Wageningen MSc. Thesis

Endocrine Disruptors in Food Contact Materials

How can the revision of Regulation (EC) 1935/2004 more effectively address endocrine disruptors in food contact materials and thereby contribute to the EU Green Deal's aims of ensuring food safety and protecting public health?

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The process of writing this thesis has been a journey in which I have learned a lot. Not only about the chosen subject, but also about myself. About underlying patterns and personal challenges, offering opportunities for growth

In these uncertain times, both globally and personally, this thesis has been a stable factor, and letting go of this is not easy for me. It is hard to believe that I am writing the last words of this thesis, but it is time to move on and start a new adventure, with new challenges and opportunities.

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Abstract

This thesis explores how the revision of Regulation (EC) 1935/2004 (FCM Regulation) can more effectively address the presence of Endocrine Disruptors (EDs) in food contact materials (FCMs) and thereby contribute to the EU Green Deal's aims of ensuring food safety and protecting public health. EDs may be present in FCMs as NIAS and can disrupt hormone signaling by mimicking hormones or blocking hormone receptors and can be harmful to human health. Due to their potential to migrate into food, the presence of EDs in FCMs raise concerns regarding food safety. The complex nature of EDs and the multitude of substances present in FCMs, combined with the lack of definition and coherence in the current regulatory EU FCM framework, may affect all actors in the supply chain and could threaten EU public health. The Farm-to-Fork (F2F) Strategy, part of the EU Green Deal, announced the revision of the FCM Regulation to protect public health and improve food safety. In response, the European Commission published an Inception Impact Assessment (IIA) that included a roadmap for the announced revision of the FCM Regulation. Stakeholders and citizens were offered to respond to this IIA. Based on the analysis of the responses to this roadmap, this thesis concludes that in order to effectively address the presence of EDs in FCMs, the revised Regulation should first focus on reducing the administrative burden for all actors in the supply chain prior to implementing more demanding rules. Establishing a foundation that prioritizes the safety of FCMs will ease the subsequent development of measures that encourage sustainable innovation and recyclability, in line with the aims of the EU Green Deal.

Keywords: FCM, Endocrine Disruptors, NIAS, EU Green Deal

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1. Introduction

1.1 Problem description

Endocrine disruptors (EDs) are substances that may interfere with the hormonal and homeostatic systems of humans and other organisms.[1] EDs can be naturally present in our food, such as the phytoestrogens in soybeans, or they can be synthetic, ending up in our food via migration of components in food packaging like bisphenol A or via residues of pesticides like DDT[2]. They can also be found in toys, cosmetics, pesticides, and in furniture.[3] Significant is the presence of EDs in food contact materials (FCMs). FCMs can be identified as materials that come into contact with food during its production, processing, storage, preparation, and serving, before its eventual consumption.[4] Such materials and articles include food packaging and containers, machinery to process food, and kitchenware and tableware.[5] When FCMs contain EDs and come in contact with food, the EDs can migrate into food if the conditions are appropriate, raising concerns about potential risks to food safety.[6]

Exposure to EDs can profoundly impact human health and the environment, such as an increased risk of developing breast cancer, infertility, and animal hermaphroditism[7]. Even though the harmful effects of these substances have been known for over two decades, these chemicals continue to be widely present in various products throughout the European Union (EU)[8].

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[1] Oya Ercan and Gurkan Tarcin, 'Overview on Endocrine Disruptors in Food and Their Effects on Infant's Health' (2022) 2 Global Pediatrics 1,1 <https://doi.org/10.1016/j.gpeds.2022.100019>.
[2] ibid.
[3] European Committee Of the Regions, 'Endocrine Disruptors: European Regions Call for Reliable Information and a Strategy to Protect Citizens and the Environment' (2019) <https://cor.europa.eu/en/news/Pages/Endocrine-disruptors.aspx>. accessed 2 February 2023.
[4] Directorate-General for Health and Food Safety, 'Food Safety' (n.d.) <https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials_en>. accessed 4 August 2023
[5] ibid.
[6] Hooi Theng Ong, Hayati Samsudin and Herlinda Soto-Valdez, 'Migration of Endocrine-Disrupting Chemicals into Food from Plastic Packaging Materials: An Overview of Chemical Risk Assessment, Techniques to Monitor Migration, and International Regulations' (2022) 62 Critical Reviews in Food Science and Nutrition 957,958 <https://doi.org/10.1080/10408398.2020.1830747>.
[7] Caren Leite Spindola Vilela, João Paulo Bassin and Raquel Silva Peixoto, 'Water Contamination by Endocrine Disruptors: Impacts, Microbiological Aspects and Trends for Environmental Protection' (2018) 235 Environmental Pollution 546,546 <https://doi.org/10.1016/j.envpol.2017.12.098>.
[8] European Commission, 'Fourth Annual Forum on Endocrine Disruptors' (2022) <https://environment.ec.europa.eu/events/fourth-annual-forum-endocrine-disruptors-2022-09-21_en>. accessed 31 October 2023

The EU has declared its commitment to enhance the protection of human health and decrease the use of hazardous chemicals such as EDs. This effort is demonstrated by initiatives such as the Chemicals Strategy for Sustainability (CSS) and the Farm to Fork (F2F) strategy, key components of the EU Green Deal.[9] In line with these strategies, the EU seeks to implement measures that reduce exposure to EDs, including reducing exposure via FCMs. To reach these aims and to develop a comprehensive framework for EDs, the European Commission organizes *"an annual Forum on Endocrine Disruptors"*.[10,11]

However, a key challenge lies in defining EDs, which is fundamental for this framework. The existing definition of an ED, as adopted by the European Commission(EC) from the World Health Organization (WHO), is rather broad and susceptible to multiple interpretations. The currently most used definition of an ED provided by the WHO is: *"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations"*.[12] Because of multiple interpretations of this definition, the database of all EDs varies per public authority, both on a national level within the EU and internationally outside the EU.[13] Furthermore, EDs are currently not covered under the hazard classes of the globally harmonized system for classification and labeling of chemicals (GHS)[14], an internationally harmonized standard managed by the United Nations that addresses the classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets.[15] This underlines the limited attention that EDs have received in this global regulatory system.

[9] Lisa Zimmermann and others, 'Implementing the EU Chemicals Strategy for Sustainability: The Case of Food Contact Chemicals of Concern' (2022) 437 Journal of Hazardous Materials 1,1 <https://doi.org/10.1016/j.jhazmat.2022.129167>.
[10] European Commission (n 8).
[11] European Committee Of the Regions (n 3).
[12] Terri Damstra and others, 'Global Assessment of the State-of-the-Science of Endocrine Disruptors' (IPCS/UNEP/ILO/WHO 2002).
[13] Ksenia J Groh and others, 'Overview of Intentionally Used Food Contact Chemicals and Their Hazards' (2020) 150 Environment International 1,2 <https://doi.org/10.1016/j.envint.2020.106225>.
[14] ibid.
[15] United Nations Economic Commission for Europe, 'About the GHS - Globally Harmonized System of Classification and Labelling of Chemicals (GHS)' (n.d.) <https://unece.org/about-ghs>. accessed 26 October 2023

Due to the ambiguity in defining EDs, measuring the toxicity and the exposure of EDs is difficult and thus the regulation of EDs and harmonization of European and domestic laws within the European Union remains a challenging matter.

The revision of Regulation (EC) No 1935/2004

One regulation with a significant impact on the extent to which humans in the EU are exposed to EDs, is Regulation (EC) 1935/2004. This Regulation sets basic EU rules for all FCMs and restricts FCMs to contain substances that migrate into food to an extent that it would endanger human health and sets other rules such as labeling rules and traceability.[16] Since certain FCMs may contain EDs, any revisions to this Regulation could have profound consequences on the level of exposure to EDs.

Unfortunately, the current EU FCM framework has significant shortcomings. The commission indicated an absence of specific EU rules leading to concerns regarding the safety of certain FCMs and issues regarding the internal market; For example, the current EU regulatory FCM framework is not up to date regarding (its) subject matter, lacks the prioritization of the most used hazardous substances, and misses the agility to promptly incorporate new scientific information.[17] Besides, the absence of specific EU rules (other than plastics) and differing national rules results in unequal health protection among EU citizens and the enforcement of rules on FCMs is generally poor.[18] These issues may lead to unwelcome ED exposure. Furthermore, the Commission stated that it is crucial to promote a decrease of harmful substances such as EDs in recycled food packaging as part of the transition towards a circular economy. This is in line with the objective of the Circular Economy Action Plan (CEAP), presented in March 2020, which aims to promote more sustainable product designs, reduce waste, and empower consumers.[19] Thus, the Commission is

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[16] European Commission, 'Inception Impact Assessment - Revision of EU rules on food contact materials' Ares(2020)7731375, 2 (Ares(2020)7731375).

[17] ibid.

[18] ibid.

[19] European Parliament, ' Circular economy: definition, importance and benefits' (2023) <https://www.europarl.europa.eu/news/en/headlines/economy/20151201STO05603/circular-economy-definition-importance-and-benefits?&at_campaign=20234-Economy&at_medium=Google_Ads&at_platform=Search&at_creation=RSA&at_goal=TR_G&at_audience=circular%20economy%20action%20plan&at_topic=Circular_Economy&at_location=NL&gclid=Cj0KCQjw0bunBhD9ARIsAAZl0E38oGneBwQvG4hVGarn2-nejoEARMVthkvv-0mwFsYMC_EM7XD87GMaAuzLEALw_wcB>. accessed 31 October 2023

actively working towards a revision of the current FCM framework to address these issues.

1.2 Research objective

To reach the European Commission's Farm to Fork (F2F) strategy's aim to ensure food safety and public health, and the European Commission's Chemicals Strategy for Sustainability (CSS) aims for a "toxic-free" environment, which are both part of the EU Green Deal, a series of European legislative frameworks need to be revised to minimize the exposure of EDs to humans and the environment.[20]

The proposed revision of Regulation (EC) 1935/2004, which will focus in particular on reducing the use of hazardous chemicals, remains crucial to reach the EU Green Deal's aims of ensuring food safety and protecting public health. The EC published an Inception Impact Assessment (IIA) to inform stakeholders about its plans regarding the revision of EU rules on FCMs with the publication of the revision initially scheduled for the second quarter of 2023, but the adoption is still upcoming.[21] My objective will be to research how regulating EDs via the revised FCM Regulation can contribute to the EU Green Deal's aims to ensure food safety and protect public health. More research regarding EDs regulation via the revised FCM legislation 1935/2004 can contribute to an increased understanding of how the revised FCM regulation can be effectively implemented and interpreted by Member States (MSs) while the demands of different stakeholders are still being taken into account.

1.3 Research questions

Main research question

1. How can the revision of Regulation (EC) 1935/2004 more effectively address endocrine disruptors in food contact materials and thereby contribute to the EU Green Deal's aims of ensuring food safety and protecting public health?

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[20] European Commission, 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' COM (2020) 381 final, 1-2 (EU F2F Strategy).
[21] European Commission, 'Revision of EU Rules on Food Contact Materials' (2023) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en>. accessed 31 October 2023

Sub-questions

2. (Technical) background: What are endocrine disruptors and what risks do they pose on human health?
3. How is the FCM Regulation positioned in the EU Regulatory framework and what material- and substance-specific measures govern food contact materials at the EU level?
4. What regulatory gaps hinder effective management of endocrine disruptors in food contact materials, and how do these gaps affect stakeholders?
5. Which EU policy initiatives have influenced the proposed revision of the FCM Regulation, and what measures addressed in the Inception Impact Assessment are considered most effective for addressing endocrine disruptors in food contact materials, based on stakeholder input?

1.4 Methodology

The methodology section is structured by chapter. Each section sets out what issues will be investigated, what type of research will be applied, and the data sources that will be used.

Chapter 2

The second chapter will present a literature review of the (technical) background of Endocrine Disruptors. Scientific articles about the technical background will be obtained from WUR Library, Scopus, and Google Scholar using the search terms "Endocrine Disruptor" and "Endocrine Disrupting Chemical EU Food Packaging". To provide the most up-to-date information, efforts will be made to only select recent articles where appropriate. Moreover, recent rapports and web pages from Competent Authorities such as the EFSA, NVWA (Dutch Food Authority), and the EC will be selected as information sources. This chapter takes an positivistic approach, based on doctrinal analysis.

Chapter 3

The third chapter will mainly contain legal doctrinal analysis to provide an overview of the rules that are part of the current regulatory EU FCM framework. Primary legal sources of the EC, which can be found on EUR-lex will be considered. For example the EU treaties, Regulation (EC) 178/2002 on General Food Law, Regulation (EU) 2017/625 on Official Controls and Other Official Activities, Regulation (EC) 2023/988 on General Product Safety, Regulation (EC)

1272/2008 on the Registration, Evaluation, Authorization, and Restriction of Chemicals, Regulation (EC) 1935/2004 on Food Contact Materials, Regulation (EC) 2023/2006 and on Good Manufacturing Practices and various EU FCM material-specific and substance- specific EU-level measures. Moreover, a visual figure is included to illustrate the positioning of the FCM Regulation within the broader EU regulatory framework.

Chapter 4

The fourth chapter will entail positive socio-legal theory by incorporating a doctrinal approach to provide an overview of the challenges and regulatory gaps that hinder effective ED management in FCMs, as well as effect theories to describe the consequences of those challenges and regulatory gaps for stakeholders. The analysis will be based on primary legal sources such as EU Regulations, as well as secondary legal sources such as policy reports of competent authorities and EU-provided web pages.

Chapter 5

The initial part of the fifth chapter will adopt a doctrinal and explanatory socio-legal approach to map and analyze various EU policy initiatives related to the EU Green Deal, such as the Farm-to-Fork (F2F) and the Circular Economy Action Plan (CEAP) that led to the announced revision of the FCM Regulation and the publication of the related Inception Impact Assessment . The subsequent part will apply a positive doctrinal socio-legal approach to provide an overview of stakeholders' opinions, followed by a more normative approach to evaluate the best policy direction. Source material includes EC policy documents as well as responses to the IIA published on the Commission's website or shared by stakeholder's organizations.

2. (Technical) Background of Endocrine Disruptors

In this chapter, we dig into the complex world of Endocrine Disruptors (EDs) and their possible effects on human health and wildlife. Initially, a concise explanation of the endocrine system and endocrine disruption is provided. Next, the process of assessing the risk of EDs is outlined, covering hazard identification, hazard characterization, exposure assessment, and risk characterization. Finally, the need for a database regarding EDs is discussed.

2.1 Hormones and the endocrine system

For the body to work properly, different parts of the body must communicate to reach a stable internal environment called homeostasis.[22] Two systems are in place to ensure this communication: the nervous system and the hormonal system, also referred to as the endocrine system.[23] These systems have different functions while complementing and interacting with each other. The nervous system allows rapid communication between various regions of the body, whereas the hormonal or endocrine system operates at a slower pace, relying on the distribution of hormones released from glands throughout the body, and receptors in various tissues that respond to these hormones, figure 1 provides a schematic representation of the major hormone-producing glands of the human body.[24] Endocrine systems are not only found in humans, but also in other mammals, birds, fish, and other species.[25]

It is difficult to define what a hormone is, as shown by the various definitions available; However, most recent definitions mentioned in Starká & Dušková 's article agree that hormones are compounds that act as signaling molecules required in multicellular organisms to carry signals to target tissues.[26] Each hormone regulates the body by connecting its unique receptor to its complementary "target cells", which are activated depending on the amount of

[22] Susanne Hiller-Sturmhöfel and Andrzej Bartke, 'The Endocrine System - An Overview' (1998) 22 Alcohol Health & Research World 153, 153.
[23] ibid.
[24] ibid 154.
[25] United States Environmental Protection Agengy, 'Overview of the Endocrine System' (n.d.) <https://www.epa.gov/endocrine-disruption/overview-endocrine-system#:~:text=Endocrine%20systems%2C%20also%20referred%20to,fish%2C%20and%20many%20other%20species.>. accessed 31 October 2023.
[26] Luboslav Starká and Michaela Dušková, 'What Is a Hormone?' (2020) 69 Physiological Research S183, S184 < https://doi.org/10.33549/physiolres.934509>.

hormone released by the gland, how the hormone is transported, the amount of hormone that reaches the target organ and for how long the hormone can activate its receptor.[27] Hormones play a crucial role in activating and regulating bodily functions such as growth and development, immunity, metabolism, reproduction and behavior.[28] There are different ways in which hormones are distinguished. Endocrine hormones act on cells or organs that are reached through the bloodstream or other aqueous systems, such as the lymphatic system, autocrine hormones act on the cells that also synthesize them, and paracrine hormones act on neighboring cells.[29]

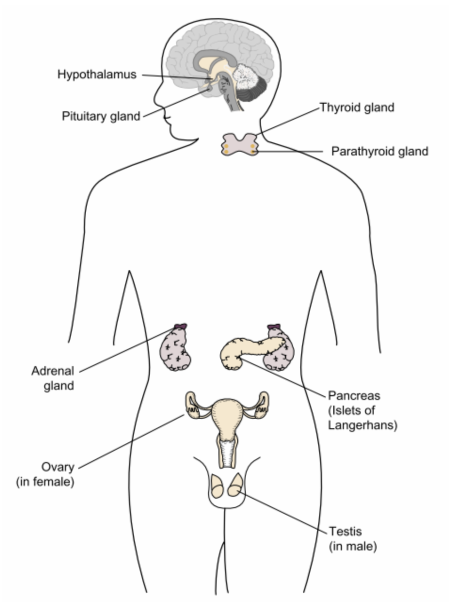

Figure 1: Schematic representation of the major hormone-producing glands in the human body

2.2 Endocrine disruptors

Substances that interact with the endocrine system but do not cause harmful effects are called endocrine active substances.[30] Endocrine active substances can be natural, for example phytoestrogens in soybeans, or synthetic; Besides, some endocrine active substances are intentionally used in medicines, such as estrogen in birth control pills.[31] Endocrine disruptors (EDs) are endocrine active

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[27] Endocrine Society, 'What EDCs Are' (n.d.) <https://www.endocrine.org/topics/edc/what-edcs-are>. accessed 31 October 2023

[28] European Chemicals Agency, 'Endocrine Disruptors' (n.d.) <https://echa.europa.eu/hot-topics/endocrine-disruptors>. accessed July 10 2023

[29] Ben Greenstein and Diana Wood, *The Endocrine System at a Glance* (3rd edn 2011, John Wiley & Sons) 10.

[30] ibid (n 28).

[31] European Food Safety Authority, 'Endocrine active substances' (n.d.) <https://www.efsa.europa.eu/en/topics/topic/endocrine-active-substances>. accessed July 15 2023

substances that can interfere with the hormonal system and, as a result, produce adverse effects in both humans and wildlife.[32] A wide range of chemicals, both natural and synthetic, can cause endocrine disruption in humans and animals.[33] The World Health Organization (WHO) provided a definition of EDs which is currently widely accepted as: *"an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations".*[34]

Whereas adverse effects can be defined as *a "change in the morphology, physiology, growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences".*[35]

Examples of EDs related to food consumption are Phytoestrogens, certain phthalates (PAEs) such as DEHP, Advanced glycation end products (AGEs), Persistent organic pollutants (POPs), certain pesticides such as DDT, Parabens and Bisphenol A.[36]

EDs can interfere with hormone signaling by mimicking hormones and triggering inappropriate responses or by binding to a hormone's receptor, which will block activation or prevent the appropriate hormonal processes from taking place.[37] Measuring the toxicity of EDs is challenging because the ability of EDs to affect cells in minuscule amounts are making traditional testing methods to assess

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[32] ibid.

[33] European Commission, 'Endocrine Disruptors' (n.d.) <https://commission.europa.eu/strategy-and-policy/policies/endocrine-disruptors_en#:~:text=Endocrine%20disruptors%20(ED)%20are%20chemicals,in%20both%20humans%20and%20wildlife>. accessed 10 July 2023.

[34] Terri Damstra and others, 'Global Assessment of the State-of-the-Science of Endocrine Disruptors' (IPCS/UNEP/ILO/WHO 2002).

