Food Standard Authority has defined a strategy for official controls on e-foods, which focuses on training competent authorities on how to carry out control tasks that would be suitable for enforcement. No specific unit that deals with monitoring of the e-foods market is created.

The guidance identifies how to solve issues such as which equipment to use to conduct a search or how to store evidence. Software recommendations focus on privately-owned commercial software, leaving out any consideration regarding the design of an *ad hoc*, publicly-owned software to conduct searches or store evidence. Control activities should be recorded, from formal web monitoring to packaging of the sample.

It also faces the issue of how to obtain and manage information that is useful to map the digital market in order to define control plans on e-foods. It makes the proposal to consider options such as establishing "a premises / property use code for internet businesses on each local authority's premises management information system" in order to increase controls on production and to be able to define control plans focussing on e-commerce.

Additionally, the FSA provides useful information on how to assess if a business has a certain degree of continuity and organisation: an undertaking has continuity when offers are placed at list once a month, but continuity itself does not make that undertaking relevant to food hygiene rules. In order to fall within the scope of hygiene rules, it must also have a degree of organization, a concept not clearly defined in the guidance document. However, the guidance does not refer to peer-to-peer trade.

Controls should be done on "high-risk products that consumers in their area can purchase over the internet" using "an intelligence led and risk based approach". There is no mention to RASFF notifications or consumers complaints. It does insist on the fact that focussing on offers that depend on an establishment based within the competent authority's territory, the impact of control tasks will increase.

In the United Kingdom, it is possible to enforce food law based on controlling distribution because there are no legal obstacles to sampling using mystery shopping techniques.

Once non-compliance has been established, competent authorities must enforce the law. The FSA guidance indicates that authorities must focus on using the measures provided in national law for food law enforcement. Additionally, a NTD can be submitted to the digital platform.

PART 3.

COMPARATIVE EVALUATION

Part 1 and 2 of this Chapter have described the legal framework and the strategies developed by Germany and the United Kingdom include e-foods in official controls. This last part compares both cases, as to the legal framework they operate in and as to how their approach faces the challenges identified in this thesis. This comparison includes also reference to the similarities and differences in Spain. Section – includes a Table that summarises how Spain, Germany and the United Kingdom deal with those challenges.

1. MARKET FINDINGS

To date, Spanish authorities have not carried out research actions to analyse non-compliance in the Spanish digital market of food products. In order to design an effective strategy for e-food control, Germany and the United Kingdom have carried out this task. While in different countries and with some years of difference, the results are interestingly similar.

First of all, data evidences that a significant part of internet-based food business operators engaging in food e-commerce do not register before proper authorities. This reality is overwhelming when dealing with internet-based operators, as the German administration identified that 40% of them have not fulfilled their registration obligation (a rate that drops to less than 15% when looking at store-based operators). This entails that they remain outside the radar of competent authorities for the performance of official controls. Given that e-commerce is a transnational phenomenon, there is no reason to believe that the situation is any different in other Member States.

A relevant proportion of internet-based operators in the European Union may be acting outside the radar of competent authorities, given that their establishments have not been properly registered.

Fostering registration of the establishments used by internet-based operators is urgent, because official control plans are significantly based on the data obtained from the

registry of food establishments. Also, it is not possible to perform official controls on production if establishments are unknown to competent authorities.

Thus, competent authorities must be proactive and search for relevant information that is useful to map the digital market of foods, and undertake actions to increase the current registration rate.

Moreover, test purchases and market analysis conducted by either the authorities or third parties showed how the non-compliance rate of certain food products is higher in the digital market than it would be in the brick-and-mortar market. In order to bring the digital market to an acceptable level of compliance, it is necessary to define control plans that focus on food establishments and food business operators that are active online.

Competent authorities must define control plans that focus on ecommerce, so that the characteristics of both the products and the operators are properly taken into account.

Data collected by G@zielt suggests that when searching for offers using the same search engines and keywords that an average consumer would, the results that appear are mostly offers placed by operators located within the Member State. Only about 15% of the remaining offers are placed from third countries and about 25% from another Member State. Thus, although there is a pressing concern to build proper cooperation between different countries, if competent authorities make sure that operators at home comply with food law requirements the overall compliance rate of the offers that are visible to the consumer would be dramatically improved.

Even if the digital market of foods is a transnational phenomenon, if competent authorities control establishments and operators within their jurisdiction, more than half of the offers visible to their consumers would be controlled. If all Member States do their part, only about 15% of those offers will be left uncontrolled in Europe.

Furthermore, both administrations report that a significant proportion of food business operators cooperate with competent authorities. Offers are voluntary corrected when possible and eliminated when necessary. Also, instruction from competent authorities result in registration of food establishments. So, even if non-compliance is that much higher in the digital market of foods, systematic constructive monitoring from competent authorities have a great impact. It appears that higher non-compliance in the digital market is not generally based on intentional infringements of the law, but on the fact that small scale internet-based operators have a lower level of awareness about their legal obligations than traditional operators.

Competent authorities should educate food business operators on their legal obligations and attempt to fix non-compliance by providing information and advice. Direct contact with operators has the potential to improve compliance.

Given that Member States are having problems applying official control's procedures to e-foods, the fact that education and cooperation are having an impact in the market is hopeful.

Those Member States whose national legislation prevents from undertaking official controls can still have a significant impact in e-food compliance by contacting and educating active food business operators individually.

Finally, Germany's monitoring activity includes offers of homemade food products placed by private individuals occasionally. Peer-to-peer offers placed in digital platforms frequently look the same than B2C offers. Therefore, consumers might not be able to tell the difference and expect the same level of compliance. G@zielt does not carry out an analysis over the continuity and degree of organization that non-professional offers from the same person entail. Instead, it assesses the risks that an offer could entail and takes action accordingly.

The FSA interprets that those undertakings that take place at least on a monthly basis and show a degree of organization are subject to EU Hygiene Regulations and thus the

establishments it uses should be registered. However, the United Kingdom has no position regarding control of digital C2C commerce of food products.

Based on the approach of both Member States, it is my view that there are two relevant issues that need to be addressed when it comes to dealing with peer-to-peer offers:

- Given that C2C falls outside the scope of Hygiene Regulations and thus is not subject to registration, how can competent authorities plan controls that can effectively control the safety of the foods that are placed in the market?
- When should competent authorities consider that an undertaking has reached "a degree of organization" that makes it relevant to Hygiene rules?

2. LEGAL FRAMEWORK

Regulation 882/2004 defines a harmonised framework for official controls in the European Union. This piece of legislation establishes rules on the organization and performance of control activities, which aim at ensuring that the official control system is effective and impartial.

The Compliance Regulation, which is governing controls until almost 2020, requires Member States to adopt multi-annual control plans that provide competent authorities with instructions on how to prioritize control activities. In order to protect the effectiveness of controls, it mandates that they should be carried out without prior warning to the food business operator.

Additionally, the Regulation identifies that food business operators have the right to appeal administrative decisions based on control activities. They must be able to cross-examine the controls carried out by competent authorities, which can be done exercising their right to a supplementary expert opinion. Also, safeguarding the operator's capacity to contest administrative decisions entails that control tasks must be documented, and all evidence of non-compliance must be properly stored.

Member States must adopt their own legislation on the particular arrangements to ensure that the Compliance Regulation rules are respected. Thus, differences arise across Europe when analysing national rules for the organization and performance of official controls.

In some countries such as Spain and Germany, national law has created challenges for competent authorities dealing with official controls of e-foods. In Spain, laws require that the food business operator, its representative or a store clerk witnesses sampling for enforcement. In Germany, the authorities interpret that it is not legal to place anonymous orders of food products based on the same idea that Spain, but also on the fact that German law prevents authorities from paying for samples.

However, in other Member States such as the United Kingdom, legislation has not created similar challenges, and thus controls on distribution are taking place.

Member States' legislation has created legal obstacles to performance of official controls on e-foods. In Spain and Germany, official authorities do not have legal base to carry out mystery shopping. However no issues arise from legislation in the United Kingdom, thus authorities can carry out controls on distribution.

3. OVERCOMING THE TECHNICAL AND LEGAL CHALLENGES IDENTIFIED IN THIS THESIS

This thesis has identified nine challenges that competent authorities face when organizing and performing official controls on the digital market. The list of challenges is in Section 3 of Chapter 2. The following table summarises how Spain, Germany and the United Kingdom deal with those challenges.

	COMPLIANCE REGULATION	SPAIN	GERMANY	UNITED KINGDOM
Challenge 1: Including C2C E- Foods In Control Plans.	Official controls must verify compliance regardless of the nature of the operator or the transaction.	Does not address this issue.	G@zielt includes C2C in monitoring but uses soft tools to remove or block unsafe offers.	Does not address this issue.
Challenge 2: Evaluating If An Undertaking Has Reached A Degree Of Organization And Continuity That Is Relevant To Food Hygiene Law	Does not address this issue.	Does not address this issue.	Does not address this issue.	There is continuity if offers are placed on a monthly basis. In order to fall within the scope of Hygiene Rules, it must also entail "a certain degree of organization," which is evaluated considering the nature of the activity and of the potential risks of the food products.
Challenge 3: Making Sure That All Operators Complete Registration.	Does not address this issue.	Does not address this issue.	Automated Software to identify unregistered operators. Also, manual investigations when a non- compliant offer is posted by an unregistered operator.	Manual investigations to identify operators responsible of food establishments within the competent authority's territory.
Challenge 4: Obtaining Accurate Information About Operators And Establishments That Engage In Food E-Commerce.	Does not address this issue.	Does not address this issue.	Does not address this issue.	Creating a code that identifies food establishments and operators that engage in e-commerce. The code is included in the fact sheet of the establishment in the information management system of the authority.
Challenge 5: Prioritizing controls	Competent authorities must follow a risk-based approach.	Does not address this issue.	Prioritizes controlling certain offers that entail risk to human health and are addressed to the German consumer.	Prioritizes controlling offers that, either come from establishments based within the territory of the competent authority, or which entail "high risk" to human health and are addressed to the German consumer.

Challenge 6: Providing An Interpretation Of The Legal Framework That Allows Competent Authorities To Use Mystery Shopping Techniques	Both controls on production and on distribution must be carried out to comply with EU law. Controls on distribution must be careful to ensure the operator's right to supplementary expert opinion.	Does not perform controls on distribution because interprets that mystery shopping is not legal under Spanish law (the operator must witness sampling). However, I believe sampling is possible if the delivered parcel is opened in presence of the operator, which witnesses sampling.	Does not perform controls on distribution because interprets that mystery shopping is not legal under German law (the operator must witness sampling and the competent authority must not pay for the samples).	Member State laws do not challenge mystery shopping, thus controls on distribution of "high-risk foods" must be carried out. The operator is informed of sampling "as soon as reasonably possible."
Challenge 7: Recording Control Activities to Safeguard the Operator's Right of Defence	Controls must be carried out following a documented procedure.	Does not address this issue.	Specific (not disclosed) software and hardware are used.	The FSA identifies software and hardware that can be used to record controls. Both monitoring and sampling must be documented.
Challenge 8: Placing Test Purchases Without Giving Away Their Identity, In Order To Ensure No Prior Warning	Controls must be carried out without prior warning to the operator.	Does not address this issue.	Specific (not disclosed) payment methods, software, and hardware are used.	The FSA identifies payment methods, software, and hardware that can be used to avoid prior warning.
Challenge 9: Obtaining A Sample Considered "Fair" For Enforcement	Sampling must ensure that the procured sample has the characteristics established in EU law, international standards or the sampling plan.	Does not address this issue.	Does not address this issue.	Must purchase enough food products to procure a fair sample.
Challenge 10: Enforcing food law	Official controls must ensure enforcement of food law. Once non- compliance is established, a variety of measures can be taken.	Does not address this issue.	If the operator doesn't cooperate, a NTD is submitted to the platform hosting the offer.	Competent authorities must enforce the law using the measures provided in national law. Only if the operator doesn't cooperate, a NTD is submitted to the digital platform.

3.1. Tackling the challenges for the organization of official controls (Challenges n°1 to 5)

3.1.1. Dealing with peer-to-peer trade of food products online

The General Food Law mandates that all food products placed in the market must be safe, thus C2C offers must comply with this requirement. However, generally these transactions are exempt from registration obligations because they do not reach a certain degree of organization and continuity. If they are not registered, how can competent authorities plan controls to verify that the food is safe?

In Germany, surveillance activities include offers placed by peers. The central unit focuses on containing food-related risks regardless of who places the food product in the market. Staff examines popular digital platforms, and seeks to identify popular offers that are manifestly unsafe. They analyse product descriptions, pictures, and the comments posted by unsatisfied consumers. The FSA guidance does not deal with this issue. However, it indicates that "high risk" offers should be closely monitored, which may be interpreted as that the nature of the operator or the transaction is not relevant.

Control activity should not exclude peer-to-peer trade. Because the operators responsible of C2C offers are not registered, the organization of official controls should include surveillance of offers in popular digital platforms.

Consideration should also be given to the question of how to evaluate that an undertaking has reached a degree of organization and continuity that makes it relevant to follow hygiene rules. Relevance to food hygiene rules entails that the establishments used to carry out that undertaking must be register before proper authorities.

Germany does not discuss this issue. None of the numerous publications of the central unit's team members analyses their status. However, the FSA's view on how to asses this issue when dealing with charity and community food provision sheds some light on how to assess organization and continuity. First, the FSA considers that those undertakings that show certain degree of continuity are those that have activity at least on a monthly basis, but that continuity alone does not turn an amateur undertaking into a food business. In order to be considered as such, the activity requires a certain degree of organization.

The degree of organization should be evaluated based on "the overall nature" of the undertaking itself (for example, the human and equipment resources necessary to offer the food) and "the likely risks to consumers health" (which entails that fresh, perishable, processed foods and dishes are considered to be more likely to entail risks to human health). However, the document is confusing as to whether both circumstances (resources needed and sensitive food products) must apply to consider that the undertaking has a degree of organization.

It is necessary to provide further clarification on how to measure the degree of organization that would turn an amateur undertaking into a food business falling within the scope of the Food Hygiene Regulations.

3.1.2. Fixing registration bugs

Effective and impartial official controls can only be ensured if they are carried out taking into account the products offered, the activities of the food chain that take place within the competent authority's territory and the type of operators that place food on its market. Prioritizing controls requires for an accurate understanding of the composition of the food chain and the market in a territory.

In order to facilitate the task of mapping the market, the Compliance Regulation mandates that competent authorities design a procedure for the registration or approval⁴²⁷ of food establishments, and that the resulting list of establishments is used for the organization and implementation of official controls.

Registration data has become and effective tool used by competent authorities when deciding how to prioritize controls using a risk-based approach. Together with the location of the establishment and detailed information on the identity of the food business responsible for those premises, the registration entry provides some information on the type of activities and products carried out there. Competent authorities can filter information based on criteria such as a food category (i.e. fish products) or a specific stage

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 $^{^{427}}$ Unless stated otherwise when referring to registration in this Chapter approval of establishments is also included.

of the food chain (i.e. packing) and they will obtain a list of the establishments (and therefore operators) that are relevant to that category.

Ensuring that all establishments are registered and that the information they provide is accurate and up to date is essential to official controls. Nevertheless, both bugs in the registration and lack of updating of the registration system itself are currently limiting the role that registration plays when it comes to mapping the digital market of foods.

Aiming at reducing the rate of non-registered operators, competent authorities in Germany and in the United Kingdom have designed public initiatives to educate food business on their obligations when it comes to food law. G@zielt, the FSA and the FSS have published guidelines for operators (which are available free of charge on their website) and carry out training activities that stress the fact that registration is their duty.

They also acknowledge that increasing the registration rate is urgent and therefore public authorities should have an active role identifying food business operators and the establishments they are responsible for. German and UK authorities try to foster registration by searching for operators that are actively trading food online, contacting them and compelling registration of their establishments.

Information that is publicly available to any surfer can be used in order to get information on the identity of food businesses. When dealing with a tailor-made website, staff performing controls should check the information in the contact page. When dealing with a platform, there should be a space dedicated to identify the user which normally includes a user name and a contact form.

Member States should use publicly available data to identify operators that have not registered their establishments and compel registration.

When these sources do not provide accurate information, the FSA provides a checklist of organisations to contact to obtain complementary information, which is useful to track legitimate operators which are not purposely hiding their identity. If the full name and address of the business appears, this data is cross-examined with the data in the register of establishments. If no establishments have been registered by that operator, the authority should contact the business and inform about the need to do so. If the information is not complete, the public official may contact the national domain name registrar and try to

identify the business by tracking down the information from the IP address, among other tools.

Competent authorities in the UK always perform manual searches, while the German central unit (that does use this technique from time to time) normally uses an automated system to obtain data about food business operators. Identification of operators is facilitated by the information obtained from *Xpider* searches carried out by the Federal Tax Authority. G@zielt acts as an intermediary and does not access the data.

The options of manual or automated search for information about operator's identity are not mutually exclusive but could complement each other. When Member States design their strategy for ecommerce control, consideration should be given to both techniques.

However, it must be noted that obtaining information from automated searches carried out by software designed for another branch of the administration may entail adoption of specific agreements or legal amendments that ensure that this transmission of information does not infringe data protection regulations.

Also, when deciding to build a system for the transmission of that information between authorities, a central body that centralises and channels information becomes highly recommended to ensure a proper information flow. It is safe to assume that, if any competent authority could contact the tax authority to obtain information from its jurisdiction, it would overload the capacities of that institution and put the system at risk.

Using data from automated software from another branch of the administration may require adoption of agreements that regulate who can access the data and how it may be used.

The FSA's analysis points out at the legal challenges that monitoring a social network may entail. This surveillance may be considered an interception of communication that must be authorised by a different authority according to national law.

Member States willing to monitor offers in social networks should ensure compliance with national legislation on cover surveillance. Moreover, as it happens in Spain, registration forms in Germany and the United Kingdom contain very scarce information about the activities carried out in an establishment. Food and activities' categories are very broad, and in none of the forms analysed had the applicant to indicate if the premises are used for e-commerce. Thus, even when an establishment is properly registered, the information available to competent authorities is not useful when dealing with e-foods. How can authorities design specific control plans focusing on e-foods if this information is not available? To date, the solution has been undertaking time and resource-consuming investigations similar to those previously explained.

Germany has not discussed this issue. The FSA, on the other hand, proposes to define a code for establishments involved in this type of trade. It suggests that a specific code should be defined for establishments that engage in e-commerce, and that this code should appear in the competent authority's information management system. This information could be obtained, among other, after visiting the establishment in the framework of regular control tasks. This mechanism would allow competent authorities to filter operators and establishment that have been assigned that code, and plan controls accordingly.

The code proposed by the FSA could be most useful to facilitate mapping the digital market, because it makes the most of inspection activities that are already being carried out, and of the information that officials could get from other sources. Furthermore, the measure does not require modifying current legislation in the United Kingdom, Germany or Spain. Therefore, the proposal of the Food Standards Agency should be considered by competent authorities in other Member States.

The competent authorities' information management system should include a code for those establishments that deal with e-commerce so they can be quickly identified. This system would maximize the use of the information that authorities get from daily controls.

Nevertheless, it is my view that the usefulness of registration data could be significantly increased by also modifying the content of registration forms. Neither Germany nor the United Kingdom has officially considered this, but the applicable legislation in both

Member States and in Spain would allow for that modification without requiring legal amendments.

Registration forms should be modified to request information about e-commerce related activities carried out in or in dependence of the establishment.

3.1.3. Ensuring that the organization of official controls respond to effective and impartial prioritization:

Compliance with Regulation 882/2004 entails that controls must be effective and impartial. To that end, the organization of official controls must ensure that controls are prioritized based on risk assessment.

Both the UK and Germany focus on monitoring offers based on risk assessment. While the United Kingdom does not provide details on which offers to consider of higher risk, G@zielt's analysis points out at specific offers: food supplements and novel foods with unauthorised ingredients, fresh and highly perishable foods offered by internet-based retailers, foods that have appeared in a notification from a rapid alert system and last but not least, foods placed on the market by private individuals occasionally.

Monitoring and material controls should prioritize the offers of efoods from the four groups previously identified, because they are considered of higher risk.

However, in the United Kingdom prioritization also entails that controls are carried out on offers that (although not entailing "high risk" to human health), have been placed by operators based within the jurisdiction of the competent authority. That way, if non-compliance is suspected, the competent authority can perform official controls at the registered establishment.

Competent authorities should also prioritize controls on those food products that are responsibility of an operator based within their jurisdiction. That way, enforcement possibilities are more varied and it is more likely that non-compliant offers are eliminated.

Controls should also prioritize those results that are more likely to be accessed by consumers. Competent authorities should search food products introducing key concepts such as the name of a specific food product on the same search engines that consumers would use. The goal is to obtain similar search results than any consumer, and therefore prioritize controlling those operators and offers that are more likely to complete a transaction. Only a small part of surfers view results from the following pages of results, thus using a risk-based approach, the first results that appear in the search engine should be prioritized. The first page is known as the Holy Grail for marketers: for example, when it comes to Google, "page 1 placement is where 90% of Google traffic comes from (...); page two drives about 5% and page three 1%" Making sure that page 1 is safe and compliant with food law is a priority.

Monitoring of offers that appear in the first page of results in a popular search engine can significantly improve the overall safety and quality of the market, therefore a risk-based approach should prioritize those offers. Attention should be paid to using search terms similar to those that an average consumer may use.

Finally, when suspecting that an offer has been placed by criminal organizations or that may entail criminal law enforcement, authorities in the United Kingdom and Germany agree on the fact that the information gathered during monitoring should be forwarded to criminal law enforcement agencies. The investigation and the measures that can be taken by those authorities are likely to better face the challenges that illegitimate operators entail.

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⁴²⁸ Sharp, E. (2014 April 30). The first page of Google's search results is the Holy Grail for marketers. Retrieved from https://www.protofuse.com/blog/details/first-page-of-google-by-the-numbers/

Competent authorities should prioritize controls on offers placed by legitimate food business operators, mirroring their activity in the brick-and-mortar market.

3.2. Tackling the challenges arising for performance of official controls (Challenges nº 6 to 10)

The initiatives developed in Germany and the United Kingdom provide valuable insight on how to deal with the challenges regarding the performance of official controls on e-foods.

3.2.1. Making sure that surveillance goes unnoticed by operators, to ensure the effectiveness of controls

The Compliance Regulation mandates that official controls are carried out without prior warning to the operator. Both German and UK's authorities provide similar answer to this issue: monitoring activities must be carried out using software and hardware (including payment methods) that does not give away the real identity of the surfer. While G@zielt does not provide details on their protocol, the FSA recommends different software options that could be used but does not imposing one on authorities. The FSA guidance for local authorities, which is of open access, includes useful recommendations and tips on those technical aspects.

Member States putting in place a system to control e-foods at the distribution stage must build their own protocol on how to choose appropriate equipment and on how to carry out research.

Additionally, the United Kingdom underlines the need to consider creative delivery options to ensure that the identity of the authority is not discovered based on identification of the customer or the delivery address. It suggests creating a "test purchase persona", with a given Google appropriate e-mail address, credit card and delivery address that hides the fact that the purchase is made by a competent authority. When it comes to arranging the delivery of a test purchase, agreements could be reached with other branches of government such as the housing department so that the products are shipped safely. Also, parcels could be delivered at a pick up point designated by the operator. The

FSA guidance for local authorities, which is of open access, includes useful recommendations and tips on those technical aspects.

Mystery shopping requires creating a test persona, with a given email address, payment method, and delivery address that hides the fact that the purchase is made by a competent authority.

3.2.2. Performing controls at the distribution stage while safeguarding the operator's capacity to contest administrative decisions:

Germany, that has created a central unit that monitors the market but does not perform control checks, does not deal with material control issues. The central unit interprets that national laws regulating sampling prevent competent authorities from using mystery shopping to obtain samples valid for enforcement.

In Germany, official controls of e-foods which are suitable for enforcement are only carried out at the production stage.

On the other hand, regulations in the United Kingdom do not preclude tests purchases. The relevant legislation states that operators must be informed of the sampling taking place "as soon as possibly feasible", but this can be done once the parcel has been received without endangering the operation. The procedure would be considered lawful when a witness (for example, a second member of the competent authority's staff) is present while manipulating the parcel and until the sample portions are sealed and labelled.

From the December the 14th 2019, the new Regulation 625/2017 for official controls will repeal Member State laws challenging mystery shopping. The Regulation specifies that sampling can take place without the operator being present. Thus, this obstacle will be eliminated for all Member States.

The feasibility of ordering e-foods anonymously for official controls depends on the applicable law in the Member State. Although the new official controls Regulation deals with this specific issue and guarantees that anonymous samples should be possible, it will not solve the problem for until almost 2020.

The impact of Regulation 625/2017 is analysed in section 4 of Chapter 4, dealing with the forthcoming legal framework for official controls.

It is my view that the mere mandate to inform the operator, its representative or the clerk of the sampling going to take place so they can witness the procedure does not preclude the possibility of sampling e-foods. Current parcel delivery methods include "click and collect" options, that entail that a third party guards the parcel until the consumer picks it up. Competent authorities could order delivery to a click and collect delivery space, notify the operator that the test purchase has been placed, and pick up the product and perform sampling in presence of the operator at the delivery place.

Competent authorities in Member States that require that the operator witnesses sampling could organise that the parcel containing the e-food is delivered to a click and collect delivery space, then notify the operator that the test purchase has been placed, and pick up the product and perform sampling in presence of the operator at the delivery place. Thus, under current Spanish laws, controlling e-foods at the distribution stage is possible.

The sample obtained from mystery shopping must be a fair sample. As recommended by the FSA, this entails that staff performing controls must ensure that the items ordered are numerous enough to procure a sample that complies with the characteristics established in EU law, international standards, or the sampling plan. For example, back to the rule that requires sampling for analysis of mycotoxins in cereal products to be at least of 1kg, in case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

When ordering an e-food, competent authorities must evaluate how much product is going to be necessary to obtain a fair sample and ensure that a witness is present throughout the sampling procurement.

The Compliance Regulation mandates that official controls are follow a documented procedure. Both the German and United Kingdom's authorities insist on the fact that all the control process, from monitoring to sample storage, must be documented. Evidence must be recorded and stored, and all relevant information must be included in an inspection or sampling report. Different software can be used to store digital evidence⁴²⁹. The FSA guidance for local authorities, which is of open access, includes useful recommendations and tips on those technical aspects.

Member States controlling e-foods at the distribution stage must build their own protocol on how to document the process, starting at initial monitoring online and until the samples are stored.

3.3. Tackling the challenges regarding food law enforcement (Challenge no 10)

Once preliminary tasks or official control activities suggest (or establishes) that an e-food does not comply with food law requirements, competent authorities must ensure that the operator readdresses the situation of non-compliance.

The German central unit does not perform checks suitable for enforcement purposes. However, G@zielt team contacts operators directly and requests informally that the non-compliant offer is removed. The experience obtained from 2011 proves that, in most cases, operators collaborate with the authority and readdress the situation.

Additionally, it forwards the information and data gathered during its preliminary monitoring tasks to the relevant competent authority in each *land* through the regional contact points. Then, the competent authority will perform checks at the production stage, which may result in measures taken once non-compliance is established. The measures to

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⁴²⁹ The validity of the solutions chosen to consider the records as evidence suited for enforcement will be based on national law.

be taken are those provided for in Member State law, which are commonly used in the brick-and-mortar market: educating food business operators, detaining and seizing food, or initiating a sanctioning procedure are the best options to address non-compliance.

Because official controls of e-foods at the distribution stage are perfectly legal in the United Kingdom, the FSA identifies that those traditional enforcement measures should be applied also regarding operators in the digital market.

Non-compliance should result in the adoption of any of the measures that are already legally established for non-compliance with food law in the traditional market.

However, both G@zielt and the FSA acknowledge that, if the operator does not collaborate, it is necessary to find alternative methods to reach the desired goal: the elimination of non-compliant food products available online. This entails contacting the relevant intermediary (for example, the digital platform hosting the offer) to request the removal or blocking of the illegal content.

This is an option that is regularly taken by the German central unit when dealing with manifestly non-compliant offers, which has identified communication channels with large online platforms such as Amazon, Alibaba and eBay. In order to obtain the platform's collaboration, the central unit initiates a notice-and-take down (NTD) procedure, which includes a file with all the evidence gathered during monitoring. This tool is also included in the recommendations that the FSA provides.

The usefulness of NTDs in food e-commerce come from the fact that too many times competent authorities cannot carry out an administrative procedure that would result in non-compliance being established and the offer legally removed. Be it for lack of legal base, or merely because the time needed to complete the administrative procedure would turn the procedure useless, NTDs have the potential to impact significantly the safety of the e-food market.

Given that the difficulties that competent officials must endure to officially control e-foods, and the time that administrative procedures require, competent authorities can use NTDs to obtain fast removal of manifestly non-compliant e-food offers.

4. ABOUT THE POSSIBILITY OF CENTRALISING SURVEILLANCE

Germany has created a central unit that carries out monitoring and preliminary control activities on e-food offers available to the German consumer. Based on an agreement adopted by all *länder* and the BVL, G@zielt is in charge of conducting "preparatory tasks," which help competent authorities in each *land* perform the corresponding official controls at the production stage.

Monitoring the digital market of foods is a responsibility of the central unit. It also acts as an intermediary between the Federal Tax Office and the *länder* contact points, and between *länder*. If monitoring results in data that could be relevant to the competent authorities, the central unit forwards this information so that enforcement measures can be considered.