[35] European Commission, 'Fitness Check on Endocrine Disruptors' SWD (2020) 251 final 166

[36] Oya Ercan and Gurkan Tarcin, 'Overview on Endocrine Disruptors in Food and Their Effects on Infant's Health' (2022) 2 Global Pediatrics 2ff <https://doi.org/10.1016/j.gpeds.2022.100019> (Ercan and Tarcin)

[37] Alina Dinu, '*Endocrine disruptors: An Overview of the Latest Developments at European Level in the Context of Plant Protection Products*' (EPRS, European Union 2019) 13 <https://doi.org/10.2861/569733>. (Dinu)

toxicity inadequate.[38] Besides, exposure to two or more different EDs simultaneously may cause unexpected negative effects, which is known as the cocktail effect.[39] Moreover, there may be no linear relationship between dose and effect for EDs, as a U curve might be more common, with low and high doses being the most harmful.[40] Furthermore, the age of exposure to an ED might be associated with different outcomes, as exposure during the prenatal development stages may induce epigenetic changes, affecting the following generations.[41]

2.3 Risk assessment of chemicals

There are two different approaches when it comes to decision-making on chemicals: hazard-based and risk-based. A hazard-based approach governs substances based on their intrinsic properties, whereas a risk-based approach takes the exposure of the substance into account, allowing more consideration of proportionality when making regulatory (risk-management) decisions.[42]

In a risk-based approach, the risk can be determined during a risk assessment containing a simple formula based on the multiplication of hazard and exposure (Risk = Hazard x Exposure).[43] Risk assessment is part of a structured decision-making process called risk analysis, encompassing risk assessment, management and communication.[44] Risk assessment is a scientifically based approach and consists of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.[45] Risk management weighs different policy alternatives while taking the necessities of different parties into account, while risk communication is the overlapping

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38 R Thomas Zoeller and others, 'Endocrine-Disrupting Chemicals and Public Health Protection: A Statement of Principles from the Endocrine Society' (2012) 153 Endocrinology 4097, 4097 <https://doi: 10.1210/en.2012-1422>.
39 Ercan and Tarcin (n 36) 2.
40 Ercan and Tarcin (n 36) 2.
41 Ercan and Tarcin (n 36) 3.
42 European Commission, 'Frequently Asked Questions, Endocrine Disruptors' (2016) <https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_2151>. accessed 25 February 2025
43 Hooi Theng Ong, Hayati Samsudin and Herlinda Soto-Valdez, 'Migration of Endocrine-Disrupting Chemicals into Food from Plastic Packaging Materials: An Overview of Chemical Risk Assessment, Techniques to Monitor Migration, and International Regulations' (2022) 62 Critical Reviews in Food Science and Nutrition 957,963 <https://doi.org/10.1080/10408398.2020.1830747>. (Ong)
44 FAO/WHO, '*Food Safety Risk Analysis. A Guide for National Food Safety Authorities*' (FAO/WHO 2006) 7.
45 ibid 7.

component that stimulates the interactive exchange of information throughout the risk analysis process.[46]

2.4 Hazard identification of endocrine disruptors

While the WHO offers a widely accepted definition for EDs, it is considered to be overly broad and open to various interpretations, as mentioned earlier. The joint EFSA/ECHA guidance document for identifying endocrine disruptors used in the context of plant protection products and biocidal products provides a more specific definition. According to this guidance document, a substance shall be considered as having ED properties if it meets all of the following criteria:[47]

a) *"It shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences";*
b) *"It has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system";*
c) *"The adverse effect is a consequence of the endocrine mode of action".*

This guidance document interprets the term 'endocrine mode of action' as 'endocrine activity' and thus points (b) and (c) should be understood as *"it has the potential to alter the function(s)" of "the endocrine system"* (b) and *"there is a biologically plausible link between the adverse effect and the endocrine activity"* (c).[48]

Another criterion that the joint EFSA/ECHA guidance document specifies is that all available relevant scientific data must be considered when identifying ED properties of substances.[49] This can be achieved with a Weight of Evidence (WoE) assessment, following the approach outlined in the guidance. This refers to Regulation (EC) No 1272/2086 on classification, labeling, and packaging of substances and mixtures (CLP Regulation); Here it states that all available

[46] ibid 7.
[47] Niklas Andersson and others, 'Guidance for the Identification of Endocrine Disruptors in the Context of Regulations (EU) No 528/2012 and (EC) No 1107/2009' (2018) 16 EFSA/ECHA 7 <https://doi: 10.2903/j.efsa.2018.5311/>.
[48] ibid 7.
[49] ibid 7.

scientific data must be considered, such as results of "*suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations".*[50] The results of this data may be about substances related to the identified substance and can be positive or negative and all collected data shall be weighted and assembled in a single WoE.[51] For the evaluation and interpretation of the standardized tests that may be used to identify EDs, the guidance document refers to another document, namely the 'guidance document on standardized test guidelines for evaluating chemicals for endocrine disruption' by the Economic Co-operation and Development (OECD GD 150 and OECD CF); These two guidance documents of the OECD include a listing of the tests available and provide aid in the evaluation of the measured effects.[52]

2.5 Hazard characterization of endocrine disruptors

The EC cumulatively characterizes EDs in terms of an endocrine mode of action, an adverse effect, and a causality between the two, as depicted in figure 2.[53] Examining the chemicals' mode of action differs from examining the effect, as the former attempts to understand the underlying mechanisms that cause the adverse effects and the latter identifies the observable 'endpoints' of toxic substances.[54] A mode of action can be identified as *A set of key events and processes starting with the interaction of an agent with a cell, through physiological and tissue or organ changes, potentially resulting in an adverse outcome.*[55]

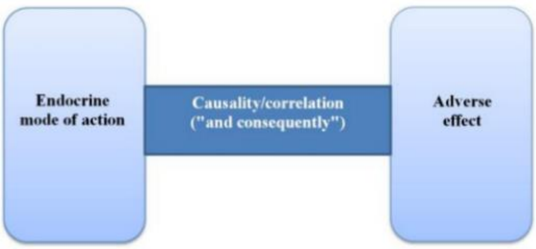

Figure 2: The Three Cumulative Characteristics of Endocrine Disruptors

[50] ibid 8.
[51] ibid 8.
[52] ibid 10.
[53] Dinu (n 37) 3.
[54] ibid (n 42).
[55] OECD, '*Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption*' (Paris, OECD Publishing 2018) 23 <https://doi.org/10.1787/9789264304741-en>.

An initiative that shows the efforts that have been made to focus on the adverse effects instead of the identification of observable endpoints, is the expert consensus statement that identified 10 Key Characteristics (KCs) of EDs.[56] These KCs are identified by the ability of substances to interact with key regulatory steps of hormone systems and can be used for identifying endocrine hazards and grouping chemicals as EDs, prioritizing and utilizing data, and providing a foundation for risk assessments.[57] The KCs consist of 1: Interacts with or activates hormone receptors; 2: Antagonizes hormone receptors; 3: Alters hormone receptor expression; 4: Alters signal transduction in hormone-responsive cells; 5: Induces epigenetic modifications in hormone-producing or hormone-responsive cells; 6: Alters hormone synthesis; 7: Alters hormone transport across cell membranes; 8: Alters hormone distribution or circulating levels of hormones; 9: Alters hormone metabolism or clearance; 10: Alters the fate of hormone-producing or hormone-responsive cells.[58]

With the help of a dose-response assessment, a safe level of exposure for consumers may be calculated.[59] However, this approach does not take the effects of combined exposure to different substances into account, and it is hard to estimate a safe daily dose when extremely small amounts may have adverse effects.

2.6 Exposure assessment endocrine disruptors

Exposure to EDs occurs through various exposure pathways, affecting both humans and wildlife. The research paper published by the Policy Department for Citizen's Rights and Constitutional Affairs of the European Union distinguished different product groups where EDs can be present.[60] First, exposure via product groups will be discussed, followed by a brief section regarding ED exposure to wildlife and the environment. While this section mainly emphasizes describing ED exposure to humans through product groups, it's important to acknowledge that

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[56] Michele A La Merrill and others, 'Consensus on the Key Characteristics of Endocrine-Disrupting Chemicals as a Basis for Hazard Identification' (2020) 16 Nature Reviews Endocrinology 45, 46 <http://dx.doi.org/10.1038/s41574-019-0273-8>.
[57] ibid 46.
[58] ibid 46-51.
[59] EFSA, 'The Four Steps of Risk Assessment' (EFSA, n.d.) <https://multimedia.efsa.europa.eu/riskassessment/index.htm>. accessed 2 October 2023
[60] Barbara Demeneix and Rémy Slama, 'Endocrine Disruptors : From Scientific Evidence to Human Health Protection' (Policy Department for Citizens' Rights and Constitititutional Affairs, European Union 2019) 37-44 (Demeneix and Slama)

there are other potential routes, such as various environmental pathways. To enhance clarity and organization, a distinction is made between the exposure pathways that affect humans and the exposure pathways that affect wildlife. Although the source of the ED is often similar as humans and the environment are interconnected, the impact of ED contamination may be different. Consequently, the prevalence of exposure to EDs is described.

ED Exposure Pathways via Product Groups: focus on affecting Humans

Food Contact Materials and Diet. EDs can be naturally occurring in the food, such as the phytoestrogens found in soybeans, or they can be formed during food processing. When foods that contain amino acids and reducing sugars are heated, a Maillard reaction may occur. This reaction is responsible for the browning of various products such as bread, cheese, processed meats, cookies, and peanut butter. Consequently, Advanced Glycation Products (AGEs) may form in a later stage, which has been associated with the pathophysiology of several diseases, such as type 2 diabetes mellitus, polycystic ovary syndrome, and allergies.[61]

Contamination with EDs is a concern throughout all stages of food production. During primary production, the raw materials can be contaminated as the extensive use of EDs in various industries may lead to widespread environmental pollution, with EDs ending up in the air, water and soil.[62] Examples are certain pesticide residues or Persistent Organic Pollutants (POPs) which can end up in the soil or irrigation and drinking water while contaminating raw materials such as crops; Besides, dairy products and meat may contain EDs due to contamination of the feed.[63] Moreover, issues might occur when mothers who are breastfeeding are contaminated with POPs, they can convey the POPs to their children.[64]

Food can be contaminated with EDs during secondary production. The presence of EDs in food packaging and other FCMs has been widely documented. Food packaging components that may contain EDs include paper, glue, inks and

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[61] Ercan and Tarcin (n 36) 3.
[62] TB Chokwe, JO Okonkwo and LL Sibali, 'Distribution, Exposure Pathways, Sources and Toxicity of Nonylphenol and Nonylphenol Ethoxylates in the Environment' (2017) 43 Water SA 529,532 <http://dx.doi.org/10.4314/wsa.v43i4.01>. (Chokwe, Okonkwo and Sibali)
[63] Ercan and Tarcin (n 36) 2.
[64] ibid 2.

cardboard.[65] When food packaging contains non-intentionally added substances (NIAS) such as breakdown products of oligomers, side products or impurities, they can be an unknown source of exposure to EDs.[66] Both known and unknown added substances in packaging and other FCMs have to potential to contaminate the food via migration from the material to the food product. The migration of substances into food can occur when food is in contact with a material and it is controlled by molecular diffusion of substances from a higher to a lower concentration.[67] The migration process can be divided into three steps, as depicted in Figure 3: first, diffusion occurs within the packaging; second, dissolution takes place at the packaging-food interface; and third, the diffusion continues within the food.[68] The extent of the migration is dependent on a range of variables, such as the contact surface area, the nature of the food, the temperature of the system and the nature of the interaction.[69]

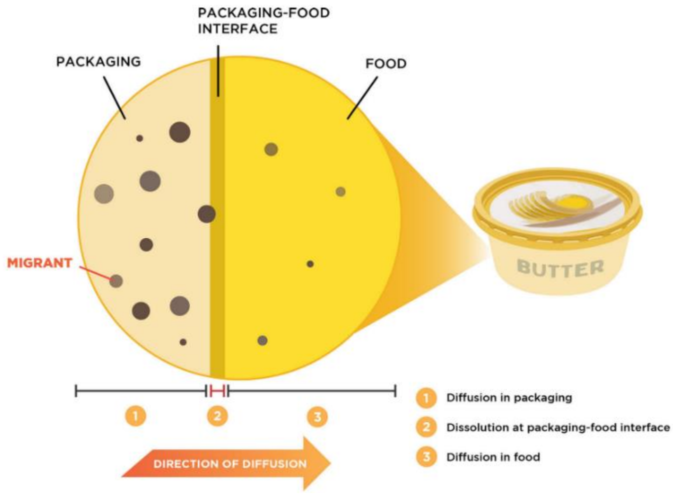

Figure 3: Migration process in a packaging-food system

A study in which FCMs for intentional use were systematically analyzed, identified 22 substances proven to be EDs are currently intentionally used in FCMs.[70] A present ED in our food system that stems from food packaging is the phthalate Di-ethylhexyl (DEHP), present in PET bottles, and its presence in the product of the PET-bottle increases with higher temperatures; Phthalates are plasticizers,

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65 Demeneix and Slama (n 60) 37.
66 Ong (n 43) 961.
67 ibid 958.
68 ibid 958.
69 ibid 958.
70 Lisa Zimmermann and others, 'Implementing the EU Chemicals Strategy for Sustainability: The Case of Food Contact Chemicals of Concern' (2022) 437 Journal of Hazardous Materials 1,4 <https://doi.org/10.1016/j.jhazmat.2022.129167>.

used to improve the extensibility and elasticity of polymers.[71] Another major ED used in the plastic and packaging industry is Bisphenol A (BPA), used for the production of hard and transparent plastics used for various food contact materials and as an inner coating for food and beverage cans. BPA has estrogen-like and anti-androgen effects causing damage to different tissues and organs, including the reproductive system, immune system and neuroendocrine system.[72] Although the use of BPA is banned in plastic bottles and packaging containing food for babies and children under 3 years old, BPA is still being used in FCMs that do not fall under this exception.[73] On 19 December 2024, the Commission adopted a ban on the use of Bisphenol A in FCMs; To allow the industry time to adapt, there will be an 18-month phase out period and very few exceptions when no other options are available.[74] Another well-known group of chemicals with endocrine-disrupting properties is Perfluoroalkyl substances (PFAS); these compounds are used for food-contacted materials and various other instances for their water and oil-repellent characteristics.[75] This diverse group of chemicals is extremely persistent in our bodies and they can lead to health problems such as liver damage, thyroid disease, obesity, fertility issues and cancer.[76]

Other product groups: Other product groups mentioned in the research paper include cosmetics and personal care products, drugs, consumer products & cleaning products and pesticides.[77] Contact with these products may lead to ED exposure.

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[71] Ercan and Tarcin (n 36) 2-3.
[72] Ya Ma and others, 'The Adverse Health Effects of Bisphenol A and Related Toxicity Mechanisms' (2019) 176 Environmental Research 1,1 <https://doi.org/10.1016/j.envres.2019.108575>.
[73] EFSA, 'Bisphenol A' (2024) <https://www.efsa.europa.eu/en/topics/topic/bisphenol#:~:text=EU%20framework&text=BPA%20has%20been%20banned%20in,set%20by%20EFSA%20in%202015>. accessed 19 July 2024
[74] European Commission/DG for Health and Food Safety, 'Commission Adopts Ban of Bisphenol A in Food Contact Materials' (2024) <https://food.ec.europa.eu/food-safety-news-0/commission-adopts-ban-bisphenol-food-contact-materials-2024-12-19_en>. accessed 1 March 2025
[75] Demeneix and Slama (n 60) 39.
[76] European Environmental Agency/EU, 'What are PFAS and How are They Dangerous for my Health?' (n.d.) <https://www.eea.europa.eu/help/faq/what-are-pfas-and-how#:~:text=They%20can%20lead%20to%20health,Europe%20%E2%80%93%20PFAS%20for%20further%20information.>. accessed 19 July 2024
[77] Demeneix and Slama (n 60) 37-44.

ED exposure pathways via the Environment: focus on affecting wildlife

EDs can be released in the environment during their initial synthesis, during their incorporation into finished products, or as a result of their disposal or recycling.[78] Estrogens for example, used for birth control, may end up via the dischargement of domestic sewage and animal waste in surface waters and groundwater; These compounds pollute the aquatic environment and can cause adverse effects such as feminization, infertility and hermaphroditism in organisms that inhabit water bodies.[79] Another issue is the accumulation of EDs in the fat tissue of organisms. In general, persistent EDs have a low water solubility and a high lipid solubility, which leads to accumulation in fat tissue.[80] An increase of toxic substances in fat tissue may lead to a process called biomagnification or bio amplification, in which the concentration of the toxic substance increases further up in the food chain.[81] Biomagnification has been indicated with various sources of EDs in fish with different feeding habits along the largest subtropical river in China.[82] EDs originating from the environment can also contaminate humans, for example via volatile or semi-volatile ED compounds existing in the air that stem from plastics, consumer goods, industrial chemicals or pesticides.[83]

Exposure Prevalence to EDs

One study that highlights the widespread exposure to EDs is a 2017 study that assessed the levels of 45 chemicals, including EDs such as Bisphenol A and DEHP and suspected EDs such as phthalates and certain pesticides, in the bodies of 1300 pregnant women and their children from 6 EU countries by measuring the levels of chemicals in their blood and urine. In 90% of children and their mothers, at least 2/3 of the investigated chemicals including various (suspected) EDs were found at detectable levels.[84] Although this study does not provide a representation of the European population due to the small sample size and it

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[78] Chokwe, Okonkwo and Sibali (n 62) 530.

[79] Marianna Ciślak and others, 'Estrogen Pollution of the European Aquatic Environment: A Critical Review' (2023) 229 Water Research 1,1 <https://doi.org/10.1016/j.watres.2022.119413>.

[80] Evantia Diamanti-Kandarakis and others, 'Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement' (2009) 30 Endocrine Reviews 293,296 <doi: 10.1210/er.2009-0002>.

[81] H. Charles J. Godfray and others, 'A Restatement of the Natural Science Evidence Base on the Effects of Endocrine Disrupting Chemicals on Wildlife' (2019) 286 The Royal Society Publishing 1,6 <http://dx.doi.org/10.1098/rspb.2018.2416>.

[82] Jing-Jing Fan and others, 'Bioaccumulation of Endocrine Disrupting Compounds in Fish with Different Feeding Habits Along the Largest Subtropical River, China' (2019) 247 Environmental Pollution 999,999 <https://doi.org/10.1016/j.envpol.2019.01.113>.

[83] Philippa D Darbre, 'Overview of Air Pollution and Endocrine Disorders' (2018) 11 International Journal of General Medicine 191,191 <doi: 10.2147/IJGM.S102230>. (Darbre)

[84] Demeneix and Slama (n 60) 45.

does not provide an accurate estimation of the exposure, it does indicate the widespread exposure to EDs of individuals within the European Union.

Measuring the exposure prevalence of EDs in wildlife might be challenging as the species of interest are often endangered and thus not available in adequate numbers to provide representative data to investigate causality.[85] Although data on wildlife is not available, estimations of ED exposure to wildlife can still be made by measuring the prevalence in air, soils and waters in which the wildlife occurs. However, providing an accurate estimation of the exposure prevalence of ED to wildlife does not fall within the scope of this thesis. Thus, one study is selected that indicates the widespread prevalence of EDs within the EU. This study investigated the presence of EDs in the environment, by measuring the effluents of 52 wastewater treatment plants from 15 different EU countries on the occurrence of various endocrine-disrupting chemicals, a total of 56 compounds with endocrine-disrupting properties were detected in ranging concentrations.[86]

2.7 Risk characterization: qualitative and quantitative health effects of ED exposure

Qualitative health effects of ED exposure on humans

The health effects of exposure to EDs are highly dependent on the age at which an individual is exposed to an ED. Mukherjee and others illustrate the major effects of ED exposure on different life stages of the human being; It is demonstrated that exposure in the developmental phases is the most detrimental, this may cause epigenetic effects during the fetal stage, developmental defects during childhood or disruptions during puberty or disruptions during adulthood.[87] Figure 4 provides a summary of human health issues linked to ED exposure, such as female and male reproductive problems, cancer, thyroid and adrenal dysfunction, developmental abnormalities, immune dysfunction, and disorders of energy metabolism.[88] The oval boxes in Figure 4

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[85] European Environment Agency, '*The Impacts of Endocrine Disrupters on Wildlife, People and their Environments*' (EEA/EC/eu2006.fi/Academy of Finland, EEA 2012) 14 <doi:10.2800/41462>.
[86] Saskia Finckh and others, 'Endocrine Disrupting Chemicals entering European Rivers: Occurrence and Adverse Mixture Effects in Treated Wastewater' (2022) 170 Environmental International 1,1 <https://doi.org/10.1016/j.envint.2022.107608>.
[87] Raktim Mukherjee and others, 'Endocrine Disruptors–"Food" for Thought' (2021) 74 Proceedings of the Zoological Society 432,434 <https://doi.org/10.1007/s12595-021-00414-1>.
[88] Darbre (n 83) 200.

indicate broad health-affected areas, whereas the square boxes indicate specific effects linked to EDs.[89]

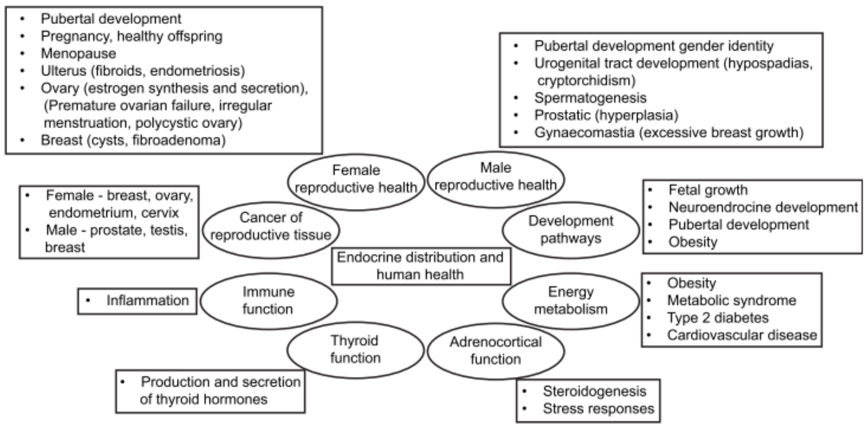

Figure 4: Outline of the influences of EDs on human health

Quantitative health effects of ED exposure on humans

Difficulty in quantifying the exposure, low standardization of studies and the presence of confounding factors complicate the establishment of a causal relationship between endocrine disorders and EDs.[90] Thus, quantifying the burden that endocrine disorders cause is difficult. Despite its complications, the article of Trasande and others attempted to estimate the disease burden and found a strong probability that exposure to some EDs leads IQ loss; and associated intellectual disability, autism, attention-deficit hyperactivity disorder, childhood obesity, adult obesity, adult diabetes, cryptorchidism, male infertility, and mortality associated with reduced testosterone.[91] Besides, it is estimated that these diseases related to ED exposure in Europe approximately costs €157 billion per year.[92] Moreover, approximately 13 million IQ points are yearly lost due to ED exposure.[93]

Qualitative and quantitative health effects of ED exposure on wildlife

In wildlife populations, associations have been documented between the reproductive and developmental effects and endocrine-disrupting chemicals

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[89] ibid.
[90] Valentina Guarnotta and others, 'Impact of Chemical Endocrine Disruptors and Hormone Modulators on the Endocrine System' (2022) 23 International Journal of Molecular Sciences 1,1 <https://doi.org/ 10.3390/ijms23105710>.
[91] L Trasande and others, 'Burden of Disease and Costs of Exposure to Endocrine Disrupting Chemicals in the European Union: An Updated Analysis' (2016) 4 Andrology 565,565 <https://doi.org/10.1111/andr.12178>.
[92] ibid 566.
[93] L Trasande and others, 'Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union' (2015) 100 Journal of Clinical Endocrinology and Metabolism 1245,1250 <https://doi.org/10.1210/jc.2014-4324>.

whereas in the aquatic environment, effects have been observed in mammals, birds, reptiles, fish, and mollusks across Europe, North America, and other regions.[94] Examples of animals that are affected by exposure to EDs are provided for all 5 animal classes. The observed effects include masculinization in female marine snails due to tributyltin exposure, DDE-induced egg-shell thinning in birds leading to severe population declines, effects on the reproductive organs of fish living in the proximity of water treatment plants, impaired reproduction and immune functions of seals due to PCBs in the food chain, and distorted sex organ development and function in alligators related to a major pesticide spill consisting DDT.[95] Identifying the quantitative health effects is beyond the scope of this thesis.