The United Kingdom has chosen a different approach. In the UK there is no centralisation of surveillance. This is a sensible approach given that the Member State is composed of four different countries, and is submerged in a process of devolution. Northern Ireland, England, Scotland and Wales could decide to create a centralised unit within their territory, but it does not seem to be the intention for the moment.

Deciding on whether a Member State should create a centralised unit should not be a decision based exclusively in economically or efficiency driven considerations. As the German experience shows, centralising entails that surveillance is going to be done by a single body that is not controlled different to the regional authority. Even if enforcement powers can still be hold by the regions, centralising surveillance giving up resources and some degree of autonomy from the regional or local authorities who did have the responsibility assigned in the first place.

Thus, while the United Kingdom's approach requires providing numerous officials with adequate training and equipment, centralising e-controls demands a sensitive and in-depth debate to evaluate adopting a unanimous political decision.

When evaluating how to structure their e-food control strategy, Member States must take into account the political implications that centralizing control implies. While placing all responsibility on individual competent authorities and public officials can reduce control efficiency, opting for centralization can raise significant reluctance and affect the adequate functioning of a central unit.

CHAPTER 4.

THE ROLE OF THE EUROPEAN

UNION: COORDINATION AND SUPPORT

1. FIRST STEPS OF THE EUROPEAN COMMISSION ON E-FOOD CONTROL: PROVIDING TRAINING AND ENSURING KNOWLEDGE-TRANSFER

The responsibility to organize and perform official controls on food products lies within the Member States. Although the European Union designed a harmonized legal framework to ensure consistency, inspections, as any other control activity, are physically carried by competent authorities according to procedures defined in Member State law. Therefore, the decisive level is that of the Member States. The role of the European Commission is to ensure proper coordination and to support their actions, whenever needed.

Since Member States began disclosing their concerns about the challenges that including the digital market of food products in official controls entailed, the priority of the European Commission has been to provide competent authorities with *ad hoc* training activities to support control staff in their tasks. Additionally, the European Commission has participated in knowledge-transfer initiatives that to identify mechanisms to increase Member State's capacity to tackle e-food trade.

1.1. Providing training to public officials in charge of official controls

In 2014, the European Commission began providing control staff in Member States with training to e-food controls, in the framework of the Better Training for Safer Food (hereinafter, "BTSF") initiative, which seeks

to establish a good level of uniformity of the controls carried out and of the decisions taken by the controlling authority pursuant to such controls, thus giving

more certainty to food businesses through equal treatment wherever controls are carried out⁴³⁰.

The "New investigation techniques for official controls" course provides participants with technical skills to better understand and navigate the Internet. Sessions cover relevant topics, such as how to deal with hypertext mark-up language (also known as "HTML"), saving complete websites, creating videos of the surveillance tasks carried out, and storing evidence for enforcement purposes.

One of the most significant contributions of this course has been to train staff on how to undertake Internet investigations to identify operators and their establishments. In fact, it is safe to assume that the recommendations included in the FSA's guidance document analysed in section 2.2 of Part 2 of Chapter 3, build on BTSF training.

Five 3-days courses had been held by the end of 2015 with an average of 30 participants per session. Between 2016 and 2017, five more training courses were completed. Currently, participants are split in two groups. Beginners, and those that attended the training in the 2014-2015 period and wish to improve their skills that are grouped in an advanced course. According to the BTSF service, twelve more trainings will be carried out by the end of 2021.

BTSF has become a very useful tool to train control staff following the "train the trainers" principle, but also to identify challenges arising from legislation in specific Member States. It was through this training that it was made clear that in some cases State laws do not allow for anonymous purchase of e-foods for enforcement purposes.

Initial BTSF course content was significantly influenced by G@zielt's experience. However, the curriculum has evolved since to incorporate experience from other Member States. It has become a forum that fosters cooperation with Member States, and has recently included participants from third countries in order to maximize knowledge-transfer.

⁴³⁰ European Commission. COM/2006/519 final. Communication of 20 September 2006 on Better training for safer food. Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/btsf comm report 2006 en.pdf

European Commission. (2013). Call for tender n° EAHC/2013/BTSF/14: Organization and implementation of training activities on new investigation techniques for official controls along the food chain under the "Better Training for Safer Food" initiative. Retrieved from http://ec.europa.eu/chafea/food/tender-2013 btsf 14.html

1.2. Transferring knowledge through working groups

By 2014, Member States were already experimenting with e-food control and some good practices had emerged. In that context, the European Commission decided that the "dissemination of best practices between the Member States [should] be done by means of working group meetings".

The Expert Group on Official Controls, which had been running since 2010, was chosen the appropriate forum to channel the discussion on how to undertake official controls on e-foods. As other similar groups,

The group meetings provide a platform to exchange views; clarify Commission's positions; provide advice and guidance; [and] identify areas in which action is needed to ensure proper and coherent enforcement of EU legislation across EU Member States⁴³².

Together with representatives from all EU Member States, the expert group includes also representatives of Norway, Iceland, Switzerland, and Liechtenstein. Also, the Network of the Heads of Food Agencies can attend its meetings as observers.

At a later stage, in 2016, the Working Group on the Strengthening of the Enforcement of EU Agri-Food Legislation on Internet Sales of Food was created to deal specifically with food ecommerce. It was based on the debates of this working group that the European Commission conduct a survey to assess the situation of e-food control in each Member State.

Member States submitted their answers to the survey in 2016, but they have not been disclosed. The only information that has been publicly reported was that some Member States monitored offers online, that registration issues were being analysed, and that individual Member States had made test purchases to verify compliance with food law.

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European Commission. (n.d.). *Expert Groups and Working Groups*. Retrieved from https://ec.europa.eu/food/safety/official controls/expert working groups en

2. 2016-2017: PROVIDING A LEGAL FRAMEWORK THAT OVERCOMES THE OBSTACLES ENSHRINED IN MEMBER STATE LEGISLATION

In May 2013 the European Commission disclosed its proposal for a new regulations of official controls (today, Regulation 625/2017). The goal of this proposal was "to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation"⁴³³.

The proposal included specific provisions on distance selling. However, the debate of the proposal showed that the initial version was not appropriate to overcome the challenges enshrined in Member States' law. Therefore, in June 2016⁴³⁴, new rules for e-food control were proposed.

Regulation 625/2017, adopted one year later, includes the rules proposed in 2016. As will be described in this section, the forthcoming framework for official controls facilitates that, from December 14th 2019:

- Food business operators must provide authorities with information on the activities they carry out by the means of distance communication, which includes e-commerce.
- Competent authorities in Member States can use mystery shopping techniques
 to control food products offered online at the distribution stage, and by
 specifying that sampling can be completed without the presence of the food
 business operator.
- Enforcement measure can include "order[ing] the cessation for an appropriate period of time of all or part of the activities (...) of the Internet sites" of operators responsible for non-compliant food products.

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⁴³³ Recital 19 of Regulation (EU) 625/2017 of 15 March 2017

⁴³⁴ COM/2013/265 final. Communication of 26 September 2016 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [....]/2013 and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation). Retrieved from http://data.consilium.europa.eu/doc/document/ST-12175-2016-ADD-1/en/pdf

The European Commission can adopt rules on performance of official controls
on animals and food products, ordered by distance selling, which are
introduced in the European market from a third country. Those rules may
include enforcement measures.

Section IV of this Chapter, which evaluates the contributions of the European Commission to e-food control, analyses the impact of the new regulation on competent authorities' ability to control the digital market of food products.

2.1. Overview of the novelties in Regulation 625/2017, for official controls

The new official controls Regulation was published in the Official Journal of the European Union on the 7th April 2017. However, most of its provisions will not be applicable until December 14th 2019.

The new Regulation maintains the general principles set in Regulation 882/2004, but aims at increasing the efficiency and transparency of official controls. Additionally, several rules are redefined in Regulation 625/2017 in order to harmonize procedures that are currently regulated by Member State law. For example, the rules on sampling in the new official controls regulation are much more detailed, which will result in automatic repealing of legislation that has proven to be obstructing effective official controls in the digital market (as analysed in section – of this Chapter).

The new legal framework for official controls extends its scope. It will cover organic production and plant protection products. However, agricultural products will remain outside the range of the scope of the general official controls system. Animal welfare policy becomes a priority in Regulation 625/2017, which calls for the creation of European Union Reference Centres for animal welfare⁴³⁵.

Additionally, Regulation 625/2017 provides specific rules to target fraud. According to the new regulation, Member States have the obligation to "perform regular and un-

⁴³⁵ The reference centers must ensure coordination among Member States when it comes to carrying out official controls in the field of animal welfare. The first reference center was designated in March 2018, and deals with pig welfare.

announced, risk based controls"⁴³⁶ and provides for the creation of EU reference centres for the authenticity and integrity of the agri-food chain. These centres must build knowhow on how to fight food fraud, and assist competent authorities in the performance of official controls. Furthermore, it mandates that penalties⁴³⁷ for food fraud must "reflect, in accordance with national law, at least either the economic advantage for the operator or, as appropriate, a percentage of the operator's turnover"⁴³⁸. The goal of all these measures on food fraud is to "restor[e] consumer and market confidence through a number of measures, including proposals to strengthen controls along the food chain and toughen penalties for fraudsters"⁴³⁹.

The new official controls regulation also modernises rules for the performance of official controls on foodstuffs imported into the European Union. It establishes a single standard digital document Common Health Entry Document (hereinafter, "CHED") that will be used by operators for the prior notification of consignments:

For each consignment of the categories of animals and goods (...) the operator responsible for the consignment shall complete the relevant part of the CHED, providing the information necessary for the immediate and complete identification of the consignment and its destination ⁴⁴⁰.

⁴³⁶ European Commission. (2017d). Questions & Answers of 7 April 2017on Commission Regulation (EC) 2017/625 (Official Controls Regulation). Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/oc_qa_ocregulation_20170407_en.pdf

⁴³⁷ Because penalties are established at the national level, the responsibility to ensure that food fraud does not appear profitable to business and criminals lies within Member States. But the debate is already on the table about who is going to be paying the penalty as situations as the horse meat scandal show that it is possible that the operator marketing a fraudulent product is not aware of the deceptive practice and becomes a victim of the fraud itself.

⁴³⁸ Paragraph 2 of article 139 of the new Official Controls Regulation.

⁴³⁹ European Parliament Research Service. (2014). *Briefing Fighting food fraud*, p. 1. Retrieved from http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2014/130679/LDM_BRI%282014%29130

⁴⁴⁰ Paragraph 1 of article 56 of Regulation 625/2017, of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC.

Information in the electronic CHED will be transmitted to Member States through another novelty, the new IT system that for a paperless communication between competent authorities that was forecasted in Action 22 of the Digital Single Market Strategy for Europe. This integrated information management system for official controls, known as IMSOC, should "link all existing (and future) computer systems, e.g. TRACES, RASFF and *Europhyt* to ensure optimal exchange of information between Member States" ⁴⁴¹. The goal is to create a "fully dematerialised environment to sustain the free and secure movement of safe food and plant products".

The new framework for official controls also clarifies the rules on Administrative Assistance & Cooperation when dealing with cases of cross-border non-compliance.

The Regulation entered into force on the 27th April 2017, but will not be applicable until the 14th December 2019⁴⁴².

2.2. Food business operators must provide information about their activities in the digital market

Competent authorities in Member States must "draw up and keep up-to-date a list of operators.⁴⁴³" To create that list, operators must provide competent authorities with "at least the following updated details: (a) their name and legal form, and b) the specific activities they carry out, including activities undertaken by means of distance communication, and the places under their control"⁴⁴⁴.

This list does not coincide with the list of registered or approved food establishments that was enshrined in article 31(2) of the Compliance Regulation. The new list focusses on operators instead of on food establishments, and according to recital 38, will include

⁴⁴¹ European Commission. (2017c). *Action 22: Implement a fully dematerialised environment to sustain the free and secure movement of safe food and plant products.* Retrieved from https://ec.europa.eu/futurium/en/content/action-22-implement-fully-dematerialised-environment-sustain-free-and-secure-movement-safe

⁴⁴² As stated in article 167 of the new Official Controls Regulation, Title III, on reference laboratories and reference centres, will be applicable from the 29th April 2018, while some rules on methods for analysis and designated laboratories will not be applicable until April 2022.

⁴⁴³ Article 10 (2) of Regulation (EU) 2017/625 of 15 March 2017

⁴⁴⁴ Article 15 of Regulation (EU) 2017/625 of 15 March 2017

information about operators that have only indirect relation to the food chain⁴⁴⁵ but whose activity may be relevant to verify compliance with food law.

Member States could request that this information is submitted as part of the application form used to register food establishments. This could measure could be taken before Regulation 625/2017 begins its application, because both the Compliance Regulation and Member State's legislation merely refers to the fact that operators have to provide information about their activities. Although competent authorities are not requesting this information, at present the legal framework permits it.

Regulation 625/2017 provides explicit legal base for competent authorities to request that food business operators submit information about their activities in the digital market.

However, they can already do so because the Compliance Regulation and Member States law merely indicate that operators must submit information on their "activities."

2.3. Harmonised rules for sampling of e-foods at the distribution stage

Even though EU food law provides a common legal framework for official controls, Member States must adopt legislation that defines the particular arrangements for the organization and performance of official controls in a manner that is consistent with the distribution of powers in their administrative structure⁴⁴⁶. Sampling is one of the areas that are regulated by Member States.

The Compliance Regulation indicates that Member States shall establish adequate procedures in order to guarantee the right of food business operators to apply for a supplementary expert opinion, and that sampling must ensure that operators can obtain

⁴⁴⁵ No further information has been yet published by EU institutions on how to interpret Recital 38 and article 10, and no academia paper deals with this issue. Article 16 of the Regulation states that a European Commission's delegated act that will provide more detail on those that must be included in the list and on setting out of categories of operators to be exempted from the list where their inclusion in such a list would constitute a disproportionate administrative burden for them compared to the risk related to their activities.

⁴⁴⁶ See section 1 of Chapter 2.

sufficient numbers of samples for cross-examination⁴⁴⁷. It does not regulate the procedure of sampling further.

Member States' legislation on this issue provides rules to obtain a "fair sample", which is the one that has been obtained in compliance with the methods established in EU law (or with international standards or the sampling plan if no EU rules exist). The goal of regulating the procedure that control staff has to follow when sampling is to verify compliance with food law using a sample that is representative of batch it was procured from, but also to ensure that the operator can cross-examine the results.

The lack of detail in the Compliance Regulation has given Member States great margin of discretion to regulate sampling procedures. Spain requires samples to be large enough to be divided in three homogeneous specimen, and that the operator witnesses sampling. Germany, which also wants the operator present but only requires to sample-portions, prevents competent authorities from paying for the items sampled. The United Kingdom agrees with Spain on the number of specimen, but does not mandate that the operator is present to witness sampling.