2.8 The development of a database with Endocrine Disruptors in FCMs

Key information of various Food Contact Chemicals (FCCs) with potentially endocrine-disrupting properties is currently unknown, as the information on chemical structures, migration patterns, exposure, and health effects of FCCs is often absent or scattered across multiple sources.[96] To identify the total exposure and the health complications of chemicals in FCMs, Groh and others initiated a research project to collect and analyze information on Food Contact Chemicals (FCCs).[97] Multiple databases were considered regarding EDs. One is the "Endocrine Disruptor List". This website was launched by the national authorities of Belgium, Denmark, France, The Netherlands and Sweden and aims to improve knowledge and inform stakeholders about the status of substances identified as (potential) EDs, while increasing transparency and coordination across legislative areas.[98] The information on this website is detailed in 2 different lists based on the EU regulations for REACH (Registration, Evaluation, Authorization and Restriction of Chemicals; (EC) 1907/2006), BPR (Biocidal Products Regulation; (EU) 528/2012, and (EU) 2017/2100), PPPR (Plant Protection Products Regulation; (EC) 1107/2009, and (EU) 2018/605), and CR (Cosmetic Products

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[94] Joseph G Vos and others, 'Health Effects of Endocrine-Disrupting Chemicals on Wildlife, with Special Reference to the European Situation' (2000) 30 Critical Reviews in Toxicology 71,71 <https://doi.org/10.1080/10408440091159176>.
[95] ibid 72.
[96] Ksenia J Groh and others, 'Overview of Intentionally Used Food Contact Chemicals and Their Hazards' (2020) 150 Environment International 1,1 <https://doi.org/10.1016/j.envint.2020.106225>. (Groh and others)
[97] ibid 1.
[98] The Danish Environmental Protection Agency, 'About This Site' (Endocrine Disruptor Lists, n.d.) <https://edlists.org/about-this-site>. accessed 3 October 2023

Regulation; (EC) 1223/2009).[99] A third hazard-based list include substances that may have ED properties and are listed by an individual National Authority, but these inclusions are not necessarily supported by other Member states.[100]
Other databases regarding EDs mentioned by research of Groh and others are the i) Endocrine Disruptor Assessment List maintained by ECHA, ii) the list of substances placed due to their endocrine disrupting properties on the Candidate List of substances of very high concern (SVHCs) for Authorization under the REACH regulation in the EU and iii) the list of recognized EDCs or potential EDCs compiled in the 2018 United Nations Environment Programs.[101] The specific EDs listed in each database may vary, and this can cause difficulties in identifying which substances are safe to use.

2.9 Chapter Summary

The endocrine / hormonal system, along with the nervous system, facilitates communication between different parts of the body and helps to maintain a stable internal environment (homeostasis). The endocrine system functions with endocrine hormones that are released from glands and interact with receptors in target tissues, to regulate bodily functions. Endocrine Disruptors (EDs) can be natural or synthetic and disrupt hormone signaling, by mimicking hormones or blocking hormone receptors. ED exposure may cause adverse effects in humans and wildlife, but measuring the toxicity of EDs is hard because of the non linear dose/response relationship and the cocktail effect.

Decision-making on chemicals such as EDs may have a hazard-based or a risk-based approach. A hazard-based approach governs substances based on their intrinsic properties, whereas a risk-based approach takes the exposure of the substance into account. Risk can be determined during a risk assessment and consists of

<u>i) hazard identification</u>; The hazard of endocrine-disrupting substances can be identified by providing a sufficient definition and properties of EDs while considering all scientific data, using a Weight of Evidence (WoE) approach. <u>ii) hazard characterization;</u> Characterizing the hazard of EDs involves an understanding of the mode of action and its subsequent adverse effects.

[99] ibid.
[100] ibid.
[101] Groh and others (n 95) 3.

iii) exposure assessment; Both humans and wildlife are affected by ED exposure. Within the scope of this thesis, an emphasis is placed on exposure via Food and FCMs, and the chemical migration process in a packaging-food system. iv) risk characterization; The qualitative effect of ED exposure on human health is the most detrimental in the developmental phases and includes effects on reproductive health, immune adrenocortical and thyroid function, energy metabolism, and developmental pathways. Quantitatively, it is estimated diseases related to ED exposure in Europe approximately costs €157 billion per year. Quantitative and quantitative effects of ED exposure on wildlife is shortly described but considered to be beyond the scope of this thesis.

Lastly, as information on EDs is often absent and scattered, the need to develop and maintain a database is emphasized.

3. Current Regulatory EU Framework on Food Contact Materials and Endocrine Disruptors

This chapter examines the position of the FCM Regulation compared to other legislations, with an emphasis on EU legislation related chemical substances such as EDs. Additionally, an overview is provided of material- and substance-specific FCM legislation.

3.1 Exploring the position of FCM legislation within the EU legislative framework

EU Legislative Objectives

One of the main objectives of the founding of the European Union (EU) is to establish an internal market that supports sustainable development through economic growth, price stability, and a competitive social market economy, while aiming for full employment, social progress and a high level of protection and improvement of the environments' quality.[102] Additionally, a high level of human health protection in the implementation of all Union policies and activities shall be ensured.[103] Moreover, the Union aims for a high level of consumer protection by protecting the health, safety, and economic interests of consumers while promoting their right to education, information and their freedom to advocate their interests.[104]

The Importance of Food Safety

Food is a product which is consumed every day by EU citizens and its safety can highly impact human health. Thus, obtaining high-quality and safety standard of accessible food is essential to achieve a high level of human health protection and a high level of consumer protection, whereas the establishment of an internal market requires legal harmonization within the EU. The wide range of proposed measures discussed in the White Paper on Food Safety (2000) demonstrates the commitment to ensure food safety for all EU citizens.[105] In this Paper, measures regarding the establishment of an independent European Food Authority, an improved legislative framework, greater harmonization of national Food Safety Control systems, and a dialogue with consumers and other

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[102] Consolidated Version of the Treaty on European Union [2016] OJ C202/13, art 3 (3).
[103] Consolidated Version of the Treaty on the Functioning of the European Union [2016] OJ C202/1, art 168 (1).
[104] ibid art 169 (1).
[105] European Commission, 'White Paper on Food Safety' COM (1999) 719 final, executive summary.

stakeholders were proposed.[106] This paper laid the foundation of the General Food Law (GFL), the current EU legal framework that covers the whole food chain.

Regulation (EC) 178/2002 on General Food Safety in relation to FCMs

The GFL Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest concerning food while ensuring the effective functioning of the internal market.[107] It lays down the general principles of governing food and feed in general, and food and feed safety in particular, at Community and national level through all stages of food and feed production, processing and distribution.[108]

The GFL also provides the definition of 'food' or 'foodstuff' as "*Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*".[109] Unlike food products, FCMs are not consumed directly thus they cannot be identified as food, unless they are part of the food product and are intended to be consumed. Nevertheless, FCMs play a critical role in determining the safety and quality of the food, as potentially harmful substances used in FCMs may migrate into the food and thus affect the quality and safety of the food.

Unsafe food, meaning food which is injurious to health or unfit for human consumption, shall not be placed on the market.[110] The European Food Safety Authority (EFSA) provides the scientific basis for law and regulations to protect consumers from food-related risks.[111] Food Business Operators (FBOs) are primarily responsible for the food safety and shall implement a procedure based on Hazard Analysis and Critical Control Points (HACCP) in order to establish a high level of food safety.[112] When scientific uncertainty regarding the possibility of harmful effects persists, provisional risk management measures may be

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[106] ibid.
[107] 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 [2002] OJ L031/1, art 1 (1) (GFL Regulation)
[108] ibid art 1 (2) and 1 (3).
[109] ibid art 2.
[110] ibid art 14 (1) and 14 (2).
[111] European Food Safety Authority, 'About Us' (n.d.) <https://www.efsa.europa.eu/en/about/about-efsa>. accessed 16 March 2025
[112] Regulation (EC) 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs Food hygiene [2004] OJ L226/13, art 1(1)(a) and art 5(1).

necessary to ensure the high level of health protection, called the precautionary principle.[113]

Contaminants and Migrating Substances in Food

Contaminants fall under the umbrella of Non-Intentionally Added Substances (NIAS) and can be side products, breakdown products or contaminants.[114] Substances can also be Intentionally Added Substances (IAS) which may be the case for substances used in active or intelligent packaging. NIAS as well as IAS in FCMs have the potential to migrate into food, which may influence the quality and safety of the food.

Council Regulation (EEC) 315/93 on laying down Community procedures for contaminants in food defines 'contaminant' as "*any substance not intentionally added to food which is present in such food as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination*".[115] This Regulation concerns contaminants in food, and is only applicable to contaminants that are not covered by more specific Community rules.[116] Contaminant levels shall be kept as low as possible, and food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at toxicological level, shall not be placed on the market; In order to protect public health, the Commission may establish the maximum tolerances for specific contaminants.[117]

Regulation (EU) 2023/915 on maximum levels for certain contaminants in food restricts selling or using food listed in Annex I with contaminants above set limits, prohibits mixing compliant and non-compliant food, and generally applies maximum contaminant levels to food on the market, including specific rules for

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[113] GFL Regulation (n 107) art 7 (1).
[114] Birgit Geueke, 'Non-intentionally added substances (NIAS)' (2018) <https://www.foodpackagingforum.org/food-packaging-health/non-intentionally-added-substances-nias>. accessed 6 March 2025
[115] Council Regulation (EEC) 315/93 of 8 February 1993 laying down Community procedures for contaminants in food [1993] OJ L37/1 as amended by Regulation (EC) 1882/2003 of 29 September 2003 [2003] OJ L284/1 and Regulation (EC) 596/2009 of 18 June 2009 [2009] OJ L188/14, art 1(1).
[116] ibid art 1 (2).
[117] ibid art 2 (1) (2) (3).

integrated cereal production.[118] Under this Regulation, Member States have the right to temporarily suspend or restrict the application of relevant provisions if there is a reason suspect that a contaminant in food constitutes a health risk, although complying with this Regulation.[119] However, Member States may not prohibit, restrict, or impede the placing on the market of foods which comply with this Regulation for reasons related to their contaminant levels.[120] This may create a legal tension in which article 4 prioritizes the precautionary principle and article 5 that prioritizes harmonization of the market.

Regulation (EC) 1935/2004 on Food Contact Materials

Regulation (EC) 1935/2004 governs FCMs. This Regulation applies to materials and articles, including active and intelligent food contact materials and articles, which in their finished state are intended or are reasonably expected to be brought in contact with food or are already in contact with food and were intended for that purpose, this Regulation does not apply for materials and articles supplied as antiques, covering or coating materials that are meant to be consumed together with the food, or fixed public water supply equipment.[121] There is a variety of FCMs which are serving different purposes, ranging from packaging to cutlery. Since FCMs are not classified as food or feed, Regulation (EC) 2023/988 on General Product Safety (GPS), which regulates products that are placed or made available on the market, remains applicable. Moreover, this Regulation is specifically applicable to risks and categories of risks which are not addressed by existing FCM legislation.[122]

Regulation (EC) 1935/2004 covers various aspects. Firstly, the general requirements state that materials and articles.[123] Besides, labels advertisements

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[118] Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 [2023] OJ L119/103, art 2 (1) (2) (3) (4)
[119] ibid art 4 (1).
[120] ibid art 5 (1).
[121] Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590EEC and 89/109/EEC [2004] OJ L338/4 as amended by Regulation (EC) 596/2009 of 18 June 2009 [2009] OJ L188/14 and Regulation (EU) 2019/1381 of 20 June 2019 [2019] OJ L231/1, art 1 (FCM Regulation)
[122] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC [2023] OJ L135/1, recital 11 and art 2
[123] FCM Regulation (n 121) art 3.

and presentations of a material or article shall not mislead consumers.[124] Article 5 of this Regulation allows the Commission to adopt specific measures for groups of materials and articles listed in Annex I.[125] In the absence of specific measures, Member States are allowed to adopt or maintain national provisions.[126] Moreover, this Regulation provides rules on labelling which may include a specification for the intended use or incorporating the appropriate symbol and offers requirements for compliance documentation and traceability.[127]

Good Manufacturing Practices (GMP) for FCMs

Materials and articles used in FCMs, including active and intelligent materials and articles, shall be manufactured in compliance with Good Manufacturing Practices (GMP).[128] Regulation (EC) 2023/2006 on Good Manufacturing Practices for materials and articles intended to come into contact with food lays down the rules on GMP for the groups of materials and articles intended to come into contact with food listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.[129] This Regulation applies to all sectors and all stages of manufacture, processing and distribution of materials and articles, excluding the production of starting substances (although the selected starting materials must adhere to pre-established specifications to ensure the material's compliance with relevant legislation) and states that the Business Operator shall establish a Quality Assurance system and a Quality Control system, and maintain appropriate documentation provided to competent authorities upon request.[130]

Legislation on Chemicals in FCMs

The Regulation (EC) 1907/2006 concerning Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH Regulation) lays down provisions on substances and mixtures that shall apply to the manufacture, placing on the market, or use of substances on their own in mixtures or in articles and to the placing on the market of mixtures.[131] Hence, the REACH

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[124] FCM Regulation (n 121) art 3.
[125] FCM Regulation (n 121) art 5.
[126] FCM Regulation (n 121) art 6.
[127] ibid.
[128] FCM Regulation (n 121) art 3.
[129] Commission Regulation (EC) 2023/2006 of 22 December 2006 on good manufacturing practice intended to come into contact with food [2006] OJ L384/75, art 1
[130] ibid art 2, 5, 6 and 7.
[131] Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

Regulation is an overarching framework that applies to all chemical substances, including but not limited to substances in clothes, furniture and electrical appliances.[132] Its provisions are underpinned by the precautionary principle, meaning that manufacturers, importers and downstream users ensure to manufacture, place on the market or use substances that do not adversely affect human health or the environment.[133] This Regulation lays down requirements for the registration of substances, data sharing, information in the supply chain, downstream users, evaluation methods, the placing on the market and use of certain dangerous substances and mixtures.[134] The European Chemicals Agency (ECHA) helps companies comply with this Regulation by e.g. evaluating individual registrations and assessing whether the risks of substances can be managed.[135] The REACH Regulation is closely linked to Regulation (EC) No 1272/2008 on the Classification, Labeling, and Packaging of substances and mixtures (CLP Regulation), which is based on the United Nations' Globally Harmonised System (GHS); This Regulation is the only legislation in the EU for the classification and labeling of substances and mixtures.[136]

The REACH Regulation concerns substances that can be present in FCMs, but it also provides specific exemptions related to FCMs.[137] One exemption states that the required chemical safety report for all substances subject to registration when in quantities of 10 tonnes or more per year per registrant does not need to include consideration of risks to human health from the end uses of FCMs.[138]

Another exemption applies to substances subject to authorization under REACH if they meet specific criteria related to human health hazards, such as having endocrine-disrupting properties; Substances used in FCMs are exempted from authorization under REACH if the substances fall within the scope of Regulation

establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L396/1 as corrected by Corrigendum [2007] OJ L136/3, article 1(2) (REACH Regulation)

[132] European Chemical Agency, 'Understanding REACH' (n.d) <https://echa.europa.eu/regulations/reach/understanding-reach>. accessed 15 March 2025

[133] REACH Regulation (n 131) art 1(3).

[134] REACH Regulation (n 131) Table of Contents.

[135] ibid (n 127).

[136] European Chemicals Agency, 'Understanding CLP' (n.d.) <https://echa.europa.eu/regulations/clp/understanding-clp>. Accessed 15 March 2025

[137] European Commission, 'Fitness Check on Endocrine Disruptors' SWD (2020) 251 final 174

[138] REACH Regulation (n 131) art 14 (5) (a).

(EC) 1935/2004, unless the chemical enters the authorization process under REACH due to environmental concerns.[139]

To enhance coherence across legislations, recital 12 of Regulation (EC) 1935/2004 implies that specified substances should undergo a safety assessment prior to their authorization to be included on the list of authorized substances as defined by specific measures, the authorization procedure and safety assessment should align with that of the REACH Regulation .[140]

Official Controls and Enforcement of FCMs

Member States shall carry out official controls in order to enforce compliance with Regulation (EC) No 1935/2004.[141] Regulation (EU) 2017/625 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, lays down rules for the performance of official controls and other official activities by the competent authorities of Member States.[142]

This Regulation applies to official controls verifying the compliance with the established rules, in various areas including food and food safety at any stage of production, processing and distribution including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food.[143]

This shall include official controls, to be performed at any stage of production, processing and distribution, on relevant substances including substances to be used in food contact materials and contaminants.[144] This regulation obligates competent authorities to have measures in place to guarantee effective, appropriate, unbiased official controls and other activities of a high and a consistent quality, as well as an adequate laboratory and appropriate and properly maintained facilities and equipment, a sufficient number of qualified

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[139] REACH Regulation (n 131) art 56 (5) (b) and art 57(f); ibid (n 141).
[140] FCM Regulation (n 121) recital 12.
[141] FCM Regulation (n 121) art 24(1).
[142] Regulation (EU) 2017/625 of the European Parliament and 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 [2017] OJ L095/1, art 1(1)(a).
[143] ibid, art 1 (2) (c).
[144] ibid, art 19 (1).

staff and to have the legal powers and procedures in place to perform official controls and other official activities.[145]

3.2 Specific FCM legislation

In addition to Regulation (EC) 1935/2004, which establishes the general principles for Food Contact Materials (FCMs), there are various Regulations and Directives that address rules for specific FCMs. This specific FCM legislation can be categorized into material and article-specific legislation and substance-specific legislation. As mentioned before, article 5 of Regulation (EC) 1935/2004 provides rules for the adoption of specific measures for groups of materials and articles, such as lists of authorized substances and migration limits. The List of groups of materials and articles that specific measures may cover consists of Active and intelligent materials and articles, Adhesives, Ceramics, Cork, Rubbers, Glass, Ion-exchange resins, Metals and alloys, Paper and board, Plastics, Printing inks, Regenerated cellulose, Silicones, Textiles, Varnishes and coatings, Waxes, and Wood.[146]

Material and article-specific legislation

Active and intelligent materials and articles: Regulation (EC) 1935/2004 defines 'Active food contact materials and articles' as *"materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food",* and 'Intelligent food contact materials and articles' as *"materials and articles which monitor the condition of packaged food or the environment surrounding the food"*.[147]

The Commission Regulation (EC) 450/2009 on active and intelligent materials and articles intended to come into contact with food, establishes specific requirements for the marketing of active and intelligent materials and articles intended to come into contact with food, in addition to the general requirements laid down in Regulation (EC) 1935/2004.[148]

The Regulation introduces provisions for the development of a Community list of authorized substances that may be used in active and intelligent components.[149]

[145] ibid, art 5.
[146] FCM Regulation (n 121), Annex I.
[147] FCM Regulation (n 121), art 2(2)(a)(b).
[148] Commission Regulation (EC) 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food [2009] OJ L135/3, art 1
[149] ibid recital 11.