Aiming at better harmonizing the sampling capacities and at facilitating controls on e-foods, the new regulation for official controls wants to ensure that test purchases have a legal base in EU law. Recital 49 of Regulation 625/2017 states the following:

For the purposes of performing official controls on trade which take place through the internet or other remote means, competent authorities should be able to obtain samples through anonymously placed orders (also known as mystery shopping) which can then be analysed, tested or subject to a verification of compliance.

With that goal in mind, the initial draft presented by the European Commission proposed the following provision:

- 1. In the case of animals and goods offered for sale by means of distance communication, samples ordered from operators by the competent authorities without identifying themselves may be used for the purposes of an official control.
- 2. Competent authorities shall take all steps to ensure that the operators from whom the samples are ordered in accordance with paragraph 1:
 - (a) are informed that such samples are being taken in the context of an official control and, where appropriate, analysed or tested for the purposes of such official control; and,

⁴⁴⁷ For details see section 1.6 of Chapter 2.

(b) where the samples referred to in paragraph 1 are analysed or tested, are entitled to exercise the right to apply for a second expert opinion provided for in Article 34(1).⁴⁴⁸

However, this version was modified in June 2016, because there was concern about the possibility that some Member States would still require that the operator is present in the moment of sample taking. The original wording of paragraph 2 was updated to explicitly mandate that operators are to be informed "once [the competent authorities] are in possession of the samples" and that such samples "have been taken."

The final version, adopted in March 2017, states this:

- 1. In the case of animals and goods offered for sale by means of distance communication, samples ordered from operators by the competent authorities without identifying themselves may be used for the purposes of an official control.
- 2. Competent authorities, once they are in possession of the samples, shall take all steps to ensure that the operators from whom these samples have been ordered in accordance with paragraph 1:
 - (a) are informed that such samples have been taken in the context of an official control and, where appropriate, are analyzed or tested for the purposes of such official control; and
 - (b) where the samples referred to in that paragraph are analyzed or tested, are able to exercise the right to a second expert opinion, as provided for in Article 35(1).

The new Regulation, while enabling mystery shopping, requires competent authorities to inform the food business operator that the purchase was made and that the sample was taken for the purpose of official controls once the process has been completed. The solution adopted at the EU level concurs with the legislation in the United Kingdom, which require that the operator is informed about the fact that a sample was taken "as soon as reasonably possible".

The underlying idea is that the operator's rights are not hindered by the fact that sampling takes place without his presence. Member States will have to adopt new rules that ensure that sampling is fair when performing test purchases.

Because European Union's regulations have direct effect, from December 14th 2019, those Member State's legal provisions obstructing sampling will be repealed. The major obstacle to perform mystery shopping in most Member States will be removed.

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⁴⁴⁸ COM/2013/265 final of 26 September 2016

Once Regulation 625/2017 is applied, competent authorities in Spain will be able to perform mystery shopping in the framework of official controls. However, rules on how to ensure that the operator can cross-examine sampling must be defined to ensure its validity.

However, some Member States will still need to update their legislation to comply with Regulation 625/2017. For example, even though paragraph 1 of article 36 states that samples may be "ordered" by competent authorities, it does not render void national legislation such as the German, which establishes that competent authorities must not pay for samples. Therefore, if such pieces of legislation are not modified, it will still be required to define a protocol that allows competent authorities to reclaim the amount paid as price of the food that is sampled.

Even though Regulation 625/2017 states that competent authorities can carry out mystery shopping, if Germany does not modify article 43 LFGB, competent authorities will still have problems to sample e-foods at the distribution stage.

Additionally, article 35 of Regulation 625/2017, which sets the rules for supplementary (now "second") expert opinion, states that where it is not possible to take a sufficient quantity of the product sampled to ensure that a second test can be carried out, the person in charge of sampling must inform the operator thereof. It is not clear if the intention of the legislator was to avoid that regulation on sampling methods would prevent from sampling e-foods (that cannot be ordered if very large quantities without it being suspicious). However, given than second expert opinion is an essential tool when it comes to ensuring right to defence, the EU Commission or the Courts will need to provide guidelines on the situations where article 31 (2) b may apply without hindering businesses fundamental rights.

2.4. Official controls on e-foods from third countries

Regulation 625/2017 provides a common framework for performance of official controls of imports from third countries, including rules on how check consignments at border

control posts and on how to carry out the controls that may take place before entering the European Union.

The new official controls regulation mandates that the EU Commission shall adopt delegated acts on how to control e-foods that have been ordered from Europe but that come from a third country. This delegated acts should aim at providing legal base to allow "customs authorities or other public authorities" to perform controls of those e-foods as they enter the market.

2.5. Order for cessation

The last novelty⁴⁴⁹ of Regulation 625/2017, when it comes to e-foods, is enshrined in article 138 (2), which deals with the actions that competent authorities can undertake when non-compliance has been established. In particular, it indicates that competent authorities shall take any measure they deem appropriate to ensure compliance, which includes "order[ing] the cessation for an appropriate period of time of all or part of the activities of the operator concerned and, where relevant, of the internet sites it operates or employs"⁴⁵⁰.

This article provides legal base for competent authorities to order of cessation of the activities carried out online.⁴⁵¹ Regulation 625/2017 also empowers the Commission to adopt delegated acts to supplement this provision before December 2022.

It is the view of the European Commission that the Compliance Regulation does already provide Member States with legal base to order cessation of activities in the digital market. Article 54 (2) of the Compliance Regulation states that competent authorities can fight non-compliance with "any other measure the competent authority deems appropriate". However, the possibility to apply this measure depends on how Member

authorities that affirms that "there are currently no powers in food law to close down offending websites."

⁴⁴⁹ However, it is the view of the Commission that, although Regulation 625/2017 clarifies that this order is legal under EU Food Law, Member States could already apply this measure as article 54 (2) of the Compliance Regulation states that competent authorities can fight non-compliance with "any other measure the competent authority deems appropriate." But it is the interpretation of most Member States that if national regulation does not include a similar passage while listing the measures that may be taken once non-compliance has been established, cessation cannot be ordered. For instance, FSA's guidance for local

⁴⁵⁰ Article 138.2 of Regulation (EU) 625/2017 of 15 March 2017

⁴⁵¹ Food Standards Agency. (2016g). Food Sold Online. Guidance for local authorities, p. 14. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf

State legislation implemented article 54(2). Spain, Germany and United Kingdom have not included this possibility among the list of measures that competent authorities can adopt in case of non-compliance.

Until December 14th 2019, competent authorities will not be able to order the cessation of the sites the operator employs unless Member State's law provides legal base to do so.

Legal base can come either by explicitly including this possibility in the list of measures, or if Member State law includes the same broad formulation that is enshrined in the Compliance Regulation.

The goal of article 138 is to make sure that, as it happens with a closure order referred to a traditional retail store or food establishment, competent authorities can order the operator to stop selling products in the digital market as well. This order of cessation of e-commerce activities is not addressed to intermediaries (hosts, i.e. digital platforms) but to the operator himself.

When ordering the cessation of activities competent authorities must

- (...) provide the operator concerned, or its representative, with:
- (a) written notification of their decision concerning the action or measure to be taken in accordance with paragraphs 1 and 2, together with the reasons for that decision; and
- (b) information on any right of appeal against such decisions and on the applicable procedure and time limits with respect to such right of appeal⁴⁵².

The notification of the order should state the period of time it applies and its scope, which could affect "all or part of the activities". Therefore, it is possible that the order does only prevent the operator from placing offers of specific e-foods. This could be the case, for example, if the established non-compliance refers to a category of food products but the rest of its merchandise has been found lawful.

Operators have the right to appeal the order. However, if postponing the cessation of the site entails "risks to human, animal or plant health, to animal welfare or, as regards GMOs

⁴⁵² Article 138 (3) of Regulation (EU) 625/2017 of 15 March 2017

and plant protection products, also to the environment" 453, competent authorities can demand prompt cessation to contain or eliminate those risks.

Competent authorities are voicing their doubts about the impact that the order of cessation may have on internet trade. Competent authorities are uncertain about how to address non-compliance if the operator refuses to temporary stop its activities in the digital market.

But, as it has been underlined throughout the thesis, this concern is in part based on the fact that the digital market today is crowded of non-compliant offers, frequently posted by illegitimate or reckless businesses. Yet the experience in Germany evidences that the market can be tamed, that reckless operators normally comply with the instructions provided by public authorities and address their issues, and that those who place unlawful offers knowingly and criminally may face the action of criminal law enforcement agencies.

⁴⁵³ Article 7 of Regulation (EU) 625/2017 of 15 March 2017.

3. THE COORDINATED CONTROL PLAN ON ONLINE OFFERED FOOD PRODUCTS

In July 2017, Commission Recommendation on a coordinated control plan on the official controls of certain food marketed through the Internet⁴⁵⁴ (hereinafter "CCP_efood") was adopted by the Standing Committee for Plants, Animals, Food and Feed (PAFF). This coordinated control plan on online offered products is the first action on the digital market of food products that is carried out under the supervision and coordination of the European Commission.

Given that Regulation 625/2017 will not be applicable until December 14th 2019, both the definition and the implementation of the coordinated action are based on the rules of the Compliance Regulation.

3.1. The definition of the coordinated control plan

Coordinated controls plans' legal base is enshrined in article 53 of Regulation 882/2004, which allows the European Commission to "recommend coordinated plans (...) where considered necessary, organised on an ad-hoc basis, in particular with a view to establishing the prevalence of hazards in feed, food or animals". To date, the EU Commission has adopted three other coordinated control plans, each one of them focusing on honey, fish substitution and horse meat⁴⁵⁵. These plans normally "rely on

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⁴⁵⁴ Commission Recommendation on a coordinated control plan on the official controls of certain food marketed through the Internet European Commission. *Commission Recommendation of 24th July on a coordinated control plan on the official control of certain foods marketed through the Internet (C(2017) 4986 final) - Your letter/email to Commissioner Vytenis Andriukaitis dated 26th July 2017*. Retrieved from https://ec.europa.eu/info/sites/info/files/pet-krecommendationc2017-4986.pdf

⁴⁵⁵ While the coordinated control plan for honey and fish substitution were adopted simultaneously through Commission Recommendation C(2015)1558 final of 12th March 2015, on a coordinated control plan with a view to establishing the prevalence of fraudulent practices in the marketing of certain foods and have been carried out during the 2015-2017 period, the one on horse meat was adopted after the explosion of the horse meat scandal by Commission Recommendation of 19 February 2013 on a coordinated control plan with a view to establish the prevalence of fraudulent practices in the marketing of certain foods, that dealt with products which were marketed and/or labelled as containing beef as well as with horsemeat destined for human consumption to detect phenylbutazone residues. It was carried out from March 2013 to July 2014. Overview reports and general information on the control plans is available here: https://ec.europa.eu/food/safety/official_controls/eu-co-ordinated-control-plans_en

harmonised sampling and methods of analysis to be implemented by all the participating countries, for a limited period, so that the results can be properly evaluated"⁴⁵⁶.

In the case of the plan for online offered food products, known as CCP_efood, sampling has not been a priority: actions focus on obtaining information on how specific food products are marketed for online purchase. With that information, both the European Commission and Member States should be able to define further policy initiatives in the (still unfamiliar) field of official controls on the digital market of foods.

As it is the case for any coordinated control plan, participation in CCP_efood was voluntary. Nevertheless, 27 countries have participated in this action⁴⁵⁷ (all of the EU, with the notable exception of the United Kingdom), which was to be developed during the last four months of 2017.

When a Member State decides to participate in a coordinated control plan, its communication with other Member States is carried out through its national liaison body, which is also responsible for organizing the development of the action at the national level. In Spain these tasks have been entrusted to AECOSAN, to the FSA in the UK and to the BVL in Germany. It is up to those authorities to distribute nationally the responsibility to carry out each task of the plan.

The goal CCP_efood was to "encourage Member States to identify and then control in a coordinated manner websites which offer for sale specific types of products which are clearly not in compliance with EU food law"⁴⁵⁸. Its specific objectives were to:

- practice and strengthen the cooperation and administrative assistance between Member State authorities on the control of Internet sales;
- practice the exchange of information via rapid alert notifications according to Article 50 of Regulation (EC) No 178/2002 (RASFF) and notification under the Administrative Assistance and Cooperation system (AAC system) according to Commission Implementing Decision (EU) 2015/19181,2;
- gain insight into misleading practices in the sale of food supplements;
- gain insight into the prevalence of unauthorised novel foods sold via Internet;

European Commission. (n.d.). *EU Co-ordinated Control Programs*. Retrieved from https://ec.europa.eu/food/safety/official controls/eu-co-ordinated-control-plans en

⁴⁵⁷ According to information provided by public officials (e-mail from Georg Schreiber, of the 22nd January 2018).

⁴⁵⁸European Commission. (n.d). *Online offered food (2017)*. Retrieved from https://ec.europa.eu/food/safety/official controls/legislation/ccp/online-offered-food-2017 en

- highlight that Internet sales of food are subject to official controls;
- build know-how on food law enforcement in Internet sales. 459

The goals was to obtain information on the digital market of food supplements and unauthorised novel food, to test competent authorities' capacity control this market, and to get practice on the use of international cooperation channels that could facilitate control task.

The CCP_efood required Member States to focus on searching "in the Internet for websites which offer products intended for sale in their respective Member State, 460" regardless of their origin. This is coherent considering that the objectives of the control plan included identifying bugs in the cooperation and administrative assistance mechanism and in RASFF. There are no instructions on how to prioritize offers, so as long as they deal with one of the identified products and they are addressed to consumers in its Member State, a competent authority can include it in its activities.

Searches were to be carried out between the 4th and the 29th of September 2017, and notifications on the actions taken were to be submitted via RASFF or the ACC before the 10th November. Upon completion of those tasks, each Member State should "report the number of websites which were checked during the control period". The results were published in February 2018, and are analysed in Section 3.2 of this Chapter.

The control plan targeted four un-authorised novel foods and any food supplement offered online using prohibited medicinal claims⁴⁶¹. The selection of those products is easy to understand:

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⁴⁵⁹ European Commission. (2018). The first EU coordinated control plan on online offered food products. Analysis of the main outcome of the implementation of the Commission Recommendation on a coordinated control plan on the official control of certain foods marketed through the Internet. Annex 1, p. 2. Retrieved from https://ec.europa.eu/food/sites/food/files/oc oof analysis main outcome en.pdf

⁴⁶⁰ Ibid

The decision to focus on unauthorised novel foods and food supplements marketed with medicinal claims put some organisations of that sector in alert: only two days after the adoption of the Recommendation, a petitioner contacted commissioner Vytenis Andriujaitis (at that moment, responsible of DG SANTE) voicing concerns about the control plan. Although no details are published on the identity of the author of the petition, the Commission's answer indicates that it "expresses the same concerns which were raised on the website of the alliance for natural health International (ANH International www.anhinternational.org), which was essentially that the control plan should focus not on the targeted food stuffs but on products which pose a genuine risk to public health and have been subject to RASFF notifications." The Commission's reply to that argument was straightforward: the four un-authorised novel foods and food supplements with medicinal claims are non-compliant with EU food law, they appear repeatedly in RASFF notifications, and they raise health concerns so focussing on those products is not only justified but it also meets the demand of the petitioner. Indeed, according to the last RASFF annual

Especially towards the end of 2016, the "influx" of notifications on food supplements became so significant, that it was impossible to properly research and classify the substances as novel food or unauthorised substance. These substances were therefore temporarily classified as "unauthorised ingredients", but some of them may turn out to be unauthorised novel food ingredients. Especially Germany was an important contributor of notifications, which can probably in part be explained by the fact that they have a specialised unit dealing with online sales. They are actively monitoring the sales of products that may pose a risk to consumers due to their composition. The increase of notifications on food supplements is likely partly due to the particular e-commerce distribution channel⁴⁶².

The selected un-authorised novel foods are Agmantine (4-aminobutyl) guanidine sulphate, acacia rigidula, epimedium grandiflorum and hoodia gordonii⁴⁶³. These novel foods are non-authorised in the EU and appear frequently on RASFF notifications.⁴⁶⁴ Furthermore, hoodia goronii, often sold online in food supplements that claim to facilitate weight loss, is a cactus under protection of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) of 1973. Listed in annex II of the Convention, which refers to "species not necessarily threatened with extinction, but in which trade must be controlled in order to avoid utilization incompatible with their survival" trade requires an export or re-export permit issued by the CITES' management authority in the country of origin and can only be imported into the EU if certain requirements are fulfilled. Nevertheless, the Commission underlines that "the presence of this plant in food and health supplements is one of the most commonly seized commodities that is infringing the CITES/EU wildlife trade rules" 466.

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report, in 2016 agmantine guanidine sulphate was object of 32 notifications, a number that more than quadruples notifications for the same substance the previous year. Therefore, no changes to CCP_efood were made.

⁴⁶² European Commission. (2016). *RASF. The Rapid Alert System for Food and Feed*. Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/rasff annual report 2013.pdf

⁴⁶³ As indicated in point 3.e) of Annex 1 to European Commission. (2018). The first EU coordinated control plan on online offered food products. Analysis of the main outcome of the implementation of the Commission Recommendation on a coordinated control plan on the official control of certain foods marketed through the Internet, p. 3. Retrieved from https://ec.europa.eu/food/sites/food/files/oc_of-analysis-main-outcome-en.pdf

⁴⁶⁴ All four products are often sold by the same retailer. For example, notification no 2017.1909, submitted by France in November 2016, identified a shipment of all four non-authorized novel foods entering the European Union from the United States.

⁴⁶⁵ Convention on International Trade in Endangered Species of Wild Fauna and Flora. (n.d). How CITES works. Retrieved from https://www.cites.org/eng/disc/how.php

⁴⁶⁶ European Commission. Commission Recommendation of 24th July on a coordinated control plan on the official control of certain foods marketed through the Internet (C(2017)4986 final) - Your letter/email to

The scope of CCP_efood also includes "offers of food supplements with information that attributes to them the property of preventing, treating or curing bone and joint diseases, or that refer to such properties within the meaning of article 7 of Regulation 1169/2011 (medicinal claim)",467.

The tasks that participant countries had to develop are described in the following sections.

3.1.1. Task 1: Identifying food business operators dealing with the targeted food products

As has been discussed throughout this thesis, a significant portion of Internet-based operators are not registered before proper authorities, a situation that has hindered competent authorities' ability to appropriately control the digital market of foods. The European Commission suggested using the information in the contact page in order to try to identify the operators and their food establishments. This is, basically, the same procedure that United Kingdom and G@zielt recommend.

Additionally, the European Commission suggest that, for those situations when the contact page on the website does not include complete information on the identity of the trader, the website www.whois.net could be used to "reveal relevant information" 468. As indicated in its terms and conditions, "the WHOIS system provides information gathered from publicly available information provided by the domain name owner to their individual registrars". The system is able to provide contact information of owners because, when registering a domain name, the Internet Corporation for Assigned Names and Numbers (ICANN) "requires your domain name registrar to submit your personal contact information to the WHOIS database" Because registrars must pay an additional fee to maintain their contact information private, by introducing a domain name

Commissioner Vytenis Andriukaitis dated 26th July 2017. Retrieved from https://ec.europa.eu/info/sites/info/files/pet-krecommendationc2017-4986.pdf

Commissioner Vytenis Andriukaitis dated 26th July

⁴⁶⁷ Article 7.1 of the Food Information Regulation identifies unfair commercial practices when it comes to food information, and gives a description to what may constitute misleading information. In particular, it states that it is misleading to attribute to the food effects or properties which it does not possess.

⁴⁶⁸ European Commission. (2018). The first EU coordinated control plan on online offered food products. Analysis of the main outcome of the implementation of the Commission Recommendation on a coordinated control plan on the official control of certain foods marketed through the Internet. Annex 1, p. 3. Retrieved from https://ec.europa.eu/food/sites/food/files/oc_oof_analysis_main_outcome_en.pdf

⁴⁶⁹ Network Solutions. (n.d). *Who is behind that domain?* Retrieved from https://www.networksolutions.com/whois/index.jsp

in whois.net's search engine, the system will give detailed information about the identity of its owner, including name, telephone numbers and addresses⁴⁷⁰.

3.1.2. Task 2: Searching for relevant offers:

The European Commission's Recommendation includes advice on how to perform searches. The first one is that control staff should use computers that "are not part of the authorities' office network".

Very basic advice is given when it comes to increasing the efficiency of searches:

- When it comes to searching for food supplements with medicinal claims, the advice is to use the terms "food supplement", "food" or "dietary supplement" together with "the expressions related to certain diseases in the area of bone and joint health" such as rheumatism or osteoporosis and shopping terms such as "purchase", "cart" or "basket". Also, it is suggested to use the name of "certain substances which are often used in connection with relevant diseases" together with the keyword "shop" or similar concepts.
- When dealing with offers of any of the fourth novel foods, the recommendation is to use the name of the food as a keyword, together with the term "shop" or similar concepts. If the authority is aware that the novel food is marketed with a commercial name (for instance, because it has previously appeared in RASFF notifications), the advice is to use that commercial name again together with terms such as "shop" or "purchase".

There are no recommendations when it comes to search engines or on how to handle the prioritize monitoring, which remained at the discretion of the Member State.

⁴⁷⁰ However, it is easily available to food operators as well as to any individual to pay the extra fee to maintain their data private and using a proxy registrar for the same purpose. This option is not only chosen by those carrying out some sort of illegal activity but also by any that is aware of the risks that having publicly available contact data entails. Therefore, the recommendation to use the whois.net system may have limited effectiveness for competent authorities.

3.1.3. Task 3: Notification of non-compliance

Once non-compliance is suspected on the basis of the information that appears on the website, the Member State must make a notification to that regard. Options for notification are set in point 3.f) of Annex 1:

- When the notification deals with "purely national" trading, notifications must be carried out through the Administrative Assistance and Cooperation System (AAC) or its equivalent for the Food Fraud Network, as an "information to Commission" notification. As such, the notification will only be visible to the Commission. The notification must include information on the website or platform where the offer is posted, the identification of the product offered, a brief description of the measures taken by the competent authority regarding that offer (optional, only if any taken), an indication if test purchases have been made, and any short remark that seems relevant to the authority.
- If the product is sold to or from another Member State, the system distinguishes between non-compliant products with or without a health concerns⁴⁷¹. If the product presents a health concern, notifications should be carried out through the RASFF system to ensure that all members receive the notification. If there is no threat to health, the Administrative Assistance and Cooperation System (AAC) or its equivalent for the Food Fraud Network should be used.
- Finally, those products that do not pose a threat to health that take place in cross-border trading to or from third countries, the notification should be considered "information to the Commission" and the same information, together with the identification of the trader's location by country and the URL of the offer should be reported.

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⁴⁷¹ Even though all products within the scope of CPP_efood have been chosen because they raise health concerns, it may occur that on individual cases the product is non-compliant with food law but does not pose a threat. This may occur when dealing with a food supplement that are marketed with medicinal claims (therefore illegal) but which ingredients are not considered a hazard. Its trade shall be deemed non-compliant with food law because it is an unfair practice under article 7.1 of FIC, but still it does not present a health concern.

Each notification should include, if possible, "a screen shot of the website (with timestamp) on which the offer was made", so that participants and the European Commission can better understand the extent of non-compliance, and compare non-compliant offers to detect patterns.

3.1.4. Sampling in the framework of CPP_efood:

The Recommendation includes among its goal to "build know-how on food law enforcement in Internet sales" but sampling has not been part of the coordinated plan. Participants "are asked to search the Internet for websites which offer products intended for sale (...) but it is not required to perform test purchases (mystery shopping)"⁴⁷³.

Sampling remained voluntary because the tasks were to be developed between 2017 and 2018, thus under current Member State law and the Compliance Regulation, which in many Member State currently does not allow for legal sampling.

However, if samples test purchases were made, the Recommendation mandated that public authorities include the results on sampling in their final report to the Commission. No advice on how to handle legal or technical challenges that sampling may entail were given.

3.2. Development and results

February 25th 2018, the European Commission published its "analysis of the main outcomes of the implementation of the" coordinated control plan. This brief document reports that "authorities focussed their controls mainly on their nationally located traders",474. This was not instructed by the original Recommendation, which merely stated that controls were to be carried out on offers of food products intended for sale in their respective Member State.

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⁴⁷² European Commission. (2018). The first EU coordinated control plan on online offered food products. Analysis of the main outcome of the implementation of the Commission Recommendation on a coordinated control plan on the official control of certain foods marketed through the Internet. Annex 1, p. 4. Retrieved from https://ec.europa.eu/food/sites/food/files/oc_oof_analysis_main_outcome_en.pdf

⁴⁷³ *Ibid.* p. 2.

⁴⁷⁴ European Commission. (2018). The first EU coordinated control plan on online offered food products. Analysis of the main outcome of the implementation of the Commission Recommendation on a coordinated control plan on the official control of certain foods marketed through the Internet. Annex 1, p. 3. Retrieved from https://ec.europa.eu/food/sites/food/files/oc_oof_analysis_main_outcome_en.pdf

Additionally, focusing on offers from operators based within the competent authority's jurisdiction may well have avoided duplicated results (no information is offered in the report). According to the Commission, this

is an appropriate approach as only traders in the authorities' jurisdiction can be physically inspected, registered and put under the risk-based official control schemes as any other stationary food retail business. In the long run, this approach should be successful in establishing a similar level of food safety in EU-based online food businesses as EU consumers experience today in stationary retail⁴⁷⁵.

This was already the conclusion of the Food Standards Agency in the United Kingdom in 2016, because competent authorities can "gain an understanding of the nature of the business and any compliance issues" ⁴⁷⁶, check if the establishment is registered in its database, and then perform controls at the production stage.

Focussing on operators that have establishments in the territory entails a great advantage from a control perspective, because competent authorities can plan visits to the premises and perform controls on production. This is the option that recommended by the FSA in the United Kingdom.

According to the report, nearly 1100 websites were checked and 779 offers were "found (...) clearly non-compliant with EU legislation", Germany controlled 36 websites, all of them relating to unauthorised novel foods and Spain checked 32 websites: 16 for food supplements and 16 for unauthorised novel food. As mentioned earlier, the United Kingdom did not participate in CCP.

While no further detail on individual Member State's performance has been provided, the following table included in the Commission's analysis summarises the findings:

⁴⁷⁵ Ibid. p. 4.

⁴⁷⁶ Food Standards Agency (2016j). *Food Sold Online. Guidance for local authorities*. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf.

⁴⁷⁷ Food Standards Agency (2016j). *Food Sold Online. Guidance for local authorities*, p. 4. Retrieved from https://www.food.gov.uk/sites/default/files/foodsoldonline-guidance-for-local-authorities.pdf.

Websites checked	1077	
Non-compliant products		
- novel foods	428	
- food supplements	351	
- total	779	
Traders of non-compliant products location		
- notifying Member State	482	
- other than the notifying Member State		
- third country	110	
Notifications of non-compliant products		
- via RASFF	139	
- via AAC	154	
- handled nationally (via Annex Π^{δ})	450	
- without health concern from third countries (via Annex III ⁷)	36	

Image 3

779 offers were found to be clearly non-compliant, but only 680 operators were identified as responsible for the non-compliant products. This implies that some traders repeatedly offer products that do not meet the terms of Food Law, which is consistent with RASFF data (as indicated in section – of this Chapter, it is common that notifications deal with shipments that include all four food products).

The report also points out that 20% (142) of the non-compliant offers were posted by operators from another Member States, while 15% (110) originated from third countries. Interestingly enough, the proportion is most similar to the one obtained in 2014 by G@zielt: in a control action that included 1100 offers addressed to the German consumer, 570 were issued by a food business operator based in Germany, 350 from a vendor based in another Member States and finally 180 from operators in a third country.

Almost four years later, data apparently confirms that administrative assistance is needed only for around 20% of the cases where non-compliance has been established. Additionally, only 10% of the offers visible and available to European consumers seem to come from third countries. Therefore, even though international cooperation is

essential, by focussing on operators at home competent authorities can make the digital single market of foods significantly safer.

The data in Germany in 2014 and the data in the European Union in 2017 suggest that, when searching for offers of e-foods using similar terms as a consumer would, more than 60% of the results will be offers from operators based within their jurisdiction.

154 notifications for non-compliant cross-border offers with no health concerns were placed via the Administrative Assistance and Cooperation IT system and 139 notifications for non-compliant cross-border offers that entailed health concerns were reported via the Rapid Alert System for Food and Feed. A significant portion of those last notifications (51) were addressed to the United States and China because the food products had been shipped from there.

It is reported that, in 440 cases, "measures were taken with the aim of closing the respective offer, including inspection of the traders' premises, warnings and fines in some cases" All No. Sadly, no further details are provided about this measures.

From this experience, the Commission concludes that, although training and knowledge-transfer initiatives carried out since 2014 have prepared competent authorities to face the digital market, "further increase in control capacities and training of additional staff in Internet investigations are required, in particular as more and more food is sold online" Accordingly, it recommends carrying out a second coordinated control plan on e-commerce.

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⁴⁷⁸ European Commission. (2018). The first EU coordinated control plan on online offered food products. Analysis of the main outcome of the implementation of the Commission Recommendation on a coordinated control plan on the official control of certain foods marketed through the Internet, p. 3. Retrieved from https://ec.europa.eu/food/sites/food/files/oc oof analysis main outcome en.pdf

⁴⁷⁹ Ibid. p. 5.