Additionally, the Regulation sets conditions of use for substances that do not require inclusion in the Community list. These substances must comply with relevant Community and national provisions as well as with Regulation (EG) 1935/2004.[150]

Furthermore, for substances not to be included in the Community list and in direct contact with food or the environment surrounding the food, the migration limit shall not exceed 0.01 mg/kg.[151] However, if an overall migration limit (OML) for a substance is established by a specific FCM Community measure, the amount of a released active substance not included in the Community list shall be excluded from the measured overall migration.[152] Moreover, such substances may exceed specific restrictions set by Community or national measures, provided it complies with the Community or national provisions applicable to food.[153]

Plastic materials and articles: Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food establishes specific requirements for the manufacture and marketing of plastic materials and articles intended to come into contact with food, already in contact with food, or which can reasonably be expected to come into contact with food.[154] This Regulation applies to materials and articles which are placed on the EU market that fall under the categories consisting exclusively of plastics, (partly) plastic multi-layer materials and articles held together by e.g. adhesives, plastic (multi-layered) materials and articles being printed/covered by a coating, and specific plastic layers or coatings, forming gaskets in caps and closures.[155]

'Plastic' is defined as a "*polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles*".[156] Whereas a 'polymer' is defined as "*any*

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[150] ibid art 9 (1).
[151] ibid art 10 (1).
[152] ibid art 9 (2).
[153] ibid art 9 (3).
[154] Commission Regulation (EU) 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food [2011] OJ L012/1 as amended by Commission Regulation (EU) 2016/1416 of 24 Augustus 2016 [2016] OJ L230/22 and Commission Regulation (EU) 2020/1245 of 2 September 2020 [2020] OJ L288/1 and Commission Regulation (EU) of 19 December 2024 [2024] OJ L3190/1, art 1.
[155] ibid art 2 (1).
[156] ibid art 3 (2).

macromolecular substance obtained by a polymerization process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances, or chemical modification of natural or synthetic macromolecules, or microbial fermentation".[157]

Article 5 of this Regulation states that only the substances included in the Union list of authorized substances may be intentionally used in the manufacture of plastic layers in plastic materials and articles, and this Union list shall contain monomers or other starting substances, additives excluding colorants, polymer production aids excluding solvents and macromolecules obtained from microbial fermentation.[158]

Some substances may be exempted to be included on the Union list, but are still granted to be used. For example, substances used as polymer production aids in the manufacture of plastic layers in plastic materials and articles, and colorants or solvents used in the manufacture of plastic layers in plastic materials and articles, with the condition that the use of these substances is subject to national law.[159] Besides, specific salts, additives, monomers and mixtures acquired by combining authorized substances without the occurrence of a chemical reaction are not included in the Union list but are authorized to be used when they are subject to the rules set out in Articles 8-12.[160] Lastly, non-intentionally added substances (NIAS) and aids to polymerization may allowed to be present in the layers of plastic materials or articles but may not be included in the Union list.[161]

Substances used in the manufacture of plastic layers in plastic materials and articles must be of a suitable technical quality and purity, and the composition must be known to the manufacturer of the substance and made available to the competent authorities on request.[162] Annex I of this Regulation sets out specific migration limits (SML) expressed in mg of substance per kg of food (mg/kg), if no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply.[163] Additionally, an overall migration limit (OML) is established, constituents from plastic materials must not

[157] ibid art 3 (3).
[158] ibid art 5 (1) (2).
[159] ibid art 6 (1) (2).
[160] ibid art 6 (3).
[161] ibid art 6 (4).
[162] ibid art 8.
[163] ibid art 11 (1) (2).

exceed 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2), another derogation of this OML applies for plastic materials and articles intended to be brought into contact with food intended for infants and young children, which shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.[164]

Specific provisions for certain materials and articles, such as plastic multi-layer materials and articles and multi-material multi-layer materials and articles have been established by this Regulation. For these layered materials, each plastic layer shall comply with this Regulation, with the exception of plastic layers which are not in direct contact with food and are separated from the food by a functional barrier, that comply with the restrictions for vinyl chloride monomer of this Regulation, and which are not substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) 1272/2008 or substances in nanoform.[165] The final plastic multi-layer material or article shall comply with the specific migration limits set out in article 11, and the overall migration limit set out in article 12, whereas articles 11 and 12 do not apply to plastic layers in multi-material multi-layer materials and articles.[166] Thus, in a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.[167]

Business operators have the obligation provide a written declaration for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles which eases the identification of materials, articles or products from intermediate stages of manufacture or substances for which it is issued, containing information laid down in Annex IV.[168] The general rules for testing compliance are set out in Annex V of this Regulation.[169]

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[164] ibid art 12 (1) (2).
[165] ibid art 13 (1) (2) (4) and art 14 (1) (2) (3) (5).
[166] ibid art 13 (5) & art 14 (4).
[167] ibid art 14 (6).
[168] ibid art 15.
[169] ibid art 18 and Annex V.

Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic food contact materials and articles establishes rules for the placing on the market, the development and operation of recycling technologies, processes and installations for these recycled plastics, and the use in contact with food of recycled plastic materials and articles which are intended to be recycled.[170] This Regulation does not apply to the use of waste to manufacture substances included in the Union list of authorized substances of Regulation (EU) No 10/2011.[171]

Commission Regulation (EU) 2022/1616 defines 'recycled plastic' as "*plastic resulting from the decontamination process of a recycling process and plastic resulting from subsequent post-processing operations and that is not yet transformed into recycled plastic materials and articles*" and 'recycled plastic materials and articles' as "*food contact materials and articles in their finished state, and that are made either fully or partly of recycled plastic*".[172] Recycling technology shall be considered suitable if it complies with the general requirements of Regulation (EC) No 1935/2004 and if it is microbiologically safe.[173] Recycled plastic materials and articles shall only be manufactured using a suitable and authorized recycling technology listed out in Annex I or a novel technology as referred to in Article 3(6) and developed in accordance with Chapter IV.[174]

Chapter III of this Regulation lays down general requirements for plastic recycling and the use of recycled plastic. The collected plastic waste shall originate from municipal waste or waste intended and used for contact with food, be manufactured pursuant to Regulation (EU) 10/2011 or recycled plastic materials and articles manufactured adhering this Regulation; The plastic waste is collected separately, and during the decontamination process, the presence of non-target plastic materials and articles must be reduced to meet the specified decontamination level.[175] In addition, the plastic waste shall be controlled

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[170] Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) 282/2008 2022/1616 [2022] OJ L243/3, art 1 (2).
[171] ibid art 1 (3).
[172] ibid art 2 (4) (5).
[173] ibid art 3 (1).
[174] ibid art 4 (3).
[175] ibid art 6 (1).

throughout the collection and pre-processing processes with the help of quality assurance systems.[176]

The decontamination process shall meet specific requirements for the plastic input and output, as well as for the process used for decontamination; Besides, the decontamination installation shall be located at a single recycling facility organized in a way that no new contaminations can occur, and it is configurated and operated in the way it is described according to the compliance monitoring summary sheet established in accordance with Article 26.[177] A 'recycling scheme', defined as *"an arrangement between legal entities to manage the use, separate collection and recycling of plastic materials and articles with the objective to limit or prevent their contamination in order to facilitate their recycling"*[178], shall be under the responsibility of a single legal entity that act as the manager of a recycling scheme, ensuring the overall functioning of the recycling scheme as well as informing the competent authority and the Commission with the purpose of registering the recycling scheme in the Union register established in accordance with Article 24.[179] Business operators and other organizations that partake in a recycling scheme shall conduct a quality assurance system in accordance with Regulation (EU) No 2023/2006 (GMP Regulation) or in the case of small food business operators, by implementing a 'hazard analysis and critical control points' (HACCP) principles, as referred to in Article 5 of Regulation (EC) 852/2004.[180]

Apart from the requirements related to novel technologies, all individual recycling processes must be authorized; The exact rules regarding the application of the authorization and the related obligations for the authority are set down in articles 17-23.[181] A public Union register shall be established to record novel technologies, recyclers, recycling processes, recycling schemes and decontamination installations.[182] Moreover, the production of recycled plastic shall be notified to the Commission and the to the competent authority prior to production; Additionally a compliance monitoring summary sheet and

[176] ibid art 6 (3).
[177] ibid art 7 (2) (3).
[178] ibid art 2 (15).
[179] ibid art 9 (1).
[180] ibid art 9 (9).
[181] ibid chapter V.
[182] ibid art 24 (1).

verification of the operation of a decontamination installation shall be submitted.[183] Official controls of recycling installations and recyclers shall include audits which shall be completed by an assessment of procedures on GMP and an examination.[184] Besides, recyclers shall provide a Declaration of Compliance (DoC).[185]

The last Regulation could be identified as either material-specific or substance-specific, namely Commission Regulation (EU) 284/2011, which lays down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China. The incentive to develop this Regulation were notifications and alerts concerning polyamide and melamine plastic kitchenware that does not comply with the requirements concerning the release of primary aromatic amines and formaldehyde into food.[186] This Regulation sets down additional conditions for the import of polyamide and melamine plastic kitchenware originating from China regarding import conditions, notifications, reporting, and controls.[187]

Ceramic articles: Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs (84/500/EEC) identifies 'ceramic articles' as *"articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added; These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enameled and/or decorated".*[188] This Directive concerns the potential migration of lead and cadmium from ceramic FCMs.[189] The quantities of lead and cadmium transferred from ceramic articles shall be determined by a test described in Annex I, using the method of

[183] ibid art 25 and 26.
[184] ibid art 27 (a) (b).
[185] ibid art 29 (1).
[186] Commission Regulation (EU) 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China [2011] OJ L77/25, recital 3
[187] ibid art 3, 4, 5, 6 and 9.
[188] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs [1984] OJ L277/12 as amended by Commission Directive 2005/31/EC of 29 April 2005 OJ L110/36 [2005], art 1 (3)
[189] ibid art 1 (2).

analysis described in Annex II and the quantities of lead and cadmium transferred from ceramic articles shall not exceed the set limits.[190] Ceramic articles which are not yet in contact with foodstuffs shall be accompanied by a written Declaration in accordance with Article 16 of Regulation (EC) 1935/2004 throughout all the marketing stages including the retail stage (details provided in Annex III).[191]

Crystal glass: Council Directive of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (69/493/EEC) applies to the products falling within heading No 70.13 of the Common Customs Tariff.[192] This Directive dictates Member States to take all necessary steps to ensure that the composition, characteristics of manufacture and labelling of the crystal glass align with the definitions and rules laid down in this Directive.[193]

Council Regulation (EEC) 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, provides a Combined Nomenclature (CN) on goods which meet the requirements of the Common Customs Tariff (CCT).[194] This tariff is common to all EU Members and applies to the import of goods from outside the EU.[195] This Regulation distinguishes all goods by subdivisions; The CN for Glass and Glassware is listed in Chapter 70.[196] The CN code 7013 is described as "*Glassware of a kind used for table, kitchen, toilet, office, indoor decoration or similar purposes";* This includes stemware or other drinking glasses and glassware of a kind used for table or kitchen purposes (other than of glass ceramics); It is important to note that there is a distinction between CN code 7013 and CN code 7010, in which CN code 7010 lists "*carboys, bottles, flasks, jars, pots, phials, ampoules and other containers, of glass, of a*

[190] ibid art 2 (1) (2).
[191] ibid art 2a (1).
[192] Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass [1969] OJ L326/36, art 1.
[193] ibid art 2.
[194] Council Regulation (EEC) 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [1987] OJ L236/1 as amended by Council Regulation (EC) 254/2000 of 31 January 2000 [2000] OJ L28/16 and Commission Implementing Regulation (EU) 2024/2522 of 23 September 2024 [2024] OJ L2522/1, art 1 (1).
[195] European Commission, 'What is the Common Customs Tariff?' (n.d.) <https://taxation-customs.ec.europa.eu/customs-4/calculation-customs-duties/customs-tariff_en>. accessed at 20 March 2025
[196] ibid (n 194) chapter 70.

kind used for the conveyance or packing of goods; preserving jars of glass; stoppers, lids and other closures, of glass".[197]

Regenerated cellulose: Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, lays down provisions regarding regenerated cellulose. Regenerated cellulose film is described as *a "thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides".* [198] Within the meaning of this Directive, the regenerated cellulose constitutes a finished product in itself or forms part of a finished product with other materials; This regenerated cellulose may be categorized as (a) uncoated regenerated cellulose film; (b) coated regenerated cellulose film with coating derived from cellulose; or (c) coated regenerated cellulose film with coating consisting of plastics.[199] Regenerated cellulose films shall be manufactured using allowed substances or groups of substances with their corresponding restrictions.[200] Substances used as coloring matter or adhesive may be used although not being included on the allowed list of substances or groups of substances, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method.[201] The regenerated cellulose category that includes a coating consisting of plastics, shall prior to coating be manufactured using only substances or groups of substances listed in the first part of Annex II, subject to the restrictions set out therein and shall using a coating which is manufactured following the provisions laid down by Directive 2002/72/EC, which is repealed by Regulation (EC) 10/2011.[202] A specific restriction is laid down for printed surfaces of regenerated cellulose film, printed surface of regenerated cellulose film shall not come into contact with foodstuff.[203]

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[197] ibid.
[198] Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs [2007] OJ L172/71, Annex I
[199] ibid art 1 (2) and art 2.
[200] ibid art 3 (1) (2).
[201] ibid art 3 (2).
[202] ibid art 4 (2).
[203] ibid art 5.

Substance-specific legislation

Bisphenol A and other Bisphenols and Bisphenol derivatives: On 19 December 2024, the Commission adopted Regulation (EU) 2024/3190, which amends Regulation (EC) 10/2011 with the addition of article 6 (6). This article sets restrictions for the use of Bisphenol A and other hazardous Bisphenols or Bisphenol derivatives, these substances may only be used in the manufacture of plastic materials and articles in accordance with Commission Regulation (EU) 2024/3190. [204] Commission Regulation (EU) 2024/3190, on the use of Bisphenol A (BPA) and other Bisphenols and Bisphenol derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, prohibits the use of Bisphenol A in the manufacture of FCMs unless it is for a specific application set out in Annex II, provided that its migration into food remains undetectable. [205] This Regulation is a specific measure within the meaning of Article 5 of the FCM regulation and applies to adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes/coatings.[206] This Regulation provides transitional provisions for single-use as well as repeat-use final food articles that do not comply with the rules in this Regulation, allowing them to be placed on the market until 20 July 2026.[207] This means that until this date, Regulation (EU) 2018/213 repealed by Article 13 of this Regulation may still be relevant. Regulation (EU) 2018/213 set prohibitions on the migration of Bisphenol A from varnishes or coatings applied to materials and articles specifically intended to come into contact with food products specifically intended for young children, such as infant formula and baby food.[208]

Certain epoxy derivatives (Bisphenol A, F and NOGE): Commission Regulation (EC) 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food lays

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[204] ibid (n 154) art 6 (6).
[205] Commission Regulation (EU) 2024/3190 of 19 December 2024 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011 and repealing Regulation (EU) 2018/213 [2023] OJ L3190/1, art 5 and Annex II.
[206] ibid art 1 (2).
[207] ibid art 11 and 12.
[208] Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials [2018] OJ L41/6, art 2 (2).

down provisions for FCMs which are manufactured with or contain 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl)ether (BADGE) and some of its derivatives, bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (BFDGE) and other novolac glycidyl ethers (NOGE).[209] 'Materials and articles' are in this Regulation defined as *"being made of any type of plastics, being covered by surface coatings and adhesives"*.[210] With regards to this Regulation, the use and presence of BADGE has been restricted (specified in Annex I) whereas the use and presence of BFDGE and NOGE has been prohibited.[211] At the marketing stages other than the retail stages, materials and articles containing BADGE and its derivatives shall be accompanied by a written declaration, and appropriate documentation shall be made available to competent authorities on demand to demonstrate compliance.[212]

Vinyl Chloride Monomer: Council Directive of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs (78/142/EEC), concerns the presence of vinyl chloride monomer in, and possible migration from, materials and articles prepared with vinyl chloride polymers or copolymers, which in their finished state are intended to come into contact with foodstuffs.[213] This Regulation notes that materials and articles shall not contain vinyl chloride monomer in a quantity exceeding the quantity laid down in Annex I (1 mg/kg of product), and the vinyl chloride in materials and articles that are in contact with foodstuffs shall not pass on to foodstuffs.[214] The detection method used should comply with the criteria set out in Annex II to ensure that no traceable levels of vinyl chloride are present.[215]

N-nitrosamines and N-nitrosatable substances: Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers, concerns the release of

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209 Commission Regulation (EC) 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food [2005] OJ L302/8, art 1 (1).
210 ibid art 1 (2).
211 ibid art 2, 3 and 4.
212 ibid art 5.
213 Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs [1978] OJ L44/15, art 1.
214 ibid art 2 (1) and Annex I.
215 ibid art 2 (2).

N-nitrosamines and substances that can be converted into N-nitrosamines, hereinafter called 'N-nitrosatable substances`, from elastomeric or rubber teats and soothers.[216] The teats and soothers shall not release any N-nitrosamines or N-nitrosatable substances (into a saliva test solution) and the teats or soothers shall not exceed 0,01 mg in total of N-nitrosamines released/kg and 0,1 mg in total of N-nitrosatable substances/kg detectable by a validated method laid down in Annex II.[217]

Mineral Oil Hydrocarbons: Commission Recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons (MOHs) in food and in materials and articles intended to come into contact with food, concerns the presence of MOHs in food. Although this Recommendation is non-binding, it clearly states that the presence of MOH in food is of concern because of their potential impacts on human health (carcinogenic and mutagenic effects and adverse effects of the liver).[218] MOHs are chemical compounds which are synthetically produced derived from crude oil and can be present in food via FCMs (including paper and board packaging), environmental contamination, lubricants for machinery used during harvesting, processing aids, or food additives.[219] This document recommends Member States to monitor the presence of MOHs and carry out further investigations in case of the MOH presence.[220]

3.3 Chapter summary

The EU's aims of establishing a functional internal market and ensuring a high level of consumer protection are embedded in the TEU and the TFEU. In the context of consumer protection, the White Paper on Food Safety laid the foundation of the GFL Regulation, which sets out general principles of food and feed safety. It also led to the establishment of the EFSA, which provides the scientific basis for laws to protect consumers from food-related risks.

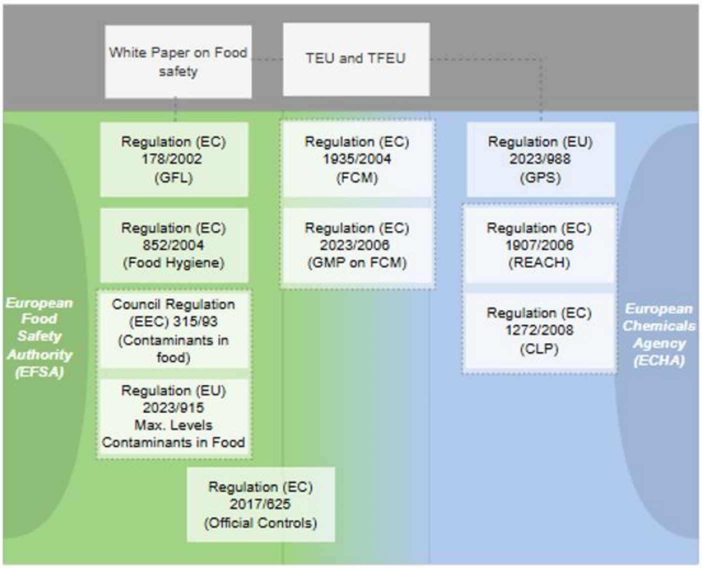
According to food hygiene laws, FBOs are primarily responsible for ensuring food safety and the implementation of a HACCP procedure is required. Contaminants

[216] Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers [1993] OJ L93/37, art 1.
[217] ibid art 2.
[218] Commission Recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food 2017/84 [2017] OJ L12/95, recital 2.
[219] ibid recital 1 and 3.
[220] ibid art 1 and 6.

in food are governed by Regulations that address contaminants and its maximum levels in food. These Regulations are only applicable to contaminants that are not covered by more specific Community rules. Contaminants that end up in food may originate from FCMs, which are ~~regulated~~ governed under Regulation (EC) 1935/2004. shall be manufactured in compliance with GMPs. To ensure the application of food and feed law, the Official Control Regulation establishes rules on official controls and related activities by the competent authorities of Member States. Since FCMs are not food or feed, the GPS Regulation applies to FCMs which are not covered by specific rules. Chemicals in products are regulated under REACH and CLP. The ECHA, the chemical equivalent of the EFSA, plays an important role in helping companies to comply with these laws and assesses risks related to chemical substances.

Article 5 of Regulation (EC) 1935/2004 provides rules for the adoption of specific measures for groups of materials and articles, listed in Annex I. Not all materials listed in Annex I are covered by a specific EU measure, allowing Member States to adopt their own national measures. A distinction is made between material-specific legislation and substance-specific legislation.

The figure below gives a graphic overview that illustrates the position of the FCM Regulation compared to other Regulations, as well as an overview of the discussed material- and substance-specific FCM measures.



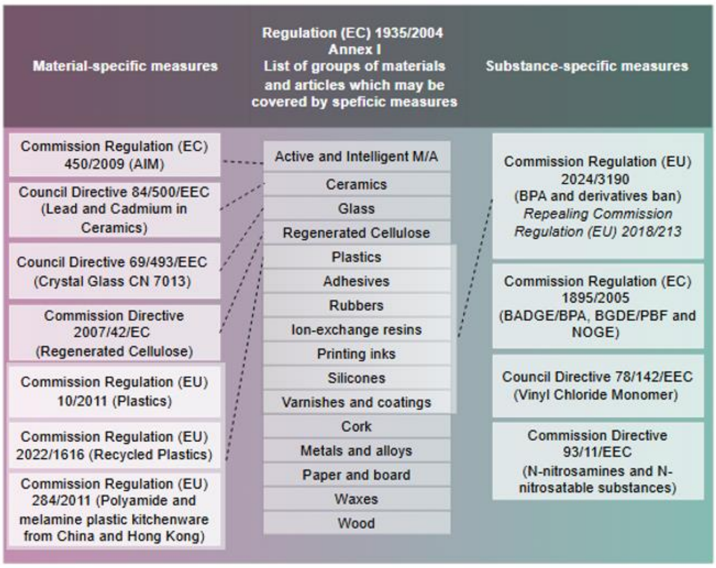


Figure 5: Chapter summary; Exploring the position of FCM legislation within the EU legislative framework (left) and Material- and substance-specific FCM legislation (right)

4. Limitations of the current EU FCM framework: shortcomings on sufficient protection against EDs

The current EU regulatory framework governing the use of EDs in FCMs has limitations in the ability to ensure food safety and to protect human health. As previously discussed in Chapter 2, hazardous substances, including those with ED properties, may be present in FCMs and can migrate from the FCM to food in such quantities that it may cause a risk to consumers. This may give cause for health concerns and may compromise the objective of ensuring food safety. This Chapter begins with an overview of the activities within the EU FCM framework that derive from the regulatory framework elaborated in Chapter 3. Subsequently, this Chapter describes the challenges of developing an EU FCM framework that incorporates EDs. It also discusses the current limitations of this EU FCM framework and provides an overview of the implications for stakeholders. Lastly, a summary of this Chapter is provided.

4.1 Activities within the EU FCM framework

In order to ensure the objective of food safety and the safety of FCMs, the European Commission has established a regulatory EU FCM framework, which is outlined in Chapter 3. The EU FCM framework requires collaboration between various actors, including national and international (control) authorities, research centers, businesses, and relevant parties to operate effectively. The key activities that arise from the established EU FCM framework including the associated actors are presented in the following sections.

The assessment and authorization of FCM substances by Authorities

FCMs encompass a wide range of substances, and to ensure the safe use of FCMs, these substances require thorough safety assessments. As mentioned in the previous chapter as well, article 5 of Regulation (EC) 1935/2004 permits the establishment of measures for specified groups of food contact materials and articles, including a list of starting substances authorized for use in the manufacturing of materials and articles, as well as purity standards or special conditions for the use of authorized substances, and overall or specific migration limits.[221]

In order to assess an intentionally added substance that falls within the specified groups of food contact materials and articles that have an established positive substance list, a business operator is required to compile a dossier of scientific information following detailed guidelines published by the EFSA, in accordance with Article 9(2) of Regulation (EC) 1935/2004.[222]

With regard to plastics, the EFSA published a document entitled *"Administrative guidance for the preparation of applications on substances to be used in plastic food contact materials".* This document is meant to guide applicants in their submission of substances to be used in plastic FCM materials and describes the administrative requirements for the submission of a dossier that supports the application of authorization for these substances. [223] It covers important procedural requirements in the dossier, such as the obligation to include a notification of the studies that the applicant is carrying out regarding the potentially authorized substance and the requirement to send a physical sample of the substance and relevant information regarding this substance to the European Union Reference Laboratory (EURL-FCM).[224]

The dossier will be transmitted to EFSA via a competent public authority of a Member State. The EFSA is then required to evaluate the dossier within six months. Subsequently, the EFSA publishes a scientific opinion indicating whether the substance in question is safe for use, the conditions under which it can be used and possible restrictions on its use. [225] After EFSA's scientific opinion is published in the EFSA Journal, the European Commission (EC) may proceed with the preparation of a draft specific measure.[226] The establishment of authorized

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[221] Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590EEC and 89/109/EEC [2004] OJ L338/4 as amended by Regulation (EC) 596/2009 of 18 June 2009 [2009] OJ L188/14 and Regulation (EU) 2019/1381 of 20 June 2019 [2019] OJ L231/1, art 5 (FCM Regulation)
[222] ibid, art 9.
[223] European Food Safety Authority, 'Administrative guidance for the preparation of applications on substances to be used in plastic food contact materials' (2021) 18 EFSA supporting publication 1,3 < https://doi.org/10.2903/sp.efsa.2021.EN-6514>.
[224] ibid (n 223) 9-11.
[225] European Commission, 'Evaluation of the legislation on food contact materials – Regulation (EC) no 1935/2004' SWD (2022) 163 final 11.
[226] ibid (n 223) 6.

lists for substances used in the manufacturing of FCMs may be perceived as beneficial for the insurance of safety, as these measures are intended to decrease the use of potentially hazardous substances in the manufacturing of FCMs by limiting the use of substances only to those authorized by public authorities.

Of the 17 groups of materials and articles listed in ANNEX I of Regulation (EC) 135/2004, only the rules for Active and Intelligent Materials and Articles (AIM), for Plastics, and for Regenerated Cellulose include provisions for developing a positive authorized list. However, as stated in Chapter 3, the positive list for AIM has not yet been included in the Regulation, and a Directive regulates the positive list for Regenerated Cellulose, requiring Member States to implement the positive list into national laws. Consequently, the authorization of substances is primarily effectively regulated for plastics FCMs.[227] Research of J. Muncke presented a comprehensive overview of the authorization process for different FCM substances, this figure indicates that only a small portion of substances ending up in in FCMs undergo inspection via the EFSA route.

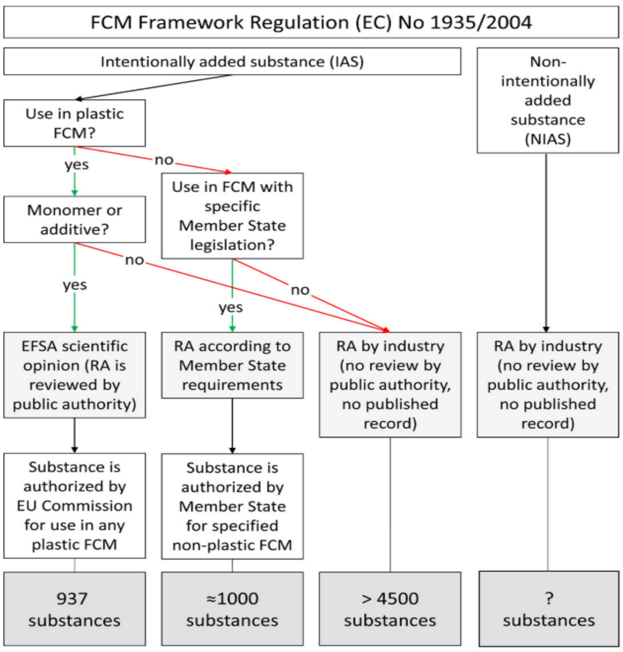

Figure 6: Risk assessment stakeholder roles for food contact chemicals in the EU[228]

[227] European Commission, 'Inception Impact Assessment - Revision of EU rules on food contact materials' Ares(2020)7731375, 2 (Ares(2020)7731375)
[228] Jane Muncke, Thomas Backhaus, Birgit Geueke and others, 'Scientific Challenges in the Risk Assessment of Food Contact Materials' (2017) 125 Environmental Health Perspectives 1,3 <https://doi.org/10.1289/EHP644>.

Compliance, traceability, and transparency by FCM business operators

As previously stated in Chapter 3, the general requirements of the FCM Regulation dictate that materials and articles shall be manufactured in compliance with good manufacturing practices (GMP) to ensure that they do not transfer their constituents to food in quantities that would endanger human health, bring an unacceptable change in the composition of the food, or bring a deterioration in the organoleptic characteristics of the food.[229] Regulation (EC) 2023/2006 lays down obligations concerning Good Manufacturing Practices (GMP) on business operators that manufacture Groups of materials and articles listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles.[230] This Regulation obligates business operators to establish and implement a Quality Assurance system; This system must include a plan to ensure quality, while taking the adequacy of personnel and the size of the business into consideration, starting materials and different operations shall be selected, which must comply with pre-established conditions.[231] A Quality Control system must include monitoring of the implementation and achievements of GMP and will identify measures to correct any failures to achieve GMP; Furthermore, it must ensure that corrective actions are available to inspections by competent authorities upon request.[232] In addition, the GMP Regulation obligates business operators to establish appropriate documentation regarding specifications, the manufacturing formulae and processing; This documentation must cover the performed manufacturing operations and the outcomes of the QC system, relevant to the compliance and safety of the finished material.[233] The business operator is obliged to make the documentation available to the competent authorities upon request.[234] The traceability of materials and articles must be ensured at all stages of manufacturing; business operators must have systems in

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[229] Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590EEC and 89/109/EEC [2004] OJ L338/4 as amended by Regulation (EC) 596/2009 of 18 June 2009 [2009] OJ L188/14 and Regulation (EU) 2019/1381 of 20 June 2019 [2019] OJ L231/1, art 3 (FCM Regulation)

[230] Commission Regulation (EC) 2023/2006 of 22 December 2006 on good manufacturing practice intended to come into contact with food [2006] OJ L384/75, recital 1 (GMP Regulation)

[231] ibid art 5.

[232] ibid art 6.

[233] ibid art 7 (1) (2).

[234] ibid art 7 (3).

place to identify the origin and destination of FCM materials, articles, substances or products throughout the manufacturing cycle.[235]

Article 5 of Regulation (EC) 1935/2004 enables the adoption of specific measures for the mentioned groups of materials and articles listed in Annex I, these specific measures may include additional rules to ensure compliance with the general requirements.[236] If these specific measures are absent, Member States may adopt or maintain national measures provided that they comply with the rules of the Treaty.[237] The materials and articles covered by the measures referred to in article 5 of Regulation (EC) 1935/2004 shall be accompanied by a written Declaration of Compliance (DoC), and if specific measures are absent, this Regulation allows Member States to retain or adopt national provisions to compel DoCs for materials and articles.[238] A DoC is a written statement confirming that materials and articles intended to come into contact with foods comply with legal requirements.[239]

Official controls by competent authorities of the Member States

The competent authorities of Member States carry out official controls with the objective of ensuring compliance with Regulation (EC) No 1935/2004.[240] As previously stated in Chapter 3, Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law establishes the rules for the performance of official controls by the Member States' competent authorities.[241] In addition, this Regulation lays down rules for the performance of official controls on the manufacture and use of materials and articles intended to come into contact with food.[242] This Regulation obligates competent authorities of Member States to have measures in place to guarantee effective, appropriate, unbiased official controls and other activities of high and consistent quality, as well as adequate laboratory facilities and equipment and a

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[235] FCM Regulation (n 229) art 17.
[236] FCM Regulation (n 229) art 5 (h).
[237] FCM Regulation (n 229) art 6.
[238] FCM Regulation (n 229) art 16.
[239] Netherlands Institute for Sustainable Packaging ‛ Fact Sheet Bisphenol A in Packaging’ (KIVD 2022)<https://kidv.nl/media/factsheets/voedselveiligheid/20220309_03_bpa_factsheet_eng_def.pdf?1.2.23>. accessed 26 March 2025
[240] FCM Regulation (n 229) art 24(1).
[241] Regulation (EU) 2017/625 of the European Parliament and 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 [2017] OJ L095/1, art(1)(a). (Official Controls Regulation)
[242] ibid art 1(2)(c).

sufficient number of qualified staff and to have the legal powers and procedures in place to perform official controls and other official activities.[243] All the National Reference Laboratories (NRL) and other official control laboratories involved in FCM analyses are accredited to ISO/IEC 17025.[244] In the event of non-compliance, the competent authorities are required to submit a report via the Rapid Alert System for Food and Feed (RASSF) or the Administrative Assistance and Cooperation (ACC) system.[245]

4.2 The challenge of developing an EU FCM framework that incorporates EDs

The development of rules related to the presence of EDs in FCMs is a challenging task in today's focus on sustainability, as the nature of EDs in general and in FCMs complicates the assessment process and the determination of safety standards. This section of the chapter addresses three main facets that complicate the development of an EU FCM framework that incorporates EDs.

A multitude of FCM substances with potential endocrine-disrupting properties

The total number of substances identified in FCMs varies considerably depending on the study. Simoneau identified approximately 8000 substances referenced by national measures implemented by Member States regarding the non-harmonized food contact materials within the EU.[246] Groh compiled a database of intentionally added food contact chemicals and listed 12285 substances that could be used globally; Of particular concern were 608 hazardous substances which were subjected to further assessment; Additionally, 1411 substances were highlighted as they present similar levels of concern but they have not been classified so far and more than a quarter of the listed substances lack accessible hazard information at this time.[247]

The multitude of substances used in the manufacturing of FCMs and a shortage of resources make comprehensive assessment within a favorable timeframe difficult. At present capacity of risk assessments and EU authorization, it is

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[243] ibid art 59.

[244] Health and Food Safety Directorate-General/European Commission, *Overview Report Official Controls over Food contact Materials in EU Member States* (Ares(2021)5987226 European Union 2021), 3. (Report Official Controls FCMs)

[245] European Commission, 'Evaluation of the legislation on food contact materials – Regulation (EC) No 1935/2004' SWD (2022) 163 final, 26. (SWD 2022 FCM Evaluation)

[246] C. Simoneau and others, *Non-harmonised food contact materials in the EU: Regulatory and market situation* (Joint Research Center (JRC) European Union 2016) 80. (JRC Report)

[247] Ksenia J Groh and others, 'Overview of Intentionally Used Food Contact Chemicals and Their Hazards' (2020) 150 Environment International 1,1 <https://doi.org/10.1016/j.envint.2020.106225>. (Groh and others)

estimated that it would take around 500 years to assess all substances used in non-harmonized FCMs, this estimate does not account for the need to re-evaluate substances when new scientific information becomes available.[248]

Besides, the current assessments and EU authorizations are limited to the starting substances and do not take Non-Intentionally Added Substances (NIAS) such as breakdown products or impurities into account.[249] NIAS may represent a large proportion of the substances that migrate into food and research by McCombie and others (2020) have identified around 30,000 and 100,000 NIAS.[250]

The Nature of EDs

The assessment of EDs and the determination of a safe threshold level is a challenging process, as outlined in Chapter 2.2, as the relation between dose and effect may not be linear with low and high doses being the most harmful. Moreover, as described in Chapter 2.2, when an individual is simultaneously exposed to multiple EDs, these substances may interact with each other, resulting in a harmful "cocktail effect". Additionally, the susceptibility to EDs varies depending on the age and life stage of the individual. Thus, assessing these substances and establishing a safe threshold level is hard.

A shift in focus toward sustainability

In 2019, the European Commission introduced the EU Green Deal, which serves as the roadmap for making the EU's economy sustainable and emphasizes the development of a circular economy.[251] A focus on the prospective circular economy highlights the importance of resource efficiency and minimizing waste. In this context, the analysis of breakdown products and impurities in (recycled) starting substances becomes increasingly important, as the end products of these starting substances may be reused.[252] This principle requires different risk assessment strategies, and EU FCM legislation should adapt accordingly.

4.3 Limitations in the EU FCM Framework Incorporating EDs

The complications regarding the development of an EU FCM framework that incorporates EDs, give rise to difficulties for the EU and the Member States in

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[248] Ares(2020)7731375 (n 227) 2.
[249] ibid.
[250] Isabelle Séverin, 'Editorial for the Special Issue "Risk Assessment of Food Contact Materials/Articles"' (2023) 11 Toxics 1,1. (Séverin)
[251] European Commission, 'The European Green Deal' COM (2019) 640 final 2.
[252] Séverin (n 250) 1.

developing effective policies. This section addresses a selection of limitations in the current EU FCM Framework incorporating EDs.

Lack of definition

Unclear definition of subject matter

Article 2 of Regulation (EC) 1935/2004 states that this Regulation shall apply to materials and articles that, in their finished state, are intended to be brought into contact with food, or are already in contact with food and were intended for that purpose, or can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.[253] However, it is rather difficult to identify what normal or foreseeable conditions of use are, as the behavior of consumers and all possible ways they may use or re-use FCMs is difficult to predict.[254]

This has led to differences in what stakeholders and citizens consider FCMs, as depicted by a public consultation regarding the revision of EU rules on FCMs published by the European Commission.[255] The questionnaires, which were completed by a sample of citizens and stakeholders, provided examples of different possible FCMs, such as "serving trays", "dining table surfaces" and "paper napkins"; Respondents were asked to evaluate the extent to which they agreed that these materials or articles should be considered as FCM and are subject to safety rules. In general, there was consensus among the interviewed citizens and stakeholders on what was considered an FCM. However, regarding some FCMs, the opinions were more scattered. For example, the results of the consumers' questionnaire indicate that a similar proportion of individuals (strongly) agree, remain neutral or (strongly) disagree that dining serving trays qualify as FCM.[256]

Besides, a divergence in opinions was noticed among various stakeholder groups regarding the identification of a specific material or article as an FCM. For instance, business associations and public authorities would mostly disagree on

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[253] FCM Regulation (n 229) art 2.
[254] SWD 2022 FCM Evaluation (n 250) 16.
[255] European Commission, 'Factual summary report – Public consultation on the revision on food contact materials (FCMs)' Ares(2023)4157469, 2-3.
[256] ibid figure 3.

categorizing lubricants used with machinery as FCMs, while most NGOs and businesses would include them as FCMs.[257]

This challenge in identifying FCMs has led to uncertainty about whether particular items placed on the market are subject to the rules. For example, it remains unclear whether plastic table cloths require a Declaration of Compliance.[258] Another issue that needs to be addressed is the overlap of regulatory frameworks. For example, medical feeding tubes can be regulated under the Medical Devices Regulation (EU) 2017/745 as well as the FCM Regulation, which some stakeholders indicate as insufficient or unclear.[259]

Another complication is the confusion regarding the definition of certain groups of materials. For example, certain elastomeric products can fall under the definition of 'plastic' of Regulation (EU) no 10/2011, or may be considered as 'rubber', depending on the interpretation of the laws; This may lead to confusion and different application of the legislation.[260]

Unclear definition of safety in EU FCM legislation

Article 3 of Regulation (EC) 1935/2004 lays down the general requirements of FCMs. The requirements state that its materials and articles should not transfer their constituents to food in quantities that could endanger human health or bring an unacceptable change in the composition of the food, under normal or foreseeable conditions.[261] Although this requirement pushed Member States to introduce safety standards and to improve the protection of human health by introducing specific rules that increase the level of safety, Article 3 of Regulation (EC) 1935/2004 in isolation is not deemed to be effective at achieving the aims of the legislation, as it does not define the level of safety expected, how it should be reached or how it can be demonstrated.[262]

Although some material-specific EU FCM Regulations and directives provide more detailed rules regarding the required level of safety, such as the Regulation on plastic FCMs, which includes a positive authorized list, other material-specific EU legislation does not include measures such as positive authorized lists. Moreover,

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257 ibid 7.
258 Ares(2020)7731375 (n 227) 3.
259 ibid.
260 SWD 2022 FCM Evaluation (n 245) 17.
261 FCM Regulation (n 229) art 3.
262 SWD 2022 FCM Evaluation (n 245) 18.

Member States may implement domestic rules regarding the level of safety they consider necessary, as indicated in Chapter 3.

Views on the appropriate level of food safety and how to achieve this level may differ between various Member States and other stakeholders, furthermore, a lack of harmonized EU standards or guidance on testing procedures was identified, resulting in the use of multiple standards across the EU with the possibility of different outcomes on the use of certain substances.[263]

Unclear definition of EDs in EU FCM legislation

Endocrine disruption is a relatively new consideration in risk assessments, and thus EDs are not always addressed in legal frameworks.[264] In the FCM Regulation as well as in more specific plastics FCM Regulation, EDs are not properly addressed, which leaves a gap in the legal FCM framework. More overarching legislations such as Regulation (EC) 1907/2006 which concerns the registration, evaluation, authorization and restriction of chemicals (REACH), and Regulation (EC) 1272/2008, which harmonizes the criteria for the classification of substances and mixtures (CLP), do include endocrine disruption in their provisions.[265]

However, the alignment of these overarching legislations with the EU FCM framework is not airtight. Substances requiring authorization under the REACH Regulation are not necessarily covered by the EU FCM framework, as substances falling under the FCM framework are exempted from authorization under the REACH Regulation unless the chemical enters the authorization process under REACH due to environmental health concerns.[266] As a result, some endocrine-disrupting substances such as DEHP are more strictly regulated under REACH than under FCM.[267]

In addition, the CLP Regulation recently included a hazard class for endocrine-disrupting properties in 2022.[268] While the Regulation for plastic FCMs refers to

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[263] ibid.
[264] European Commission, 'Fitness Check on endocrine disruptors' SWD (2020) 251 final 10. (SWD 2020 Fitness Check on EDs)
[265] SWD 2020 Fitness Check on EDs (n 264) 170; European Commission, 'Commission sets up rules to identify endocrine disruptors and long-lasting chemicals and to improve labelling' (*European Commission,* 19 December 2022) <https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7775>. Accessed 31 March 2025
[266] SWD 2020 Fitness Check on EDs (n 264) 174.
[267] SWD 2020 Fitness Check on EDs (n 264) 54.
[268] ibid (n 265).

the hazard classification of the CLP Regulation for substances that are mutagenic, carcinogenic or toxic to reproduction (CMRs) and specifically states that CMRs should not be used in FCMs,[269] the Plastics FCM Regulation does not yet refer to CLP's hazard class for endocrine disruption. Legal reference to EDs within the EU FCM framework is currently only made to CMR substances, which require assessment even when they are used behind a functional barrier.[270] Although some substances identified as CMRs may also have endocrine-disrupting properties, not all endocrine-disrupting substances are classified as CMRs.[271]

Unclear definition of compliance and enforcement requirements in EU FCM legislation

All material-specific EU FCM legislation requires that the applicable FCMs are accompanied by a written Declaration of Compliance (DoC), to demonstrate their compliance with the corresponding rules.[272] However, a DoC and supporting documentation (SD) are not required when the material-specific EU FCM legislation is not applicable.[273] In the absence of these requirements, there are indications that traceability requirements may be compromised.[274]

Moreover, the information provided on some DoCs appear to be insufficient. Analysis of DoCs indicated that many were incorrectly filled-in and incomplete, main shortcomings were found in referencing rules on Good Manufacturing Practices (GMP), clear identification of substances used, dual use additives, functional barriers and appropriate use specifications.[275]

Official controls on FCMs are also challenging due to the limited availability of effective analytical methods, and difficulties in ensuring that control staff possess the necessary level of expertise.[276] When inspections do occur, they tend to be superficial in nature, mainly checking for the presence of generic DoCs rather than in-dept assessments.[277]

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[269] Commission Regulation (EU) 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food [2011] OJ L012/1, recital 27.
[270] SWD 2020 Fitness Check on EDs (n 264) 174.
[271] SWD 2020 Fitness Check on EDs (n 264) 31.
[272] SWD 2022 FCM Evaluation (n 245) 13.
[273] ibid 35.
[274] ibid 18.
[275] ibid 23.
[276] Report Official Controls FCMs (n 244) I.
[277] ibid.