4. RECAPITULATION

The European Commission has avoided leading a coordinated strategy to control the digital market of food products. Instead, it has fed on the initiative of Member States, and to Germany⁴⁸⁰ in particular. This decision was based on the fact that official controls is a responsibility of the Member States. European Regulations only provide a harmonised general framework to ensure consistency of controls across the European Union, leaving great margin of discretion to the members as to how to regulate the organisation and execution of official controls.

The first action of the European Commission in the field of e-food control was to organise training courses for control staff on online investigations, which began in 2014. Course content was initially designed building on the experience of the German administration. It has evolved since, and now combines good practices for investigation drawn from other Member States.

Additionally, it has been necessary to update the legal framework at the EU level to ensure that competent authorities in all Member States have legal base to control e-foods at the distribution stage. During BTSF training, it was made clear that the Compliance Regulation was leaving too much at the discretion of Member States law, because national implementation measures were creating challenges to e-food control that were not enshrined in EU law.

The new Regulation 625/2017 provides a legal framework that is suitable for performing official controls on e-foods once it starts its application, December 14th 2019. First of all, it will improve competent authorities' ability to map the digital market by specifying that food business operators must provide information about their e-commerce related activities. Second of all, the new regulation for official controls makes sure that competent authorities in all Member States can legally purchase e-foods using mystery shopping techniques, and that it is lawful that the operator is only informed after the sample has

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⁴⁸⁰ The influence of G@zielt has recently been demonstrated again, as the recommendations that the European Commission is offering Member States to perform market surveillance of non-food products is, in great extent, based on the German experience. Commission Notice on the market surveillance of products sold online. At European Commission. *Commission Recommendation of 24th July on a coordinated control plan on the official control of certain foods marketed through the Internet (C(2017) 4986 final) - Your letter/email to Commissioner Vytenis Andriukaitis dated 26th July 2017*. Retrieved from https://ec.europa.eu/info/sites/info/files/pet-krecommendationc2017-4986.pdf

been procured. This is an important improvement, as officials throughout the European Union have been actively expressing their concern on this issue. Furthermore, the new Regulation also provides legal base for competent authorities to order operators to stop offering food online during a specific time frame once non-compliance has been established if the circumstances advise so. Thus, the web shop or the individual space in a digital platform where offers are posted, is treated as a retail store would.

Interestingly enough, the contribution made by Regulation 625/2017 to e-food control is not creating an innovative legal framework or a new situation in EU Food Law. On a closer look, the success of the regulation comes from clarifying competent authorities' powers in the digital single market.

- The Compliance Regulation already provided legal base for competent authorities' to request information about e-commerce related activities. Regulation 852/2004 states that "food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment". As analysed in this thesis, it does not specify how to classify activities. National regulations in Spain, Germany and the UK are also vague. In all three Member States, the concept of activity could perfectly accommodate e-commerce. Competent authorities there could already request that registration information includes activities carried out online.
- Regarding the possibility of taking samples anonymously and informing the operator after the sample has been procured, this is also possible under current EU law as acknowledges the fact that several Member States (such as the United Kingdom) are already doing it. However, the wording in Member States' legislation has often created obstacles not envisaged in the European framework. Provisions affirm that the sample must be taken "in front of the operator" or that "the public official must identify himself" before taking the sample, generating unnecessary challenges to competent authorities seeking to make test purchases suitable for enforcement.
- The order for cessation of digital sales is already feasible with Regulation 882/2004. As the EU Commission itself acknowledged, the Compliance Regulation establishes that once non-compliance had been established

measures to be taken included "any other measure the competent authority deems appropriate." Again, it is Member States' regulation that has put stones under the wheels of authorities, because they usually make a list of the measures to be taken in the event of non-compliance, and do not refer to cessation of online sales.

Thus, Member states do not have to wait for the new official controls regulation to apply to improve their e-food control capacities. By modifying Member State regulations, or even just administrative protocols, some of the issues challenging them today can be solved.

From the 14th December 2019, competent authorities in all Member States are going to be able to apply all of those measures. Challenges n° 4 (obtaining accurate information about operators and establishments that engage in food e-commerce) and n° 6 (providing an interpretation of the legal framework that allows competent authorities to use mystery shopping techniques) will be overcome across the EU thanks to Regulation 625/2017.

Additionally, the coordinated control plan has had the success of implicating almost all Member States (with the notable exception of the United Kingdom) in e-food control. It has provided competent authorities with a valuable example on how to plan controls and on how to monitor the market.

It has also provided valuable information to assess the impact that controls within a jurisdiction can have in the overall safety and quality of the digital market of foods. The notifications issued in the framework of CCP_efood in fall 2017 match the results obtained by G@zielt in 2014, on the origin of non-compliant offers. Only about 15% of non-compliant offers that are actually viewed by consumers come from outside the European Union.

By controlling the EU market one jurisdiction (and Member State) at a time, compliance can increase significantly.

However, most of the challenges identified in this thesis will remain. The following table identifies the remaining challenges and recommendations on how to overcome each of them, which are analysed in the Conclusion section of this thesis.

	REGULATION 625/2017	REMAINING CHALLENGE	PROPOSALS BASED ON THE COMPARATIVE STUDY
Challenge 1: Including C2C E- Foods In Control Plans.	Official controls must verify compliance regardless of the nature of the operator or the transaction.	How to monitor the safety of C2C given that they do not have to be registered?	Including supervision of contents in popular platforms in control plan. Based on the German experience.
Challenge 2: Evaluating If An Undertaking Has Reached A Degree Of Organization And Continuity That Is Relevant To Food Hygiene Law	Does not address this issue.	Undertakings carried out every month have continuity. How to assess the degree of organization?	There is continuity if offers are placed on a monthly basis. In order to fall within the scope of Hygiene Rules, it must also entail "a certain degree of organization," which is evaluated considering the nature of the activity and of the potential risks of the food products. Based on the United Kingdom's experience.
Challenge 3: Making Sure That All Operators Complete Registration.	Does not address this issue.	How to identify active operators and get them to register their establishments?	Competent authorities must be proactive and search for food business operators that have active establishments within their jurisdiction, which have not been registered. Searches can be carried out manually, cross-referencing information in the contact page of the website with the establishment's registration database. Automated software can also be used. Based on both Member States experience and in the coordinated control action at CCP_efood.

Challenge 4: Obtaining Accurate Information About Operators And Establishments That Engage In Food E-Commerce.	Food business operators must inform of their activities, including by means of distance communication	How to channel this information so that it can be used to plan controls?	Creating a code that identifies food establishments and operators that engage in e-commerce. The code is then included in the fact sheet of the establishment in the information management system of the authority. Based on the United Kingdom's experience. Additional, personal proposal: Requesting this information in the application form used to register food establishments.
Challenge 5: Prioritizing controls	Competent authorities must follow a risk-based approach.	Which offers should be controlled first?	Prioritize controlling offers that, either come from establishments based within the territory of the competent authority, or which entail "high risk" to human health. Based on both Member States experience and in the coordinated control action at CCP_efood.
Challenge 6: Providing An Interpretation Of The Legal Framework That Allows Competent Authorities To Use Mystery Shopping Techniques	Both controls on production and on distribution must be carried out to comply with EU law. Sampling of e-foods can be done using mystery shopping techniques and informing the operator after sampling has occurred.	Sampling can be carried out in all Member States, but protocols must be defined to ensure that the samples have been properly manipulated.	Member States should ensure that sampling is carried out in front of a witness. Based on the United Kingdom's experience. Additional, personal proposal: Sampling can be videotaped, so that operators can cross-examine the process.

Challenge 7: Recording Control Activities to Safeguard the Operator's Right of Defence	Controls must be carried out following a documented procedure.	What and how should be recorded?	Specific software and hardware are used. Both monitoring and sampling must be documented. Based on both Member States experience.
Challenge 8: Placing Test Purchases Without Giving Away Their Identity, In Order To Ensure No Prior Warning	Controls must be carried out without prior warning to the operator.	How to avoid that the IP or the delivery address identify the authority?	It is necessary to create a "test persona," with a given name, address, e-mail account and payment method. The order must be placed from a computer that is not located in the authority's premises or that uses software to avoid identifying its location. Based on both Member States experience. Additional, personal proposal: Organize delivery to a "click and collect" point.
Challenge 9: Obtaining A Sample Considered "Fair" For Enforcement	Where it is not possible to take a sufficient quantity to perform multiple sample-portions, inform the operator.	Does this exception apply to food products ordered via mystery shopping?	This issue is has not been analysed yet by either Spain, Germany, the United Kingdom of the European Commission. Additional, personal proposal: This exception should only apply if regulated sampling methods do not provide rules for sampling of individual items.
Challenge 10: Enforcing food law	Once non-compliance is established, measures can include ordering the cessation of e-commerce.	When to order cessation and to place a NTD?	The order of cessation can only be applied to those situations where it would be recommended to temporary close a store in the brick-and-mortar market. Thus, not any situation of non-compliance allows for ordering cessation of activities online. Although Germany and the United Kingdom use NTD frequently, this option should only be used once proper administrative measures have failed, or if prompt action is required to contain or eliminate risk.

CONCLUSIONES Y PROPUESTAS

La legislación alimentaria ha contribuido significativamente a conseguir un alto nivel de seguridad y calidad en mercado de alimentos europeo, dotando a los poderes públicos de herramientas para anticipar y contener posibles riesgos para los consumidores, los animales o el medio ambiente. No obstante, los sistemas de control parecen no adaptarse a la realidad del mercado digital que ahora afianza su despegue.

Realizar controles sobre las ofertas de productos alimenticios disponibles en Internet o de aplicaciones digitales (@limentos) plantea retos importantes a las autoridades encargadas de verificar el cumplimiento de la legislación alimentaria, y por lo tanto para conseguir que el mercado digital tenga un nivel de seguridad y calidad equivalente al que ha conseguido el mercado tradicional (físico).

Del trabajo de investigación realizado para elaborar esta tesis doctoral, se deducen una serie de Conclusiones y Propuestas que se resumen a continuación:

1. CONCLUSIONES RESPECTO DEL MERCADO DIGITAL DE ALIMENTOS

1.1 El mercado digital no es un reflejo del mercado tradicional, sino una dimensión alternativa con características propias.

Las normas comunitarias y nacionales que regulan control oficial de los alimentos están diseñadas sobre el modelo del mercado tradicional, un mercado que ha avanzado al ritmo de la civilización y que, tras siglos de esfuerzo, ha conseguido poner orden en la oferta y compra de alimentos al igual que ha ocurrido con la del resto de bienes y servicios. Así, los explotadores del sector agroalimentario (concepto empleado en la legislación para identificar a las empresas alimentarias responsables de cumplir con las obligaciones derivadas de la legislación alimentaria en cada momento de la cadena) reconocen que el Derecho Alimentario les obliga a comprobar de forma sistemática que sus productos son seguros, y que cumplen con todos los requerimientos de la legislación alimentaria. La legislación establece sistemas de control de riesgos, por ejemplo, en cuanto a la manipulación y almacenamiento de alimentos frescos y altamente perecederos. Se prohíbe el uso de determinadas sustancias en alimentos, por ser consideradas no seguras.

La capacidad de control actual de las autoridades, unida al coste que tienen para un explotador las informaciones acerca de sus posibles incumplimientos, ha favorecido el compromiso de todos los actores de la cadena alimentaria con el cumplimiento de la ley.

Sin embargo, esto no ocurre así en el mercado digital y se constata que:

a. Una proporción importante de explotadores que operan exclusivamente en Internet parece estar actuando fuera del radar de las autoridades competentes.

La normativa de la Unión Europea obliga a los explotadores del sector alimentario a registrar sus establecimientos ante las autoridades competentes para poder ofrecer sus productos legalmente y, además, aquellos que manipulen productos especialmente sensibles -como los de origen animal-, deben solicitar una autorización previa a la actividad. Ello permite a la autoridad de control identificar quién introduce alimentos en el mercado nacional y plantear programas de control de acuerdo con esta información.

Pero gran parte de los explotadores que no operan en el mercado tradicional de alimentos sino en el de @limentos, no cumplen con este importante trámite administrativo y no existen por lo tanto a los ojos del control oficial. Puesto que un sistema de control oficial eficaz e imparcial requiere una comprensión precisa de las características de la cadena alimentaria y del mercado en un territorio, deben tomarse medidas para identificar a los explotadores activos y forzar el registro de sus establecimientos.

Para lograr un control efectivo, las autoridades competentes deben mapear el mercado digital de alimentos mediante la identificación de aquellos explotadores activos en el mercado. Para ello, se debe mejorar la tasa de registro de sus establecimientos.

b. En el mercado digital cambian los parámetros para de determinación del riesgo.

Tal y como analiza esta tesis, los suplementos alimenticios y los productos alimenticios frescos y perecederos comprados en el mercado digital presentan una mayor tasa de incumplimiento del Derecho Alimentario que los mismos productos comprados en una tienda tradicional. Frecuentemente, los suplementos

alimenticios incorporan sustancias prohibidas por el derecho europeo y los alimentos frescos no son manipulados con arreglo a las reglas de higiene y seguridad de los alimentos (por ejemplo, asegurando el mantenimiento de la cadena del frío), por lo que su consumo conlleva importantes riesgos para la salud de los consumidores.

Si bien estos productos ya son considerados sensibles en el mercado tradicional, cuando son puestos a disposición de los consumidores a través de plataformas digitales, el riesgo para la salud de los consumidores aumenta. Este riesgo aumenta ya que, puesto que el establecimiento del explotador ha escapado al control de la autoridad, el producto ha llegado al mercado sin que se haya podido verificar el cumplimiento de las diversas normas de seguridad, higiene, integridad e identidad.

Como se analiza en el Capítulo 3 de esta tesis, las autoridades de Alemania y del Reino Unido han llegado a la conclusión de que las altas tasas de incumplimiento y no registro a menudo no se deben a la voluntad deliberada de incumplimiento, sino que derivan del desconocimiento de la ley por parte de los explotadores. La experiencia de estos dos Estados Miembros muestra hasta qué punto puede influir sobre los explotadores digitales la información y asesoramiento prestado por la Administración.

Para conseguir alcanzar niveles aceptables de seguridad y calidad en el mercado digital las autoridades competentes deben invertir tiempo en contactar individualmente y educar a los explotadores de empresas alimentarias sobre sus obligaciones legales. En un marco en el control oficial está plagado de obstáculos que solamente pueden ser solventados de forma creativa, el contacto directo puede mejorar significativamente la seguridad y la calidad de los @limentos.

Por lo tanto, las autoridades competentes debe ser mejorar la seguridad y la calidad de las ofertas de *@limentos* para equiparar este nuevo mercado al tradicional. Para ello, los planes de control oficial deben adaptar su evaluación del riesgo a las características descritas.

1.2 En el mercado digital entran en juego nuevos actores que influyen indirectamente en la seguridad y la calidad de los productos disponibles.