Lack of coherence

Lack of coherence across different (sectorial) frameworks incorporating EDs

Endocrine-disrupting substances are present in a wide range of products and materials, as well as in the environment. Hence, the presence of EDs is addressed in various European sectorial legislative frameworks. Figure 6 depicts an overview of the main EU legislation mapped against pathways of endocrine disruptors' exposure to humans and the environment in each product's life cycle, from manufacturing to waste.[278] These different sectorial frameworks rely on the identification and assessment undertaken by various EU scientific assessment bodies, such as the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the Scientific Committee on Consumer Safety (SCCS).[279]

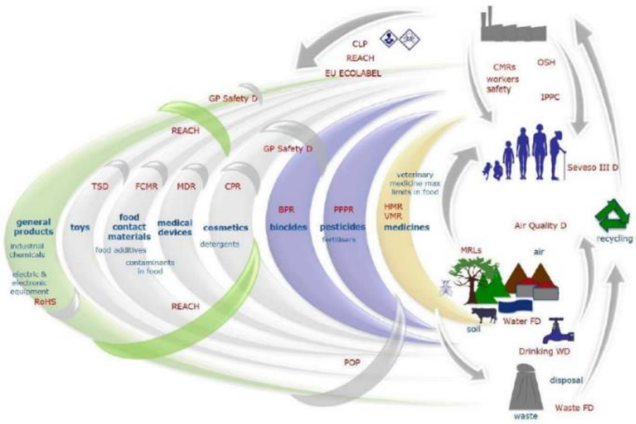

Figure 7: Main EU legislation mapped against pathways for ED´s exposure to humans and the environment

However, many stakeholders have criticized the current lack of a unified and horizontal approach in the identification of EDs among the EU scientific assessment bodies, as this gap creates uncertainty and confusion regarding the legislative consequences.[280] This uncertainty is exemplified by the difficulty in selecting an appropriate risk management approach, due to the scientific fundamental question of whether EDs should be considered as (all) threshold or non-threshold substances; Without a scientific consensus on this matter,

[278] SWD 2020 Fitness Check on EDs (n 264) 17.
[279] SWD 2020 Fitness Check on EDs (n 264) 10.
[280] SWD 2020 Fitness Check on EDs (n 264) 31.

legislative frameworks either opt for a generic risk approach with derogations (Plant Protection Products Regulation and Biocidal Regulation) or determine case by case whether a safe threshold can be quantified (REACH Regulation).[281] Furthermore, the FCM Regulation and the Cosmetic Products Regulation lack specific provisions for the assessment of EDs and lack guidance on how to deal with EDs for which it is not possible to quantify a safe threshold.[282]

Lack of coherence across material-specific FCM measures and across national measures

As discussed in Chapter 3, Annex I of Regulation (EC) 1935/2004 identifies 17 different groups of materials and articles, which may be covered by specific measures in accordance with Article 5 of this Regulation. However, not all of the these groups are covered by specific EU legislation other than the general FCM Regulation. For example, there are no specific EU measures for materials and articles used in FCMs made of adhesives, cork, rubbers, printing inks, ion-exchange resins, metals and alloys, paper and board, silicones, textiles, varnishes and coatings, waxes, and wood.[283] Besides, the scope and detail of the existing material-specific EU FCM measures may vary.[284]

The lack of harmonized EU rules for specific materials and articles in FCMs enables Member States to adopt national provisions under Article 6 of Regulation (EC) 1935/2004. The JRC science report on non-harmonized FCMs in the EU shows that 19 of the 26 Member States have made use of this possibility and that these 19 countries all implemented different national rules for more than one FCM, with the Netherlands applying additional rules for all listed FCMs.[285] Material-specific national legislation may contain positive and negative lists, specific and overall migration limits, limits for substance quantities, details on GMPs, Documentation of Compliance and supporting documents, and frameworks for sanctions and enforcements.[286]

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[281] SWD 2020 Fitness Check on EDs (n 264) 32.
[282] ibid.
[283] Safe Food Advocacy Europe, 'Food Contact Materials (FCMs) - Feedback tot the European Commission's Evaluation and Fitness Check Roadmap' (SAFE n.d.), 6 <https://www.safefoodadvocacy.eu/wp-content/uploads/2020/04/SAFE-Food-Contact-Materials-Evaluation-Feedback-for-the-Commission.pdf>.
[284] Ares(2020)7731375 (n 227) 1.
[285] JRC Report (n 246) 50.
[286] JRC Report (n 246) 52.

Major challenges were identified during the compilation of listed substances in national legislation, as each national material-specific FCM legislation used a different method to list the mentioned substances. The national legislation contained different types of nomenclature (with spelling errors) as well as inappropriate and generic chemical names (restrictions for rubbers were found to be formulated as "solvents").[287] Although the compilation of substances mentioned in national FCM legislation was carried out by chemists, the examination often faced challenges in identifying of the substances, making comparisons difficult and time-consuming.[288]

4.4 Possible implications for stakeholders within the EU FCM framework

The limitations of the EU FCM framework incorporating EDs and the challenges of developing an EU FCM framework in general may have a negative impact on the activities of the relevant stakeholders. This section provides a selection of possible implications for the activities and stakeholders within the EU FCM framework.

Implications for the assessment and authorization of substances by Authorities

A lack of available resources to assess a vast number of substances may hamper the consistent prioritization of the most hazardous substances in FCMs. Many laboratories, including the National Reference Laboratories (NRLs) are not able to sufficiently analyze complex substances with specific migration limits or detect the presence of substances not specifically addressed by EFSA.[289]

This may partly be due to reaction products being initially considered as "covered" by the European Commission as long as the overall migration limit was respected.[290] Consequentially, most migrating substances, even in plastic FCMs, are not specifically regulated; Despite concerns about the health impact of around 400 migrating substances present in plastic FCMs, accredited methods to test migration limits are only available for 20 of these substances.[291] Another reason that may hamper the ability of laboratories to assess a sufficient number

[287] JRC Report (n 246) 235.
[288] JRC Report (n 246) 53.
[289] Report Official Controls FCMs (n 244) 4.
[290] Koni Grob, 'The Role of the European Food Safety Authority (EFSA) in a Better European Regulation of Food Contact Materials–Some Proposals' (2019) 36 Food Additives and Contaminants 1,1 <https://doi.org/10.1080/19440049.2019.1662494>.
[291] Ares(2020)7731375 (n 232) 2.

of substances, is the lack of requirements for Member States to analyze a minimum number of samples per year. [292]

While collaboration between different sectorial frameworks could help to manage the authorization and assessment of substances, the current FCM framework unfortunately lacks a mechanism to rapidly incorporate new scientific information made available by various EU scientific assessment bodies, including assessment bodies other other than EFSA. [293] For example, legislation on FCM risk assessments lacks specificity to ensure the protection of vulnerable groups,[294] albeit its significance is being addressed in a numerous studies. This issue is not unique to FCMs but applies to various frameworks addressing EDs, establishing clearer definitions for vulnerable groups may stimulate prospective implementation of specific provisions targeted at these groups.[295]

Implications for compliance and traceability by businesses operators

The FCM Regulation is considered to be technically complex and difficult to understand, creating a challenge for business operators to ensure compliance.[296] This complexity is further amplified by the multitude of national measures adopted by Member States, due to the lack of harmonized EU-specific rules for most FCMs other than plastics. [297] This creates a fragmented regulatory landscape, where businesses operators have to comply with different requirements depending on the country, causing problems for the functioning of the internal market. [298] Moreover, recent EU policies promoting recycling and waste reduction will likely increase the challenge of ensuring compliance to safety requirements of FCMs in the future. [299] Additionally, compliance to traceability requirements is hampered by the incomplete and inefficient exchange of information between business operators, in particular when different businesses operate in different Member States. [300]

The current compliance system is particularly burdensome for small and medium-sized enterprises (SMEs). Whereas bigger companies have certain

[292] Report Official Controls FCMs (n 244) 4.
[293] Ares(2020)7731375 (n 227) 2.
[294] Ares(2020)7731375 (n 227) 2.
[295] SWD 2020 Fitness Check on EDs (n 264) 32.
[296] SWD 2022 FCM Evaluation (n 245) 22.
[297] Ares(2020)7731375 (n 227) 2.
[298] Ares(2020)7731375 (n 227) 2.
[299] SWD 2022 FCM Evaluation (n 245) 60.
[300] SWD 2022 FCM Evaluation (n 245) 17.

resources to ensure compliance, SMEs do not have the resources to establish an advanced system on which they can rely. Detailed technical rules might be too demanding or too difficult to understand in relation with their business, and as FCM legislation is not coherent among Member States, the SMEs might be restricted in marketing their products across the EU may be forced to choose specific markets in advance, as addressing multiple rules in various Member States is beyond reach; Additionally, SMEs usually can't afford the cost of applying for substance assessments for authorization and have to depend on applications of bigger companies.[301]

As a result, it is complex for businesses to ensure compliance with the FCM Regulation. Research by the DG Health and Food Safety verifying the presence of DoCs in Member States has shown that the compliance level was only around 60%, and when the content of the DoC was properly examined, the compliance rates dropped to 10-30%.[302]

Implications for official controls by Member States' authorities

Reaching a sufficient level of Official Controls is challenging. Analytical methods for certain FCMs, such as paper and cardboard, and for the presence of certain substances like NIAS, are limited.[303] Besides, as there is relatively few staff qualified to conduct official controls on food and FCMs, and their expertise is often considered insufficient.[304] Other underlying problems that were identified include the inability to identify all relevant businesses, industrial equipment being often overlooked during official controls, a lack of effective training for inspectors, a lack of comprehensive checklists and other guidance documents, poor documentation of controls and laboratories not having the resources or the ability to perform unforeseen analytical samples.[305]

These challenges inhibit the effectiveness of Official Controls. Furthermore, Official Controls of FCMs are often limited to verifying the presence of a DoC.[306] Cases of non-compliance may be undetected, potentially compromising food safety. Even when cases of non-compliance are identified, it is unclear in which

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[301] Ares(2020)7731375 (n 227) 3.
[302] Report Official Controls FCMs (n 244) 9
[303] ibid.
[304] ibid.
[305] SWD 2022 FCM Evaluation (n 245) 27.
[306] ibid.

cases the competent authority must create an RASFF report.[307] Besides, RASFF notifications are not sufficiently followed by enforcement measures and penalties. In 2017 and 2018, the RASFF system recorded 258 FCM-related notifications, including 82 alerts (74 for high migration values) and 97 border rejections (90 from China) and despite these issues, audits in 2018 found that no Member State visited had withdrawn non-compliant FCM-related food commodities from the market.[308]

Implications for EU public health

The current FCM framework of the EU is characterized by a lack of definition and coherence, which may have concerning implications for public health. Due to a lack of harmonized safety standards across Member States, consumer exposure to hazardous substances such as EDs can vary per country. Research by L. Zimmerman systematically analyzed the food contact materials listed for international use in FCM in the EU and identified a list of 388 known food contact chemicals of concern (FCCoCs).[309] Among these, 22 were identified as EDCs, with evidence indicating the presence of 16 in FCMs. Notably, the list includes only chemicals that were intentionally added during manufacturing and excludes non-intentionally added substances (NIAS), which may number up to 100,000 chemicals, potentially transferring from FCMs into food and beverages. All these chemicals may have negative consequences for health after exposure, and their potential interactions may result in a "cocktail effect".

Infants, children and pregnant women are particularly vulnerable for exposure to EDs.[310] Legislative efforts to improve the protection of these vulnerable groups have been initiated. The ban of Bisphenol A in baby bottles is one such measure specifically targeting them.[311] However, the rise in use of substitutes such as Bisphenol S could be a cause of concern.[312] Fortunately, in December 2024, the

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[307] Report Official Controls FCMs (n 244) 10.
[308] Report Official Controls FCMs (n 244) 8.
[309] Lisa Zimmermann and others, 'Implementing the EU Chemicals Strategy for Sustainability: The Case of Food Contact Chemicals of Concern' (2022) 437 Journal of Hazardous Materials 1,2 <https://doi.org/10.1016/j.jhazmat.2022.129167>.
[310] Elsi Haverinen and others, 'Metabolic Syndrome and Endocrine Disrupting Chemicals: An Overview of Exposure and Health Effects' (2021) 18 International Journal of Environmental Research and Public Health 1,7 <https://doi.org/10.3390/ ijerph182413047>.
[311] European Commission, 'Bisphenol A: EU Ban on use in baby bottles enter into force next week' (European Commission 25 February 2011) <https://ec.europa.eu/commission/presscorner/detail/en/ip_11_229>. accessed 1 April 2025
[312] Min Kyong Moon, 'Concern about the Safety of Bisphenol a Substitutes' (2019) 43 Diabetes and Metabolism Journal 46,48 <https://doi.org/10.4093/dmj.2019.0027>.

Commission adopted an ban on the use of Bisphenol A and derivatives in all FCMs with a 18-month phase out period.[313] While this measure may significantly reduce the risk of harmful Bisphenol substitution, it does not eliminate the possibility that other hazardous substances may be used in their place.

Additionally, recycling of FCMs, which has been promoted as a sustainable alternative, may also raise concerns for consumers. While this ecological shift has positive purposes, the use of recycled materials in FCM has not been investigated enough in the area of human health safety, as new research found that thousands of chemicals are being used in paper and board packaging without their safety being properly assessed.[314]

4.5 Chapter Summary

The EU FCM framework requires collaboration between various stakeholders to operate effectively. Competent Authorities need to assess and authorize substances in FCMs, FCM businesses operators have to comply with safety and traceability requirements, and competent Authorities of the Member States need to carry out Official Controls. However, challenges hamper the development of effective policies, such as a multitude of substances in FCMs that need assessment and authorization, including many complex substances with potential ED-properties, and the EU's ambition to shift toward a circular economy and promote FCM recycling. This has led to limitations in the EU FCM framework.

Lack of definition; The unclear definition of the subject matter has led to uncertainty about which rules apply to certain FCMs. Besides, article 3 of the FCM Regulation in itself does not define the level of safety expected, how it should be reached or how it can be demonstrated, which has consequences for materials that are not covered in material-specific legislation. Besides, a DoC is not always required and many are incomplete, which has implications for compliance and enforcement. Moreover, EDs are not properly addressed in FCM legislation.

Lack of coherence; As not all groups of materials mentioned in the Annex of the FCM Regulations have specific measures, thus many MSs adopted national rules. Moreover, the inconsistencies occur in the incorporation of EDs across different

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[313] European Commission, 'Commission adopts ban of Bisphenol A in food contact materials' (2024) <https://food.ec.europa.eu/food-safety-news-0/commission-adopts-ban-bisphenol-food-contact-materials-2024-12-19_en>. accessed 4 May 2025

[314] ibid (n 283) 4.

sectorial frameworks and the FCM Regulation does not include EDs in their provisions, this creates confusion regarding legislative consequences of ED presence in products.

The addressed challenges and the legislative EU FCM framework's lack of definition and coherence has implications for all stakeholders involved in the supply chain.

Assessment / authorization of substances by Authorities; Laboratories struggle to analyze a sufficient number of complex substances, due to a lack of available testing methods as well as a lack of requirements for MSs to analyze a minimum number of samples per year. More collaboration between various EU assessment bodies could help to manage authorization and assessment of substances including EDs, but the current FCM framework lacks a mechanism to incorporate information from other assessment bodies than EFSA.

Compliance / Traceability by businesses operators; The FCM Regulation and the multitude of national measures are considered be complex and difficult to understand. It is hard for businesses operators to ensure compliance, especially for SMEs.

Official Controls by member States' authorities; Official controls are hampered by limited analytic methods for certain substances in FCMs, a lack of qualified staff, inadequate training availabilities for inspectors, overlooked industrial equipment and poor documentation. This inhibits the effectiveness of official controls, which are currently often limited to verifying the presence of a DoC. Even when cases of non-compliance are identified, the required consequences are unclear.

Eu public health; Research by L Zimmerman identified sixteen used substances indicated as EDCs used substances in FCMs, this list does not include the presence of hazardous NIAS. Vulnerable groups such as children and pregnant women are a source of concern, and recycling may also raise concerns for consumers, as the use of recycled materials in FCM has not been investigated enough in the area of human health safety.

In conclusion, the uncertainties within the current FCM framework impact all relevant stakeholders, which may result in unnecessary ED exposure.

5. The revision of the EU FCM Framework: Enhancing protection against EDs

The previous chapter highlighted that the current EU FCM framework does not sufficiently protect human health, as it still leads to the presence of hazardous substances in FCMs such as EDs. Additionally, the lack of harmonization results in an uneven protection for consumers across the EU. This is not in line with the objectives of the EU Green Deal. This chapter begins with discussing various policies driving the revision of the FCM framework and its ED management. The next subchapter provides an overview of the Commission's published initiatives related to or the revision of the EU FCM Framework. This is followed by an overview of the main policy themes and pillars in the revision of EU FCM rules. The final subchapter consists of an overview of stakeholder's perspectives on the plans of the Commission regarding the FCM revision.

5.1 Policies driving the revision of the FCM framework and its ED management

Ongoing challenges such as climate change, population growth and pollution have unfavorable consequences for both humans and the environment. These challenges contribute to issues such as poverty, inequality and food insecurity while also driving the rise in biodiversity loss and environmental pollution. In response, various initiatives have been launched on a national, regional and global level. This subchapter provides an overview of the key policies that paved the way for the Commission's initiative to revise the FCM Regulation.

2015: Transforming our world: the 2030 Agenda for Sustainable Development

This Agenda, established in 2015 by the United Nations, is a plan of action for people, the planet and prosperity.[315] A plan with a vision in mind where all life can thrive, in which the world is free of poverty, hunger and disease, and where food is sufficient, safe, affordable and nutritious.[316] A plan where also conditions are created for inclusivity and sustainable economic growth.[317] The organization is committed to achieving sustainable development in three dimensions: economic, social and environmental; And committed to achieving this by the implementation of this Agenda by 2030. After a thorough process of

[315] United Nations, 'Transforming our world: The 2030 Agenda for Sustainable Development' (A/RES/70/1, United Nations 2015) 5.
[316] ibid 7.
[317] ibid 6.

intergovernmental negotiations[318], the UN agreed to 17 Sustainable Development Goals which are further defined by 169 associated targets[319] outlined in this Agenda. As the established goals are universal and involve the entire world, the agenda is accepted by all countries and applies to all.[320] Member States as well as other actors are encouraged to develop (national) responses and other contributions to the overall implementation of this Agenda.[321] The revision of the FCM Regulation and its ED management is closely

linked to the following SDGs and their related targets[322]:

Goal 2. End hunger, achieve food security and improved nutrition and promote sustainable agriculture
2.1 By 2030, end hunger and ensure access by all people, in particular the poor and people in vulnerable situations, including infants, to safe, nutritious and sufficient food all year round
2.4 By 2030, ensure sustainable food production systems and implement resilient agricultural practices that increase productivity and production, that help maintain ecosystems, that strengthen capacity for adaptation to climate change, extreme weather, drought, flooding and other disasters and that progressively improve land and soil quality
Goal 3. Ensure healthy lives and promote well-being for all at all ages
3.9 By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination
3.d Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks
Goal 12. Ensure sustainable consumption and production patterns
12.4 By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment
12.5 By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse

[318] ibid 16.
[319] ibid 5.
[320] ibid 7.
[321] ibid 38-40.
[322] ibid 19-27.

2019: The European Green Deal

The European Green Deal is an integral part of the EU Commission's strategy to implement the United Nation's 2030 Agenda and the Sustainable Development Goals.[323] It is a response to environmental-related challenges while reinforcing the development of a fair and prosperous European Union, with a modern, competitive economy free from greenhouse gases in 2050, and where economic growth is decoupled from resource use.[324] The EU Green Deal aims to protect the health and well-being of citizens from environment-related risks while protecting and enhancing the Union's natural capital.[325] This Communication presents an initial roadmap of the key policies and measures needed to achieve the European Green Deal; As needs evolve, the prospective policies and measures will be updated as necessary.[326] The figure below illustrates the key aspects of the EU Green Deal.

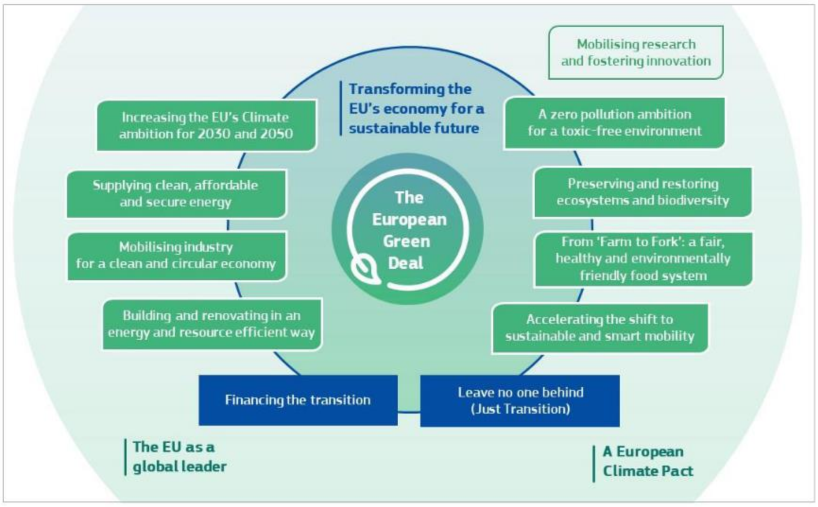

Figure 8: Key aspects of the European Green Deal

To achieve the goals of the EU Green Deal, the commission will launch new initiatives and work with Member States to enforce and implement existing policies and legislation.[327] The EU Green Deal laid the foundation for various strategies published by the Commission. Below are a few key strategies relevant to the revision of the EU FCM framework and its ED management.

[323] European Commission, 'The European Green Deal' COM (2019) 640 final 3. (EU Green Deal)
[324] ibid 2.
[325] ibid 2.
[326] ibid 2-3.
[327] ibid 4.