De acuerdo con el Derecho Alimentario europeo, todo aquel que lleve a cabo una actividad relacionada con cualquiera de las etapas de la producción, la transformación y la distribución de alimentos es considerado explotador de empresa alimentaria y como tal debe registrar sus establecimientos ante las autoridades competentes. Ello supone, entre otros, que una gran superficie que distribuye alimentos de un tercero, o aquel que almacena temporalmente la mercancía, forma parte de la cadena alimentaria y es considerado explotador obligado al registro. Por lo tanto, debe velar por que se cumpla el objetivo último del derecho alimentario europeo: que los productos alimenticios puestos a disposición del ciudadano sean seguros. Incluso un bróker (aquel que no llega a tomar posesión de los alimentos que compra y vende a un tercero) es considerado un explotador de empresa alimentaria y por lo tanto debe cumplir con todas las obligaciones establecidas en la ley.

En cambio, cuando un explotador de empresa alimentaria oferta sus productos a través de plataformas digitales (como *Amazon*, *eBay*, *Alibaba* o *Facebook*) la plataforma es considerada legalmente un intermediario que no tiene responsabilidades respecto del contenido ofertado. La plataforma ofrece un servicio de la sociedad de la información, no forma parte de la cadena alimentaria. En base a la Directiva del Comercio Electrónico, las plataformas no tienen obligación de supervisar el contenido que almacenan. Sus responsabilidades empiezan únicamente cuando obtienen información de que almacenan un contenido ilegal identificado de forma individualizada (no sirven advertencias generalizadas).

Además, se ha constatado que existen abundantes plataformas digitales que facilitan que los particulares oferten alimentos. La diversidad de las ofertas es importante: desde pan casero a menús completos, pasando por ofertas de productos frescos adquiridos en un establecimiento tradicional que se sabe no se va a consumir a tiempo. Pero, en la mayoría de plataformas, la frontera entre la oferta particular y la profesional es difícil de identificar, hasta el punto que a menudo no es posible distinguir si una oferta corresponde a un particular o a un profesional. En estos casos, resulta sumamente difícil y en ocasiones imposible distinguir entre una y otra, por lo que un consumidor podría confundirlas.

Por lo tanto, las autoridades de control deben clarificar el papel debe jugar el control oficial respecto de las ofertas de particulares. Para ello, deben evaluar si se mantienen fuera de su ámbito de aplicación aquellas actividades de particulares que no tengan "una cierta continuidad de las actividades y un cierto grado de organización", de acuerdo con el Considerando 9 del Reglamento 852/2004, y de ser así abordar cómo contener los riesgos para la salud humana derivados de estas ofertas.

1.3 A pesar de que el comercio electrónico es un fenómeno trasnacional, es posible equiparar el nivel de cumplimiento del mercado digital con el del mercado tradicional, si cada autoridad competente controla aquellos operadores con establecimientos dentro de jurisdicción.

Los datos obtenidos por las autoridades alemanas -analizados en la Parte 1 del Capítulo 3 de esta tesis-, sugieren que entre aquellas ofertas no conformes a derecho a las que accede el consumidor mediante motores de búsqueda populares, más de la mitad son responsabilidad de explotadores cuyos establecimientos se sitúan dentro del Estado Miembros. Del resto, la mayoría proviene de otro país de la Unión Europea y solo entorno al 15% depende de un explotador situado en un tercer país. Estos datos han sido recientemente confirmados a nivel de la Unión Europea gracias al plan de control coordinado llevado a cabo en otoño de 2017 y analizado en el Capítulo 4 de esta tesis.

En contra de la creencia instalada, a pesar de que el mercado digital de alimentos es un fenómeno transnacional, al controlar los establecimientos dentro de su territorio las autoridades competentes podrían controlar más de la mitad de las ofertas no acordes a Derecho dirigidas a sus ciudadanos. A diferencia con lo que ocurre para otros bienes de consumo, en la Unión Europea los consumidores suelen preferir adquirir productos sino locales, que ha puesto en el mercado una empresa a la que identifican, presente en su comunidad. Por eso carnicerías de barrio, verdulerías y cadenas de supermercado han dado el salto al mercado digital.

Por lo tanto, si todos los Estados miembros cumplen su cometido, solo una pequeña proporción de las ofertas no conformes quedarán sin control en Europa y requerirían la colaboración de terceros Estados para su eliminación.

2. CONCLUSIONES SOBRE EL MARCO JURIDICO

2.1 A pesar de que el sistema de control oficial se construye a partir de un reglamento de la Unión Europea, las decisiones finales –empezando por las normativas-radican en los Estados Miembros.

Los reglamentos (actual y futuro) de la Unión Europea establecen los principios básicos que rigen la organización, planificación y ejecución del control oficial, dejando un alto grado de discrecionalidad a los Estados Miembros para regular y ejecutar los pormenores concretos dentro de su territorio. El objetivo de la norma europea es establecer un marco jurídico armonizado para garantizar la coherencia. No obstante, las inspecciones, como cualquier otra actividad de control, son llevadas a cabo por las autoridades competentes de acuerdo con los procedimientos definidos en la legislación de los Estados miembros, lo cual confiere a cada Estado una decisiva facultad de decisión. El papel de la Comisión Europea es fundamentalmente el de coordinar la actuación de los Estados, y proporcionar apoyo en el diseño de políticas públicas de control oficial.

Es en la normativa estatal en la que se enraízan gran parte de los obstáculos legales al control oficial de @limentos. En el ámbito del control oficial de @limentos, la actividad de coordinación y soporte de la Comisión Europea, en lo que respecta al control oficial de los alimentos ofertados en el mercado digital, se ha nutrido de las iniciativas de los Estados Miembros y, en particular, de Alemania. Como ha puesto de manifiesto el estudio comparado realizado en esta tesis, la normativa española y alemana prohíbe *de facto* la toma de muestras sobre aquellos productos que se obtengan mediante técnicas de compra misteriosa. Además, la regulación en estos dos países y en el Reino Unido no exige a los explotadores de la empresa alimentaria proporcionar información sobre su actividad en el mercado digital, a pesar de que la regulación europea sí lo admitiría.

Por lo tanto, a pesar de que el comercio de alimentos se desarrolla en un mercado único Europeo, y que la normativa alimentaria opta por lo general por la armonización, el control oficial se lleva a cabo en base a la normativa de Estado Miembro en el que se realiza una tarea de control.

- 2.2 El nuevo Reglamento de control oficial proporciona un marco legal adecuado para realizar controles oficiales de @limentos.
 - a. En primer lugar, el Reglamento 625/2017, que entra en vigor a partir del 14 de diciembre de 2019, mejora la capacidad de las autoridades competentes para identificar a los explotadores de empresas alimentarias activos en el mercado digital de alimentos, ya que incorpora de forma expresa la obligación de proporcionar información sobre las actividades relacionadas con el comercio electrónico. Si bien la norma europea no establece cómo ni cuándo debe darse cumplimiento a esta obligación, lo más eficaz es que este dato se facilite en el momento de alta en el registro de establecimientos alimentarios. Para ello, es necesario únicamente que las autoridades competentes modifiquen los formularios de registro, sin que sea necesario cambiar la ley.
 - b. En segundo lugar, la nueva regulación garantiza que las autoridades competentes en todos los Estados miembros puedan adquirir @limentos con fines de control oficial utilizando técnicas de compra misteriosa, en las que la autoridad crea una personalidad ficticia para evitar que la empresa advierta que está siendo investigada. El Reglamento aclara igualmente que no atenta contra los derechos de los explotadores no estar presente en el momento de la toma de muestra, y señala que es acorde a Derecho que el explotador solo reciba información del control una vez que se ha adquirido la muestra. Esta es una facilidad importante, ya que el personal de control en numerosos Estados de la Unión Europea ha expresado activamente sus dudas respecto de estas prácticas tan necesarias para garantizar que las actividades de control sean eficaces. Y es que, si la autoridad encarga un e-alimento en su propio nombre, es posible que el explotador se vea tentado a manipular la muestra.

La normativa de varios Estados Miembros establecía la obligación de realizar la toma de muestra en presencia del explotador como salvaguarda de sus derechos, puesto que las actas de inspección y de muestreo ostentan una presunción de veracidad. Por lo tanto, *cuando se elimine este requisito*, *la autoridad competente deberá modificar sus protocolos para asegurar que se ponen nuevas salvaguardas*. Por ejemplo, realizando una grabación del

proceso de toma de muestra, o exigiendo la presencia de otro testigo. De lo contrario, la capacidad del explotador de verificar y contrastar lo adecuado del procedimiento se verá gravemente disminuida.

Como ha puesto de manifiesto el estudio comparado realizado en esta tesis, la normativa española y alemana prohíbe *de facto* la toma de muestras sobre aquellos productos que se obtengan mediante técnicas de compra misteriosa. Además, la regulación en estos dos países y en el Reino Unido no exige a los explotadores de la empresa alimentaria proporcionar información sobre su actividad en el mercado digital, a pesar de que la regulación europea sí lo admitiría.

c. En tercer lugar, el nuevo Reglamento proporciona una base legal para que las autoridades competentes ordenen a los explotadores el cese en la oferta de alimentos en línea durante un período de tiempo específico, como respuesta a incumplimientos de la legislación alimentaria y si las circunstancias así lo aconsejan. Con esta medida, se equiparan las facultades de la autoridad competente en relación con la tienda en línea puede quedar sujeta a órdenes de cese temporal de actividad como si fuera una tienda minorista.

Sin embargo, los Estados Miembros tienen la tarea pendiente de regular en qué circunstancias procede ordenar el cese de la actividad digital, como ocurre con la orden de cierre de instalaciones propia del mercado tradicional y que suele exigir la comisión de una infracción grave de la normativa alimentaria. A partir del 14 de diciembre de 2019, las autoridades competentes en todos los Estados miembros podrán de aplicar esas medidas en virtud del principio de aplicación directa de los reglamentos de la Unión Europea.

Por lo tanto, no será necesario esperar a modificaciones de la legislación nacional, la cual quedará tácitamente derogada. Ello no es baladí, en tanto que como se ha analizado en los Capítulos 2 y 4 de esta tesis, los Estados Miembros optaron en su día por regular a nivel nacional cómo debían detallarse las previsiones legales del Reglamento 882/2004, generando por el camino requisitos no previstos en la norma comunitaria.

2.3.Los Estados Miembros no tienen que esperar a que se aplique la nueva regulación de controles oficiales para mejorar sus capacidades de control sobre los @limentos.

Curiosamente, la contribución del Reglamento 625/2017 al control de los alimentos electrónicos no ha sido crear un marco jurídico en la UE. En una mirada más cercana, se aprecia que la ventaja de la regulación es esclarecer con mayor detalle las capacidades de las autoridades competentes en el mercado único digital. El objetivo de estos cambios normativos es el de eliminar aquellos obstáculos al control oficial enraizados en la normativa de los Estados Miembros.

- a. En primer lugar, el marco legal comunitario actual ya proporciona una base legal para que las autoridades competentes soliciten información sobre las actividades relacionadas con el comercio electrónico. El Reglamento 852/2004 establece que "los explotadores de empresas alimentarias también garantizarán que la autoridad competente siempre tenga información actualizada sobre los establecimientos, incluso notificando cualquier cambio significativo en las actividades y cualquier cierre de un establecimiento existente". Como se analiza en esta tesis, no especifica cómo clasificar las actividades. Las regulaciones nacionales en España, Alemania y el Reino Unido también son vagas respecto del concepto de "actividad" y suelen utilizar categorías poco precisas como envasado, fabricación, almacenamiento y distribución, filtrando además por categorías amplias de alimento (como por ejemplo, "envasado de productos de la pesca"). Ante tal falta de concreción, en los tres Estados miembros sería posible crear una nueva categoría de actividad complementaria referida al comercio electrónico.
- b. En segundo lugar, la posibilidad de tomar muestras de forma anónima e informar al explotador después de la obtención de la muestra, también es posible en virtud de la legislación vigente de la UE. El Reglamento 882/2004 únicamente establece que es competencia de los Estados Miembros definir un procedimiento de toma de muestra adecuado para salvaguardar el derecho de las empresas a solicitar un dictamen de expertos. Sin embargo, la redacción de la legislación nacional crea en varios países obstáculos no previstos en el marco europeo. Las

disposiciones en España y Alemania, por ejemplo, afirman que la muestra debe tomarse "ante el explotador" o que "el funcionario público debe identificarse" antes de tomar la muestra, lo que genera desafíos innecesarios a las autoridades competentes que buscan realizar compras de prueba adecuadas para su cumplimiento. Otros Estados, como el Reino Unido, indican por el contrario que es necesario que haya un testigo durante la toma de muestras que asegure la autenticidad del contenido del acta de muestreo, y que basta con informar al explotador de que ha sido sometido a muestreo "tan pronto como sea posible." Modificar ya la norma nacional en España o Alemania facilitaría la compra misteriosa y por ende el control material de los @limentos en la fase de distribución.

c. En tercer lugar, la orden de cese de las ofertas digitales ya es factible con el Reglamento 882/2004. El Reglamento establece que una vez haya quedado acreditado el incumplimiento de la legislación alimentaria, las medidas que puede tomar la autoridad incluyen "cualquier otra medida que la autoridad competente considere apropiada". Una vez más, es la regulación nacional la que ha puesto las piedras bajo las ruedas de las autoridades: generalmente la norma nacional hace una lista de las medidas que pueden adoptarse en caso de incumplimiento y no se refieren al cese de las ventas en línea.

Por lo tanto, según todo lo anterior, la modificación de determinados preceptos legales nacionales, o incluso solamente de los protocolos adoptados por las autoridades de control, pueden resolver en gran medida los obstáculos que impiden el control oficial de los @limentos, ello sin necesidad de esperar al 14 de diciembre de 2019.

3. PROPUESTAS DE ACTUACIÓN PARA LOS ESTADOS MIEMBROS

3.1. Respecto del control oficial de los @limentos ofrecidos por particulares:

Ni la Comisión Europea ni los Estados Miembros ha tratado la cuestión de cómo integrar las ofertas de @limentos de los particulares en el control oficial. Como se analiza en la sección—del Capítulo 1, el Derecho alimentario europeo se aplica a todos los alimentos puestos a disposición de los consumidores, independientemente de quién sea responsable de dicho producto. Los alimentos que ofrecen los particulares deben ser seguros, y únicamente quedan exentos de cumplir con la normativa de higiene europea. Por lo tanto, el control oficial debe incluir las ofertas entre particulares.

Pero, ¿cómo pueden las autoridades competentes organizar actividades de control sobre si no tienen información precisa sobre quién ofrece qué alimentos a través de plataformas de comercio entre particulares? Los particulares no están obligados a registrarse a pesar de tener la consideración de explotadores alimentarios, y la información que aportan las plataformas digitales sobre la identidad del responsable de la oferta no son suficientes para planificar un control sistemático sobre los explotadores activos. Es por ello que los planes de control oficial deben identificar aquellas plataformas que son más populares entre los consumidores, e incluir entre las actividades el monitoreo regular de las ofertas publicadas en la plataforma. La organización del control oficial eficaz sobre el comercio entre particulares depende por tanto de la identificación de aquellas plataformas que permiten el comercio de alimentos entre particulares.