Farm to Fork Strategy: for a fair, healthy and environmentally-friendly food system:
As a part of the EU Green Deal, the commission presented the 'Farm to Fork' Strategy in spring 2020, which covers all stages of the food chain.[328] The Commission stated that European food currently is a global standard for food that is safe, plentiful, nutritious and of high quality; Thus, this strategy aims to elevate this standard by making European food the global standard for sustainability as well.[329] As Food packaging plays a crucial role in the sustainability of food systems, this strategy announced the **revision of the FCM Regulation** to improve food safety and public health (in particular by reducing the use of hazardous chemicals), while supporting the use of innovative and sustainable packaging solutions that contribute to the prevention of food waste.[330]

Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment: The EU Green Deal has set the ambition to create a toxic-free environment with zero pollution.[331] To achieve this goal, the Commission presented the Chemicals Strategy for Sustainability (CSS), which aims to help the protection of human health (vulnerable groups in particular) and the environment as well as encourage innovation for the development of safe and sustainable alternatives.[332]

In order to reach these aims, the existing chemicals policy should react faster to challenges caused by hazardous chemicals; Moreover, hazardous substances should be minimized and substituted whenever possible, and the most harmful ones for non-essential societal use, in particular in consumer products, should be phased out completely.[333] This necessary innovation will be driven by a more coherent, more predictable and stronger regulatory framework, combined with non-regulatory incentives.[334]

This strategy proposes a roadmap and timeline for actions to support the development of safe and sustainable chemicals, increase the protection of human health and the environment, simplify and strengthen the legal framework on

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328 ibid 12.
329 European Commission, 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' COM (2020) 381 final 1-2. (EU F2F Strategy)
330 ibid 12.
331 EU Green Deal (n 323) 14.
332 EU Green Deal (n 323) 15.
333 European Commission, 'Chemicals Strategy for Sustainability Towards a Toxic-Free Environment' COM (2020) 667 final 2. (EU CSS)
334 ibid 3.

chemicals, build a comprehensive knowledge base to support evidence-based policymaking, and set the example for a global management of chemicals.[335]

One of the key approaches to simplify and consolidate the current legal framework proposed by this strategy is the one **'substance, one assessment'** approach. Chemical safety assessments are currently being initiated under various pieces of legislation by various actors at different points in time, and unifying these assessments by this approach may lead to less inconsistencies, faster procedures and a more efficient use of resources.[336] Moreover, This strategy will attempt to gradually change the status quo by adopting the **'generic approach to risk management'** for chemicals as the default, a preventive approach already used for carcinogens; This will be key for consumer products such as FCMs, where clear criteria for essential use must be redefined.[337]

This strategy highlights the risks of EDs and emphasizes the need for a generic approach regarding the risk management of EDs; It acknowledges that the current EU Regulatory framework is overall fragmented and not all pieces of legislation can identify EDs, the legal framework needs to be consolidated and simplified to ensure that endocrine disruptors are accurately recognized and that exposure is minimized.[338]

This strategy also highlights the dangers of exposure to unintentional chemical mixtures, due to their cumulative and synergistic effects[339]. The Commission will make efforts to introduce **'a mixture assessment factor'** for the chemical safety assessment of substances in the REACH Regulation and reinforce provisions to take account of the combination effects in other relevant legislation, such as legislation on water, food additives, toys or FCMs.[340]

Circular Economy Action Plan: For a cleaner and more competitive Europe: As a part of the EU Green Deal, the Commission introduced a new circular economy action plan (CEAP) to help modernize the EU's circular economy domestically and globally; This plan aims to accelerate the development of lead markets for climate-neutral

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[335] ibid 4.
[336] ibid 14-15.
[337] ibid 9-10.
[338] ibid 11.
[339] ibid 12.
[340] ibid.

and circular products in the EU and beyond.[341] The Commission will focus on stimulating the design of reusable and recyclable packaging while exploring ways to simplify packaging materials regarding the number of materials and polymers used.[342]

Besides this, the Commission will establish rules for the safe recycling of plastic materials (other than PET) into FCMs.[343]

To assure the quality of collected waste intended for reuse in products such as FCMs, it is essential to standardize the use of quality management systems.[344] Another measure considered by the Commission to increase the sustainability of food distribution and consumption includes efforts to determine the scope of a legislative initiative on reuse, which aims to substitute single-use packaging, tableware and cutlery by reusable products in food services.[345]

This plan addresses concerns regarding the safety of secondary raw materials, in particular when banned substances persist in recycled materials.[346] This may hamper reaching the objective of a toxic-free environment, a key aim of the Chemicals Strategy for Sustainability (CSS). To increase confidence in using secondary raw materials, the Commission has proposed several initiatives, such as supporting the development of high-quality sorting and removing contaminants from waste, or improving the classification and management of hazardous substances and identifying those substances in waste.[347]

5.2 Published initiatives related to the revision of the EU FCM Framework

The Commission published three key initiatives related to the revision of the FCM Regulation and its ED management. The Commission department responsible for these initiatives is the Commission Department Directorate-General for Health and Food Safety (DG SANTE). This department is responsible for EU policy on food safety and health and for monitoring the implementation of related laws and

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[341] EU Green Deal (n 323) 7.
[342] European Commission, 'A new Circular Economy Action Plan For a cleaner and more competitive Europe' COM (2020) 98 final 8. (EU CEAP)
[343] ibid 9.
[344] ibid 13.
[345] ibid 12.
[346] ibid 13.
[347] ibid 14.

aims to protect the citizens' health and monitor their food, making sure it is safe.[348]

The first two initiatives that are being discussed focus on the evaluation and the revision of the FCM; These are handled by a sub-division of DG SANTE that is responsible for developing food safety, sustainability and innovation, called unit E.[349] While these two initiatives are distinct, they are (inter)connected due to the revision of the FCM being partly based on the evaluation. The last initiative that will be discussed concerns EDs and a review of the related EU rules. This initiative is handled by unit F, the subdivision of DG SANTE that is responsible for handling policies regarding health, food audits and analysis.[350]

2017-2022: Evaluation of Food Contact Materials (FCM)

In 2017, the Commission published a roadmap of the Commission's plans regarding the Evaluation of Food Contact materials.[351] The purpose of this initiative is to assess the functioning of the FCM Regulation as a whole, whether this Regulation works effectively and meets expectations; Not only for materials that are covered by EU measures but also concerning materials that are not covered by EU measures, which may be subject to national measures.[352]

For the completion of this evaluation, consultations were conducted with relevant stakeholders to seek their opinion on the main evaluation criteria (relevance, efficiency, effectiveness, coherence and EU added-value), while also identifying unexpected impacts or issues as a consequence of the current Regulation.[353] In 2022, the evaluation of the FCM legislation was completed and the final version of the Staff Working Document regarding this initiative was published.[354]

2020-Ongoing: Revision of EU rules on food contact materials

The initiative regarding the Revision of EU rules on food contact materials, announced in the Farm to Fork Strategy as a part of the EU Green Deal, aims to

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[348] European Commission, 'Health and Food Safety' (European Commission, n.d.) <https://commission.europa.eu/about/departments-and-executive-agencies/health-and-food-safety_en>. accessed 2 April 2025
[349] European Commission/DG Sante, 'DG Sante' (European Commission/DG Sante, 1 April 2025) <https://commission.europa.eu/document/download/277adfe3-745d-40ad-b530-450af9d715e2_en?filename=organisation-chart-dg-sante_en.pdf>. accessed 2 April 2025
[350] ibid.
[351] European Commission, 'Evaluation of Food Contact Materials' Ares(2017)5809429, 2
[352] European Commission, 'Evaluation of Food Contact Materials (FCM) – About this initiative' (European Commission, 9 June 2022) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1212-Evaluation-of-Food-Contact-Materials-FCM-_en>. accessed 2 April 2025
[353] ibid (n 351) 2.
[354] ibid (n 352).

create a proposal for a modernized FCM regulation that ensures food safety, reduces the presence and use of hazardous chemicals, includes the latest technologies, and promotes safe reusable and recyclable solutions.[355] The revision will be based on the findings of the evaluation of current FCM legislation but it will also reflect the ambition of other strategies, including the CEAP and the CSS.[356]

The Commission published an Inception Impact Assessment (IIA) that provided a context and a problem definition; Besides, the objectives and policy options were provided and the potential impact of those policy options was assessed.[357] After the IIA was published, the Commission held a public consultation period from October 2022 till January 2023 to give the opportunity to all interested parties to provide feedback.[358] The Commission adoption was planned for the second quarter of 2023 but the feedback has been upcoming till this date.[359]

2019-2020: Harmful chemicals – Endocrine Disruptors, review of EU rules

This initiative assessed whether the variety of EU measures handling EDs are sufficient to protect human health and the environment, by assessing the coherence and relevance of the EU chemicals legislation and by assessing its effectiveness in minimizing overall exposure to EDs.[360] [361]

In particular, it paid attention to legislation that does not contain specific provisions for EDs, such as legislation on toys, cosmetics and FCMs.[362] It also examined whether the different pieces of legislation considered the protection of vulnerable groups that are in particularly sensitive to EDs.[363] A public

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355 European Commission, 'Revision of EU rules on food contact materials – About this initiative' (European Commission, 11 January 2023) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en>. accessed 2 April 2025

356 European Commission, 'Revision of EU Rules on FCMs' (European Commission, 5 May 2023) <https://food.ec.europa.eu/food-safety/chemical-safety/food-contact-materials/revision-eu-rules_en>. accessed 2 April 2025

357 European Commission, 'Inception Impact Assessment - Revision of EU rules on food contact materials' Ares(2020)7731375 1-2. (Ares(2020)7731375)

358 ibid (n 355).

359 ibid.

360 European Commission, 'Harmful chemicals – endocrine disruptors, review of EU rules' (European Commission, 14 October 2020) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2142-Harmful-chemicals-endocrine-disruptors-review-of-EU-rules_en>. accessed 2 April 2025

361 European Commission, 'Fitness Check on endocrine disruptors' SWD (2020) 251 final 13. (SWD 2020 Fitness Check on EDs)

362 European Commission, 'Fitness Check on Endocrine Disruptors' Ares(2019)3752914 2. (Ares(2019)3752914)

363 SWD 2020 Fitness Check on EDs (n 361) 13.

consultation regarding this initiative was held in Q4 of 2019, offering the possibility to reply on the published roadmap and consult key stakeholders and public authorities as appropriate.[364]

Following the consultation period, the Commission gathered an analyzed the existing data on this topic and published the final version of the Staff Working Document regarding the 'Fitness Check on endocrine disruptors' in 2020.[365]

5.3 Main policy themes and pillars in the revision of EU FCM rules

The following section will discuss six pillars provided by the Commission in which the improvements of the current issues of the current EU FCM framework are proposed. As this info originated from two sources, the following section will be referenced to by the source of the Inception Impact Assessment and the PowerPoint slide of the Commission that provides and overview of the six pillars.[366]

Pillars A, B and C focus on ensuring the safety and sustainability of the final material, whereas pillars D, E and F focus on ensuring the exchange of information in the supply chain, support for SMEs and enforcement of the rules.

Moreover, in 2021, the Commission hosted a webinar regarding the evaluation and revision of the EU rules on Food Contact Materials. [367] During this webinar as well as in the IIA, two options regarding the prospective legislative pathways were presented. Option one was to use the current regulatory framework as a cornerstone and option two was to develop a new regulatory framework, replacing the current Regulation.

A. Shifting the focus onto final materials

Currently, the legal framework is mainly focused on the safety of the starting substances used in the manufacture of FCMs. To improve the safety of FCMs, the Commission plans to set its focus on the safety if the final material/combination of materials, while addressing all substances that may potentially migrate into

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[364] Ares(2019)3752914 (n 362) 2.
[365]SWD 2020 Fitness Check on EDs (n 361) 1.
[366] Ares(2020)7731375 (n 361) 4-7; European Commission, 'Revision of EU FCM rules: Main policy themes and pillars' (European Commission, n.d.) <https://food.ec.europa.eu/document/download/2e1b1eb0-66fe-45e6-bf6d-ffd64a735fca_en?filename=cs_fcm_revision_policy-pillars_202305.pdf>. accessed 2 April 2025
[367] European Commission, 'Webinar on the evaluation and revision of the EU rules on Food Contact Materials' (European Commission, 20 January 2021), slide 20 <https://food.ec.europa.eu/document/download/a779accc-cca5-41cb-81d4-dd42301cfd49_en?filename=cs_fcm_eval-workshop_20210120_pres.pdf>. accessed 2 April 2025

food. To realize this, rules and legal requirements regarding the necessary level of safety and how to achieve this will be redefined. Besides, rules on GMPs will be strengthened.

B. Prioritizing the assessment and management of substances

The Commission proposed a tiered approach to prioritize the regulation of substances, in which several factors such as hazard properties, their use, potential migration and eventual exposure are taken into account. Risk assessments should also consider the most up-to-date scientific information in which the risk assessments are revised regularly if new scientific information becomes available. Besides, during risk assessment, a bigger emphasis would be placed on vulnerable groups such as pregnant women and children. In line with the 'one-substance, one-assessment' approach of the CSS, the proposal would further clarify the distinctive role of Agencies such as EFSA and ECHA in the assessment of the most hazardous substances, making full use of available data under REACH.

Tier 1 substances: These substances are labeled as the most hazardous substances, such as CMRs and EDs. The Commission would introduce a generic approach regarding those substances, a preventive approach already used for carcinogens.

Tier 2 substances: Substances with incidental specific concerns such as those in nano-form or those migrating in high amounts, would need a safety assessment using available knowledge from EU risk assessment bodies including those in Member States.

Tier 3 substances: For safer substances that migrate in low amounts, business operators using them will be responsible for risk assessments under guidance of enforcement bodies. Still, the presented information as a result of the risk assessments shall be reviewed by enforcement bodies.

C. Supporting safer and more sustainable alternatives

New rules will be introduced regarding the assessment of less traditional and more sustainable production sources. The Commission will also expand rules to prioritize and support safe re-use and recycling, prevent contamination risks and to further support goals on sustainability in the entire life-cycle of food packaging, in line with the F2F Strategy.

D. Improving quality and accessibility of supply chain information

The Commission will establish clear and consistent rules on data requirements and information transfer throughout the supply chain. Besides, a DoC would be required for all FCMs. Moreover, efforts would be made to fully digitalize the information system, to make it easier for businesses, especially SMEs, to ensure compliance and aid enforcement by Member States' authorities.

E. System for ensuring compliance of the final FCM

The Commission proposes new rules on data requirements and information transfer with the optional help of notified and delegated bodies, whereas a more digitalized information system will help businesses to ensure compliance and for Member States to enforce it.

F. Improving analytical methods

Rules on testing migration and other analytical methods are strengthened. Moreover, the Commission would encourage the further development of test methods and technical standards as required.

5.4 Perspectives of stakeholders on the Commission's plans

Various stakeholders have expressed their views regarding the 6 pillars mentioned in the IIA published by the Commission. For the completion of this sub-chapter, various documents that were published by stakeholders as a reaction on the IIA, both on the Commission's website during the consultation period and on their own platforms, were selected and analyzed. During this review, several overlapping themes related to the provided 6 pillars and a divergence in opinions on how these should be addressed emerged. This section aims to provide an overview of the most reoccurring themes and the differences in perspectives of stakeholders.

Relationship of FCM Regulation with other (legislative) frameworks

Safe Food Advocacy Europe (SAFE) urges for better coordination between chemicals legislation (REACH) and the FCM Regulation to guarantee that harmful substances phased out under REACH are also eliminated from FCMs.[368] Better coordination with REACH would also support the development of the "one substance, one assessment" approach. However, multiple Business Associations noted that the direction of this approach should be more carefully defined and

[368] Safe Food Advocacy Europe, 'SAFE response to Road map: Revision of EU rules on food contact materials Document' (SAFE 27 January 2021) 2. (SAFE)

addressed the importance of details on how it will be practically implemented.[369] The NGO Rethink Plastic goes further, arguing that substances identified in the REACH SVHC Candidate list and CLP Annex 6 must be automatically banned.[370] Additionally, there is a need for more clarification of the respective role and cooperation of the Agencies responsible for the assessment of chemical and food safety (EFSA & ECHA) to move forward.[371]

Option one vs. Option two

As described in the previous section, the Commission proposed two pathways for the revision of the FCM Regulation. The first option uses the current regulatory framework as a cornerstone and the second option entails the development of a new regulatory framework to replace the current one.

Most stakeholders from business or sectoral associations prefer option one, arguing that the current regulatory framework adequately serves its objectives and provides a good basis; However, its effectiveness is hampered by inadequate rules on implementation and enforcement at a horizontal level; To work effectively, the framework needs to be further detailed and harmonized.[372] It is also argued by Normpack to go for option one to keep a more continuous but evolving regulatory field, instead of an entirely new situation for the industry.[373]

Most NGOs support option two, arguing that the current legislative framework fails to protect consumer health and interests and requires a significant overhaul

[369] The Association of European Producers of steel for packaging, 'No title' (APEAL 29 January 2021), 2 (APEAL); CITPA/FEFCO/CEPI/ECMA/EPPA, 'No title' (representing paper and board value chain, CITPA/FEFCO/CEPI/ECMA/EPPA 27 January 2021) 2. (CITPA/FEFCO/CEPI/ECMA/EPPA); The European Container Glass Federation, 'Inception Impact Assessment Roadmap: Container Glass Packaging for Food Contact' (FEVE January 2021) 3. (FEVE); Packaging Joint Industry Taskforce, 'PIJTIF feedback to the Inception Impact Assessment on Revision of EU rules on food Contact Materials' (PIJITF 27 January 2021) 1. (PIJITF)

[370] Rethink Plastic, 'Revision of EU rules of FCMs – Inception Impact Assessment' (Rethink Plastic January 2021) 1. (Rethink Plastic)

[371] Association of the European Adhesive and Sealant Industry, 'FEICA Position on the roadmap fort he revision of EU rules on food contact materials' (FEICA 27 Januari 2021) 2. (FEICA); Health and Environment Alliance, 'Response to the European Commission public consultation on the inception impact assessment fort he review of the Food Contact Materials legislation' (HEAL January 2021) 3. (HEAL)

[372] EU Fish Processors and Traders Association, 'AIPCE CEP on Roadmap for Food contact Materials' (AIPCE CEP, 27 January 2021) 1. (AIPCE CEP); FEICA (n 375) 1;PLASTICS Industry Association, 'PLASTICS Comments on Revision of EU Rules on Food Contact Materials' (PLASTICS n.d.) 1. (PLASTICS); PIJITF (n 369) 3.

[373] Normpack, 'Feedback to the Inception Impact Assessment (IIA) on the revision of EU rules for food contact materials' (Normpack, 28 January 2021) 1. (Normpack)

to address its structural issues.[374] ClientEarth provided a valuable theory on why the current framework is ineffective and in need of a significant overhaul, highlighting a fundamental mismatch between the aims and provided tools. In the FCM sector, the supply chain runs across three different domains: food contact chemicals (FCCs), FCMs and food contact articles (FCAs), illustrated by the figure below adopted from Muncke and others; The FCM Regulation is supposed to address the safety of materials, but it has the aim of product regulation while using the tools of chemical regulation; This mismatch has resulted in triple failure: the regulation does not address the safety of the FCA, while it indirectly addresses the safety of FCMs and lacks the capacity to address the safety of FCCs.[375]

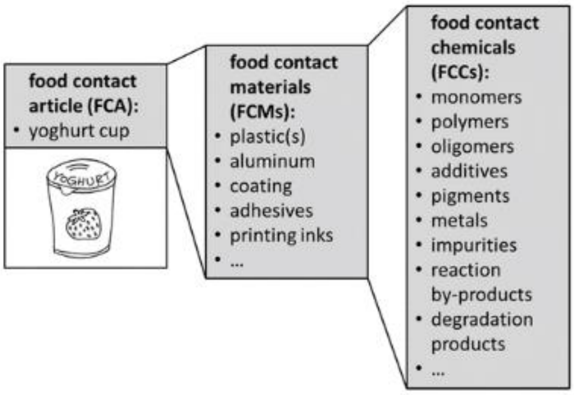

Figure 9: Representation of different sections of the Food Contact Article supply chain, adopted from Muncke and others.