Las autoridades competentes extreman sus desvelos para analizar, caso por caso, qué particulares deberían ser controlados como explotadores profesionales. Su preocupación se basa, principalmente, no en poder exigir el cumplimiento de los estrictos controles microbiológicos de la normativa de higiene, sino en exigir que el particular se registre para poder organizar el control. La normativa Europea únicamente declara que quedan fuera del ámbito de aplicación de los reglamentos de higiene aquellas iniciativas que impliquen "una cierta continuidad" (una vez al mes, según el Reino Unido) y "un cierto grado de organización." Sin embargo, esta resbaladiza cuestión perderá relevancia y

quedará en un segundo plano si las autoridades se centran en organizar el control identificando a las plataformas activas en lugar de a sus usuarios.

3.2. Respecto de cómo "mapear" el mercado digital

Como se ha puesto de manifiesto en repetidas ocasiones a lo largo de esta tesis, control oficial eficaz e imparcial requiere una comprensión precisa de las características de la cadena alimentaria y del mercado en un territorio, por lo que las autoridades deben tomar medidas para identificar a los explotadores activos y forzar el registro de sus establecimientos. Tal y como se analiza en la sección 1.3.2 del Capítulo 2 de esta tesis, la identificación de los explotadores activos y de sus establecimientos es indispensable para mejorar la seguridad y la calidad del mercado, puesto que es visitando dichos establecimientos que las autoridades pueden obtener un mayor impacto derivado de su actividad inspectora. Al controlar el mercado en la fase de producción (en el establecimiento), no solamente se verifica la conformidad a Derecho de unos pocos productos sino que (entre otros) se comprueba el funcionamiento general del establecimiento, la formación y capacitación de los empleados, y se comprueba las condiciones higiénicas en las que se manipula el producto. Si la autoridad desconoce la localización del establecimiento, la única posibilidad de control está en la distribución.

1. Las autoridades competentes deben tener un papel proactivo para identificar explotadores digitales y sus establecimientos.

Para ello, deben buscar activamente información que permita dicha identificación utilizando los datos disponibles en la página web en la que se almacena la oferta, y cruzar la información obtenida con la habida en otras fuentes. Por ejemplo, si el explotador se identifica con el nombre de la empresa en la pestaña de "Contacto" de la oferta (cosa que debería hacer puesto que así lo exige el Derecho Alimentario y la normativa en materia de consumidores y la de comercio electrónico) puede utilizar dicho nombre para constatar si existen establecimientos registrados a nombre de dicha empresa y así localizar el origen de su actividad. En caso negativo, puede utilizar datos de acceso abierto (información web, noticias, o registro mercantil) para identificar la sede o las oficinas de la empresa, ponerse en contacto e instar al registro. En cuanto a los detalles técnicos para el monitoreo, se recomienda consultar la guía para autoridades locales emitida por la Food Standards Agency del Reino Unido, disponible en acceso abierto, que detalla el

- software y equipamiento adecuado para realizar esta actividad así como buenas prácticas de investigación.
- Cuando una autoridad competente tenga conocimiento de que un explotador está presente en el mercado digital, su sistema de gestión de la información debería reflejar este dato.
 - Siguiendo el ejemplo del Reino Unido, debe valorar la creación de un código que permita identificar a estos explotadores y así poder organizar planes de control *ad hoc*. Este sistema maximizaría el uso de la información que obtienen las autoridades en los controles llevados a cabo de forma rutinaria en establecimientos alimentarios del mercado tradicional.
- 3. Es necesario modificar los formularios de registro para incluir como actividad desarrollada en dependencia de dicho establecimiento la oferta electrónica.
 - A pesar de existir amplio margen para recabar información pormenorizada, a día de hoy los formularios no requieren que el explotador indique si opera online a pesar de que este dato es valioso para el control oficial. El objetivo de esta propuesta es facilitar que todos aquellos establecimientos registrados en el futuro y que participen en el comercio electrónico estén incluidos desde el primer momento en los planes de control oficial.
- 4. La búsqueda de información para el monitoreo puede llevarse a cabo de forma manual, o pueden diseñarse como es el caso en Alemania estrategias de monitoreo automático.
 - Las opciones de búsqueda manual o automática de información sobre la identidad del explotador no son mutuamente excluyentes por lo que cuando los Estados miembros diseñen su estrategia para el control del comercio electrónico, se debe considerar ambas técnicas. Dado el tiempo y la dedicación de recursos que exige la búsqueda manual, un software automatizado que procesa búsquedas mediante palabras clave puede resultar operativo si bien el coste económico derivado de su obtención puede ser elevado. Sin embargo, debe tenerse en cuenta de que el uso de datos de software automatizado pensado para otra rama de la administración puede requerir la adopción de acuerdos legales que regulen quién puede acceder a los datos y cómo se pueden usar al pasar a manos de las autoridades competentes en materia de derecho alimentario.

3.3. Respecto de la priorización de las actividades de control

Las autoridades competentes en materia de control oficial cuentan con recursos humanos y técnicos limitados, por lo que se busca optimizar el resultados de las actividades de control poniendo más recursos en aquellas áreas en las que pueden tener un mayor impacto. En base a lo analizado en este trabajo de tesis doctoral, se puede constatar y proponer que:

- 1. Deben centrarse en la supervisión y el control de las ofertas presentadas por explotadores legítimos, al igual que ocurre en el mercado tradicional de alimentos.
 - La popularidad y la existencia de ofertas susceptibles de ser constitutivas de delito pueden abrumar a las autoridades, pero el control de éstas debe preferiblemente dejarse en manos de las fuerzas de seguridad del Estado o de aquellos cuerpos encargados de crímenes alimentarios en aquellos Estados Miembros en los que existan.
- 2. Las autoridades competentes deben priorizar el monitoreo y control material de aquellos alimentos que son responsabilidad de un explotador que se encuentra dentro de su jurisdicción territorial.

A pesar de que legalmente la autoridad es competente para controlar cualquier oferta dirigida a sus ciudadanos, la capacidad para exigir el cumplimiento de la ley si se determina un incumplimiento es limitada cuando el explotador y sus establecimientos se hayan fuera del territorio nacional. Por un lado, una autoridad competente únicamente está autorizada a controlar los establecimientos sitos en su territorio, por lo que si para determinar un incumplimiento se requiere una visita al establecimiento será necesario poner en marcha sofisticados mecanismos de cooperación administrativa en los que la autoridad de otro Estados se persone en dichos locales. Por el otro, si se decide a controlar materialmente un alimento adquirido a distancia y se acredita su no conformidad, la capacidad de la autoridad para exigir el cumplimiento de la ley y de sus resoluciones disminuye.

Por lo tanto, si durante el monitoreo de ofertas sensibles se localiza un alimento sospechoso de entrañar riesgos pero que proviene de fuera de un establecimiento sito fuera de la jurisdicción, la información recopilada durante el monitoreo debe transmitirse a la autoridad competente correspondiente, evitando así asignar

- recursos económicos y personales en acciones de control que difícilmente terminarán con el restablecimiento de la legalidad.
- 3. El monitoreo y los controles materiales deben priorizar las ofertas de @limentos de los tres grupos previamente identificados como de mayor riesgo: los suplementos alimenticios y nuevos alimentos no autorizados, los alimentos frescos o perecederos, y aquellos identificados como "de la economía colaborativa." Como se analiza en el Capítulo 1 de esta tesis, las ofertas que se encuentran en cualquiera de estas categorías entrañan riesgos importantes para la salud de los consumidores, por lo que es urgente actuar para contener sus efectos negativos.
- 4. Las actividades de control deben priorizar las ofertas que aparecen en la primera página de resultados en un motor de búsqueda popular. Puesto que el 95% de los usuarios no llega a visualizar los resultados de la segunda página, garantizar que aquellas ofertas mejor posicionadas son acorde a Derecho puede mejorar significativamente la seguridad y calidad general del mercado. Un enfoque basado en el riesgo debe priorizar esas ofertas. Se debe prestar atención al uso de términos de búsqueda similares a los que un consumidor promedio suele usar.

3.4. Respecto del control material de los @limentos en la fase de distribución

Si bien las actividades de control en la fase de distribución tienen un papel secundario en el mercado tradicional de alimentos, éstas adquieren un papel fundamental en el mercado digital. Y es que si gran parte de los establecimientos no pueden ser controlados ya que no se conoce su existencia, omitir controles en la distribución supone no realizar control alguno sobre el mercado digital. Sin embargo, como se ha analizado a lo largo de esta tesis, las autoridades competentes se enfrentan a obstáculos a la hora de llevar a cabo controles materiales de @limentos garantizando al mismo tiempo el cumplimiento del marco jurídico actual. Dicho marco exige que los controles deben llevarse a cabo sin aviso previo al explotador, pero asegurando sus derechos de defensa, para lo que se establece la obligación de documentar la totalidad del proceso y, en el caso de los controles materiales que pueden derivar en un control analítico, la obligación de asegurar que la toma de muestras se realiza con arreglo a un proceso legalmente establecido que permitirá repetir la prueba analítica en caso de que la integridad de la muestra se vea comprometida

o que el explotador quiera ejercer lo que se conoce como su "derecho a una segunda opinión de experto."

- 1. Es necesario asegurar que la adquisición de @limentos para fines de control oficial no revela la identidad de la autoridad competente, para lo que se necesita hardware y software que permita realizar la compra por una personalidad ficticia y sin mostrar la localización del comprador. La guía para autoridades locales emitida por la Food Standards Agency del Reino Unido, disponible en acceso abierto, que detalla el software y equipamiento adecuado para realizar esta tarea. Si el explotador puede identificar que la autoridad le está controlando, se pone en riesgo la eficacia de la actividad de control.
- 2. En aquellos Estados en los que la normativa nacional establezca que el explotador esté presente en la toma de muestras (requerimiento que seguirá vigente hasta Diciembre de 2019), deben buscarse métodos creativos para superar este obstáculo. Por ejemplo, es posible organizar la entrega de la compra misteriosa en un apartado de correos o en un punto "click and collect" y no recoger ni manipular el envío hasta no notificar al explotador, para que pueda decidir si quiere estar presente en el momento de la apertura.
- 3. Los Estados miembros deben establecer un sistema para documentar el proceso de control material, desde la realización del pedido hasta la manipulación de la muestra obtenida. Esta documentación del proceso es necesaria para cumplir con el Reglamento 882/2004 y garantizar el derecho de defensa del explotador implicado. De nuevo, la guía para autoridades locales emitida por la Food Standards Agency del Reino Unido, disponible en acceso abierto, detalla el software y equipamiento adecuado para realizar esta tarea.
- 4. Las autoridades competentes deben velar por encargar suficiente producto para garantizar la validez de la muestra con arreglo a los métodos de muestreo actuales. Tal y como se indica en el Capítulo 2 de esta tesis, existen métodos de muestreo legalmente establecidos que requieren que la muestra se obtenga a partir de una determinada cantidad de producto envasado. De no respetarse las reglas de muestro, la muestra obtenida para el control analítico no es válida a efectos de control oficial.

3.5. Respecto de las acciones en caso de incumplimiento

Las actividades de monitoreo y control material tienen por objetivo verificar el cumplimiento de la normativa alimentaria para mejorar la seguridad y calidad del mercado digital de alimentos. En este sentido, el hecho de que las autoridades competentes puedan exigir el cumplimiento de la ley una vez determinado el incumplimiento es fundamental.

Una vez haya quedado acreditado que un explotador o sus productos incumplen la normativa alimentaria aplicable, la autoridad competente debe adoptar aquellas medidas previstas en la legislación del Estado Miembro. Estas medidas incluyen la destrucción de la mercancía, el cierre de las instalaciones, o, a partir de Diciembre de 2019, el cese de sus actividades en el mercado digital. Todas estas decisiones deben tomarse siguiendo el procedimiento administrativo establecido en la normativa vigente.

La autoridad competente puede, además, utilizar otros mecanismos para asegurar el cumplimiento de la ley y la eliminación de ofertas no conformes. Estas medidas pueden ser utilizadas cuando sea necesario actuar con rapidez para eliminar o contener los riesgos,

Las autoridades competentes pueden usar las Notice and take-down procedures (solicitudes de retirada de contenido) habilitadas por las propias plataformas para obtener la eliminación rápida de las ofertas que manifiestamente incumplen el derecho alimentario. Las NTD son una herramienta desarrollada por los intermediarios digitales por la que aceptan eliminar contenido ilegal a petición de un tercero, sin que sea necesario acreditar legalmente que dicha ilegalidad existe. Debe tenerse en cuenta que los intermediarios pierden su exención de responsabilidad secundaria si no eliminan los contenidos ilegales rápidamente tras ser informados según dicha normativa.

3.6. Respecto de la decisión de centralizar el control oficial de los @limentos

1. Los Estados miembros deben decidir si mantienen el reparto de responsabilidades en el control oficial propio del mercado tradicional o bien si centralizan parte de las tareas de control en un único ente. Tal y como analiza el Capítulo 3 de esta tesis, esta ha sido la opción elegida por Alemania desde 2011, en donde la unidad

central G@zielt realiza las tareas de monitoreo del mercado y control material de @limentos en exclusiva y luego transmite los resultados obtenidos a la autoridad competente en cada uno de los *länder*. Esto ha permitido optimizar recursos y crear un cuerpo especializado en control digital pionero en el mundo, pero también ha supuesto que las autoridades competentes renuncien a parte de su capacidad de control y transfieran fondos al gobierno central para financiar las operaciones de G@zielt.

- 2. Los Estados miembros deben tener en cuenta las implicaciones políticas que implica el control centralizado ya que optar por la centralización puede generar una gran reticencia y afectar el funcionamiento adecuado de una unidad central. Dado que la Comisión Europea ha evitado posicionarse sobre qué forma es más adecuada de organizar el control oficial de alimentos, los Estados Miembros no deben decidir si centralizar el control exclusivamente en base a cuestiones de eficacia operativas. Esta decisión debe tener en cuenta que pueden darse circunstancias políticas que desaconsejen la actuación centralizada.
 - Además, como se ha indicado en el Capítulo 3, la unidad alemana se pronunció, ya en 2016, a favor de crear una única "unidad central de investigación" para el territorio europeo financiada por todos los Estados miembros. Dicha unidad debería ocuparse de las ofertas en todos los idiomas de la UE y realizar búsquedas en línea y luego enviar información relevante sobre el incumplimiento a las autoridades competentes de cada Estado miembro, o podría entrar directamente a exigir su aplicación.
- 3. Futuras investigaciones deben considerar cuidadosamente las implicaciones, la conveniencia y la viabilidad de esta propuesta, dado que cuenta con el aval de la unidad central alemana, cuyo responsable dirige hoy la política europea al respecto.

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