Shift of focus to final materials

NGOs, as well as Business and Sectoral Associations, welcome the shift in focus from the starting materials to the final materials. However, some organizations have expressed concerns. NGOs are mainly concerned with the lack of clarification of this aim, and whether the migration of NIAS is sufficiently addressed.[376] Rethink Plastic argues that the roadmap should focus on

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[374] BEUC The European Consumer Organisation, 'Revision of EU Rules on food contact materials – BEUC comments to the Open Public Consultation' (BEUC n.d.) 1. (BEUC); Clientearth, 'Revision of EU rules on FCM – Contribution to the IIA Ares (2020) 77831375' (ClientEarth January 2021) 1. (ClientEarth); Foodwatch, 'Response to the Inception Impact Assessment on Food Contact Materials' (Foodwatch 29 January 2021), 1 (Foodwatch); Zero Waste Europe, 'Zero Waste Europe's response to the Inception Impact Assessment on the revision of EU rules on Food Contact Materials' (ZWE January 2021) 2. (ZWE); HEAL (n 371) 2; Rethink plastic (n 370) 2.
[375] ClientEarth (n 374) 1-2.
[376] CHEM Trust Protecting humans and wildlife from harmful chemicals, 'CHEM Trust's additional comments on the European Commission's consultation on the revision of EU rules on food contact

minimizing presence instead of focusing on migration, which is a simpler and more CEAP-fit approach.[377] Besides, it is unclear how this shift in focus can be achieved and how it can be aligned with approaches of other sectors.[378] Lastly, a clear mention of the safety of the final article would be welcomed,[379] which is also endorsed by several business and sectoral associations.[380]

Some associations argue that the risk assessment of starting substances should remain a cornerstone of FCM legislation, as the safety of starting substances is still a pre-condition and a shared responsibility of each actor.[381] A well-defined approach to shared responsibility will benefit every actor in the supply chain, in particular SMEs.[382]

Another point of consideration highlighted by two associations is the current existence of positive lists and their relation to this shift. Positive lists are currently established for starting substances and it will be an immense, if not impossible task to create a positive list for substances in the final material.[383] The second best option according to the ECMA would be the creation of transparent inventory lists with all substances somewhere regulated with the adopted limits, indicating also in which FCM the substances may appear.[384]

Prioritizing the assessment and management of substances

Many stakeholders consider prioritizing the management and assessment of substances to be important and support the tiered approach.[385] The commitment to increase the protection of vulnerable groups is also welcomed.[386] However,

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materials' (CHEM Trust January 2023) 4. (CHEM Trust); Health Care Without Harm Europe, 'Roadmap feedback Revision of EU rules on food contact materials' (HCWH n.d.) 2. (HCWH)
[377] Rethink Plastic (n 370) 1.
[378] BEUC (n 374) 3.
[379] HEAL (n 371) 2.
[380] Glass Alliance Europe, 'Glass Alliance Europe Position Paper on the Revision of the Framework FCM Legislation' (Glass Alliance Europe, n.d.) 1. (Glass Alliance Europe); UNESDA Soft Drinks Europe, 'UNESDA submission to the European Commission Inception Impact Assessment on the revision of rules on Food Contact Materials' (UNESDA 29 January 2021) 3. (UNESDA)
[381] European Carton makers Association, 'ECMA Comments
Revision of the EU rules on food contact materials (FCM's) Inception Impact Assessment' (ECMA n.d.) 1. (ECMA); UNESDA (n 380) 2.
[382] CITPA/FEFCO/CEPI/ECMA/EPPA (n 373) 1.
[383] Flexible Packaging Europe, 'FPE Response to the "INCEPTION IMPACT ASSESSMENT"' (FPE 29 January 2021) 1. (FPE); FEICA (n 371) 2.
[384] ECMA (n 381) 1.
[385] ECMA (n 381) 3.
[386] Foodwatch (n 374) 1.

conducting a full toxicological assessment for all unevaluated substances will not be possible, challenging the successful implementation of the tiered approach.[387]

Furthermore, SAFE addressed the importance of assessing EDs in FCMs, as chemicals migrating from FCMs into food are not subject to any ED effects assessment; Additionally, some chemicals might not be tested if their exposure is considered to be below the toxicologically established no-effect level.[388] Considering the specific properties of EDs, including their effect at very low doses, HEAL believes that EDs should not be tolerated in FCMs[389].

Additionally, it is unclear for stakeholders where NIAS fit in this tiered approach.[390] While the tiered approach can be useful, it cannot be seen as a solution for everything; The Commission should opt to challenge the opinions of relevant stakeholders to ensure full engagement of the food contact sector.[391]

The Commission has proposed a generic approach for the substances with the most hazardous properties such as EDs, the so-called tier 1 substances. This approach aims to prohibit substances of concern in FCMs.[392] Multiple NGOs endorse this approach and argue that the new regulatory framework should ban the presence of the most hazardous substances.[393] Zero Waste Europe goes even further and argues that it should consider phasing out beyond tier 1 substances, considering their specific use in FCMs.[394]

Business and sectoral organizations are more critical of the introduction of a generic approach.[395] There is a lack of clarity regarding its exact definition.[396] Moreover, it is argued that if this generic approach is mainly hazard-based, it could lead to regrettable substitutions, where the alternative substances have equivalent or worse effects.[397]

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387 ECMA (n 381) 1.
388 SAFE (n 368) 6.
389 HEAL (n 368) 1.
390 HEAL (n 371) 2.
391 APEAL (n 369) 2.
392 CHEM Trust (n 376) 6.
393 BEUC (n 374) 3; CHEM trust (n 376) 6; Foodwatch (n 374) 1; HEAL (n 371) 2.
394 ZWE (n 374) 1.
395 APEAL (n 369) 2; CITPA/FEFCO/CEPI/ECMA/EPPA (n 369) 2; PIJITF (n 369) 1;UNESDA (n 380) 1.
396 APEAL (n 369) 2.
397 ibid.

The proposed approach for tier 3 suggests a significant role for the industry in terms of self-regulation. Different NGOs have expressed their concerns regarding the importance that is given to self-regulation by the industry.[398] The option of self-regulation by the industry could be explored, but integrity should be protected and provisions are needed to prevent potential conflicts of interest.[399]

Supporting safer and more sustainable alternatives

The sustainability of FCMs is a broad concept and that covers various aspects. In response to the IIA, the stakeholders have mainly commented on the recyclability of FCMs. NGOs as well as business or sectoral associations welcome the incentive to increase the sustainability of the FCM supply chain by promoting the use of safer and more sustainable materials and supporting safe recycling.[400]

Several comments provided additional legislative aspects on sustainability. PIJITF and Feica, two sectoral associations, emphasized that new rules should be flexible to enable businesses to innovate and facilitate faster substitution of substances of concern and the development of sustainable alternatives.[401] Additionally, some NGOs advocated for introducing legal targets to minimize the environmental impact of FCMs.[402]

While most stakeholders acknowledge the importance of sustainability, some NGOs stress that the core objective of the FCM legislation is to ensure food safety. They argue that additional requirements on sustainability issues other than safety may distract attention from the chemical safety of FCMs and require different people to be involved.[403] Ensuring the safety of recycled plastics is more difficult than it is for virgin plastics, there is a risk of contamination during the recycling process and there is no guarantee that recycled content in products does not pose a risk to public health.[404] Some stakeholders believe that other legislation is more appropriate to address additional sustainability requirements.[405]

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398 ClientEarth (n 374) 7; ZWE (n 374) 1.
399 BEUC (n 374) 4; HEAL (n 371) 2.
400 ECMA (n 381) 2; ZWE (n 374) 2.
401 FEICA (n 371) 2; PIJITF (n 369) 2.
402 BEUC (n 374) 3; ZWE (n 374) 2.
403 CHEM Trust (n 376) 3.
404 SAFE (n 368) 4; HCWH (n 376) 2.
405 CHEM Trust (n 376) 3; Glass Alliance Europe (n 380) 1.

Improving quality and accessibility of (supply chain) information

There is a broad consensus among stakeholders on the need to improve the quality and accessibility of supply chain information. When supply chain actors have knowledge about the materials they use, they can make informed and potentially safer decisions and consider alternatives, contributing to safer options being available to consumers.[406]

Some stakeholders support the introduction of a DoC (Declaration of Compliance) for all FCMs, although the paper and board value chain does not want to see the introduction of a DoC as a one-size-fits-all solution, the proposal is supported as it can increase the transparency of information.[407] APEAL agrees with the introduction of a simplified and digitalized IT system at the EU level, but this should be evaluated based on effectiveness, efficiency, and user-friendliness, so that external expertise is not required in the act of submission of information to the authorities.[408] Moreover, the BEUC stresses the need to improve the availability of information for control authorities.[409]

Lastly, improving the transparency towards consumers is crucial according to multiple NGOs, this will empower consumers to make informed choices with the information provided, e.g. through labels.[410] However, BEUC warns that it is crucial to avoid overloading food contact articles with labels, as it this may confuse consumers and can create a false sense of security and trust.[411]

System for ensuring compliance of the final FCM

Several stakeholders have commented on the alternative option of involving delegated or notified bodies in compliance checks alongside the Member States' competent authorities. While this approach may have the potential to improve compliance, the IIA lacks details on how this would work in practice or what it might entail.[412] The BEUC only considers this as an acceptable option with strict oversight by Member States over the private entities and if control of enforcement can be guaranteed.[413] HEAL is also wary of this approach, as it may put the integrity of the compliance system at risk; HEAL prefers to develop an

[406] CHEM Trust (n 372) 4; BEUC (n 370) 4.
[407] CITPA/FEFCO/CEPI/ECMA/EPPA (n 369) 3; FEICA (n 371) 2.
[408] APEAL (n 369) 2-3.
[409] BEUC (n 374) 3.
[410] HEAL (n 371) 3; CHEM Trust (n 376) 6; ZWE (n 374) 2.
[411] BEUC (n 374) 6.
[412] FPE (n 383) 3; BEUC (n 374) 5.
[413] BEUC (n 374) 3.

approach that supports the increase of capacities of national public authorities.[414] BEUC suggests collecting fees from operators to cover the costs of performing official controls.[415]

Harmonized rules for all types of materials help to reduce complexity and lower compliance costs for businesses.[416] Moreover, it may lead to more uniform levels of protection.[417]

Improving analytical methods

Shifting focus from the starting substances to the final product increases the number of substances that need to be analyzed. To guarantee consistency, SAFE advocates for the adoption of a single EU standard for analytical testing of FCMs, as differing standards create uncertainty.[418] Additionally, the Commission should set rules on uniform conditions and for certain products, in particular high-risk items such as online products and imported goods.[419]

5.5 Summary Chapter

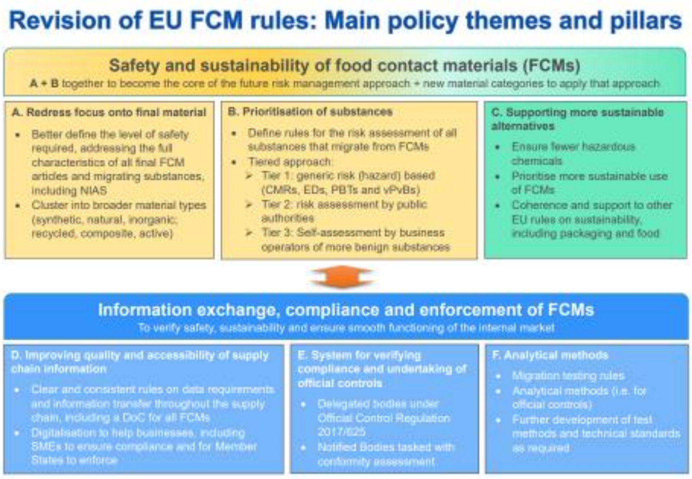
Various policies have contributed to the realization of the revision of the EU FCM framework. The 2030 Agenda for Sustainable Development outlined goals such as achieving food security, promoting healthy lives and ensuring sustainable consumption and production patterns, and minimizing the presence of hazardous chemicals such as EDs. To reach these goals, the Commission launched the EU Green Deal, which laid the foundation of the Chemicals Strategy for Sustainability, the Circular Economy Action Plan and the Farm-to-Fork Strategy. The last strategy announced the revision of the FCM Regulation. In response, the commission published two initiatives related to the revision of the FCM Regulation, which resulted in the publication of the Staff Working Document on the evaluation of the FCM Regulation as well as the publication of the Inception Impact Assessment (IIA) on the revision of the FCM Regulation. Moreover, an initiative was published regarding Harmful Chemicals including EDs.

The IIA proposed two legislative pathways to move forward. The first option uses the current regulatory framework as a cornerstone and option two entails the

[414] HEAL (n 371) 3.
[415] BEUC (n 374) 4.
[416] FEVE (n 369) 1.
[417] HCWH (n 376) 1.
[418] SAFE (n 368) 3.
[419] BEUC (n 374) 5.

development of a new regulatory framework. Business associations prefer option two, arguing that the current framework provides a sufficient base to achieve the policy's objectives but needs more detailed rules. In contrast, NGOs and consumer organizations prefer option one, arguing that the current framework is inadequate for achieving the intended goals and requires fundamental changes. *Developing a new framework where all groups of materials are equally addressed may take more time to establish, but could offer greater benefits for ensuring the safety of FCMs in the long term. On the other hand, maintaining the current framework may be easier for industry stakeholders to comply with and could allow for more immediate, short-term improvements.*

Moreover, the IIA proposed six pillars that **focus on improving safety and sustainability** (pillar A, B and C) and on **improving exchange of information in the supply chain, support for SMEs and enforcement of the rules** (pillar D, E and F). Several associations provided comments on these pillars. An overview of these six pillars is provided below.[420]



Improving safety and sustainability of FCMs: Most organizations support focusing on the final material and adopting a tiered approach. However, concerns are raised regarding lack of clarity, in particular whether the focus should be on minimizing migration or presence in the final material and the lack of attention given to NIAS. Since assessing and categorizing all substances is not feasible, creating an inventory could be a first step. Business associations also argue that starting substances should still be safe and that this has to be a shared

[420] ibid (n 366).

responsibility. NGOs address the importance of appropriate assessment of EDs, some argue that EDs should not be tolerated due to their low-level effects. They also question the significant role given to the industry in assessing tier 3 substances, emphasizing potential conflicts of interest. Some sectorial organizations are critical of a generic approach, arguing that it could lead to regrettable or possibly more harmful substitutions. Supporting more sustainable alternatives is generally welcomed. Sectoral associations emphasize that rules should remain flexible to allow for innovation, while NGOs highlight that the primary goal should remain ensuring food and chemical safety, which is challenging when it comes to recycled materials.

To minimize the presence of EDs in FCMs, focusing on the final material is important. Targeting the presence of harmful substances in FCMs instead of potential migration may be more manageable and still significantly contributes safety of FCMs. A tiered approach could help to prioritize the assessment of the most harmful substances, but first clarity is needed on whether to focus on starting substances or substances in the final material, focus on presence or migration, how to address NIAS and substances that have non-linear effects and how to categorize substances before their assessment. It is not recommended to give businesses more responsibility to assess and authorize tier 3 substances, as integrity must be ensured. Finding a balance between sustainability and safety is crucial. Encouraging innovation and the introduction of more sustainable alternatives is could enhance FCM safety, but it also brings risks if those alternatives haven't been properly assessed. The core objective of ensuring a high level of safety must remain clear and should not be compromised. Stricter rules regarding safety of FCMs may be beneficial for sustainability in the long term; the safer FCMs are due to strict rules, the safer they are to recycle.

<u>Improving exchange of information in the supply chain, strengthen SME's position and enforcement of the rules</u>: There is a broad consensus among stakeholders on the need to improve quality and availability of supply chain information. The introduction of a DoC for all FCMs is welcomed, but not as a one-size-fits-all solution. A digital IT system is also supported, but should be effective and easy to use. NGOs stress the need for consumer information but also warn that too much detail could be overwhelming and may create a false sense of trust. Sectoral as well as consumer organizations indicate that details on

the role of delegated bodies to ensure compliance are lacking. Concerns are raised regarding integrity, strengthening the capacity of national public authorities with fees paid by business operators could be an option. Harmonized rules across all material types would also reduce complexity, lower compliance costs, and ensure uniform levels of protection. To improve analytical methods, NGOs advocate for a single standard for testing to simplify procedures and improve effectiveness as well as more focus to high-risk products such as online products and imported goods.

Improving quality and accessibility of supply chain information is beneficial for all stakeholders, especially if the focus is redirected to the final material (Pillar A), stakeholders can make better choices which materials to use. Since current DoCs are often incomplete, improving information requirements should be prioritized rather than simply increasing the amount of documentation. A digitalized IT system may improve information flow and traceability, as long as it is user-friendly reduces the administrative burden, especially for SMEs. Effective consumer information may not be a priority, as it places the responsibly on consumers to make safe choices. All FCMs should be inherently safe to use without depending on consumer knowledge. The use of delegated bodies should not weaken the integrity of the system of ensuring compliance. The option to introduce fees for business operators fund official controls is preferred. In addition, harmonizing rules across the EU would reduce the complexity and costs of ensuring compliance. To improve analytical methods, the priority should be to develop a single, harmonized testing standard and to ensure consistency across laboratories. Once this foundation is in place, there will be room for improvements such as intensifying the analysis of high-risk products.

Even though it was not strongly reflected in the six pillars, many stakeholders emphasized the need for better coordination between REACH and FCM and their associated assessment bodies. This will support the 'one substance, one assessment approach' and enhance the effectiveness of substance authorizations. However, clear definitions regarding the implementation is needed to make this work effectively. *Improving coordination between REACH and FCM is important for the 'one substance, one assessment' approach, but details are needed how it will be executed and who bears responsibility for each part of the process.*

6. Conclusion, Discussion and Recommendations

6.1 Conclusion

This thesis explores the challenges of regulating Endocrine Disruptors (EDs) in Food Contact Material (FCMs) within the EU and aims to answer the question *"How can the revision of Regulation (EC) 1935/2004 more effectively address endocrine disruptors in food contact materials and thereby contribute to the EU Green Deal's aims of ensuring food safety and protecting public health?"*

To provide context for this regulatory challenge, it is important to understand the nature of EDs and the risks they pose on human health. Endocrine Disruptors (EDs) disrupt hormone signaling by mimicking hormones or blocking hormone receptors. Humans can be exposed to EDs through migration from Food Contact Materials (FCMs) into food. Exposure to EDs can be harmful, especially in the developmental phases, but measuring ED toxicity is hard due to a nonlinear dose/response relationship and the cocktail effect. Exposure to EDs has been associated with various effects on human health such as female and male reproductive problems, cancer, thyroid and adrenal dysfunction, developmental abnormalities, immune dysfunction, and disorders of energy metabolism. Besides, it is estimated that diseases related to ED exposure in Europe cost approximately costs €157 billion per year. Moreover, approximately 13 million IQ points are lost yearly due to ED exposure.

To understand how the EU addresses the risk of EDs in FCMs, it is necessary to examine the position of the FCM Regulation within the broader EU regulatory framework. Regulation (EC) 1935/2004 governs FCMs in the EU, applying to food contact materials and articles which in their finished state are intended or reasonably expected to come in contact with food. This Regulation is part of the wider EU regulatory framework, guided by the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU). These treaties aim to establish a functioning internal market and ensure a high level of consumer protection. Consequently, several overlapping regulatory frameworks have been developed alongside the FCM Regulation. Two important frameworks in the context of this thesis are the General Food Law (GFL) Regulation, which sets out general principles for food and feed safety, and the General Product

Safety (GPS) Regulation, which governs product safety. Because FCMs are products that interact with food, they hold a complex regulatory space, requiring coordination between the mentioned Regulations and agencies such as the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA). Article 5 of the FCM Regulation allows specific measures for materials and groups of materials listed in Annex I of the FCM Regulation, but not all materials listed have corresponding EU-level measures. Consequently, not all FCM-materials are equally addressed. While certain materials and substances are covered such as plastics and Bisphenol A, other materials and substances like adhesives, rubbers, printing inks, silicones, waxes and alloys, lack specific measures. If specific measures are absent, Member States (MSs) have the opportunity to adopt their own measures under article 5 of the FCM Regulation.

Challenges such as a multitude of complex substances with potential ED-properties in FCMs that need assessment and authorization and the EU's increasing focus on sustainability have contributed to limitations within the EU FCM framework. A major regulatory issue is an overall lack of definition, in particular regarding subject matter, safety, EDs and compliance / enforcement requirements. Another regulatory issue is the lack of coherence across different sectorial frameworks incorporating EDs, material-specific FCM legislation and national measures. These challenges and regulatory gaps have significant consequences for various stakeholders and the effective management of EDs in FCMs. For instance, the assessment and authorization of substances by competent authorities is hindered by a lack of testing methods for complex substances, capacity issues and inadequate coordination between EU assessment bodies. Moreover, the risks associated with Non-Intentionally Added Substances (NIAS) and recycled materials remain insufficiently studied. Business operators, SMEs in particular, face difficulties in ensuring compliance due to the complexity of the FCM framework and the multitude of national measures. Besides, a Declaration of Compliance (DoC) is not always required and many are incomplete. Official Controls by authorities of Member States are also impacted by limited testing methods, poor documentation, a shortage of qualified staff, and inadequate training. As a result, Official Controls are often limited to verifying the presence of a DoC, and even when non-compliance is identified, consequences are unclear. From a public health perspective, the lack of a clear regulatory FCM framework increases the risk of unnecessary ED exposure and creates an uneven protection among EU citizens. This has consequences for public health, in particular for vulnerable groups such as infants and young children.

Various policy initiatives have influenced the announced revision of the FCM Regulation. The 2030 Agenda for Sustainable Development set goals such as achieving food security, ensuring sustainable consumption patterns, and minimizing presence of hazardous chemicals like EDs. In response, the Commission launched the EU Green Deal, laying the foundation of the Chemicals Strategy for Sustainability, the Circular Economy Action Plan (CEAP) and the Farm-to-Fork (F2F) Strategy. The F2F Strategy announced the revision of the FCM Regulation. This led to two publications of the Commission: the Staff Working Document on the evaluation of the FCM Regulation and the Inception Impact Assessment (IIA) on the revision of the FCM Regulation. Based on NGOs stakeholder comments on the IIA, developing a new framework may have greater benefits in the long term for ensuring the safety of FCMs and addressing EDs. But maintaining and improving the current framework may be easier for industry stakeholders to comply with and could allow for more immediate, short-term improvements. Regarding improving safety and sustainability of FCMs, the IIA's plan of focusing on the final material and adopting a tiered approach is supported by most stakeholders, but concerns are raised about the consequences of a limited feasibility to address all substances in the final material and the insufficient attention given to NIAS. NGOs highlight the importance of appropriate assessment of EDs and are weary of the significant role given to the industry in assessing tier 3 substances, emphasizing potential conflicts of interest. To enhance innovation, Supporting more sustainable alternatives is welcomed by sectoral associations that welcome more flexible rules to enhance innovation. NGOs argue that the primary goal must be food and chemical safety, especially with recycled FCMs. Concerning improving quality and availability of supply chain information, the IIA's plan of introducing a digital system is supported, provided that the system is effective and easy to use. Details of introducing a DoC for all FCMs should be further clarified, as well as the exact role of delegated bodies to ease the burden of competent authorities as concerns are raised about the incomplete submission of DoCs and the integrity of delegated bodies. Harmonizing rules across all material types and testing standards is supported, this would reduce complexity and lowers compliance costs in particular for SMEs, and contributes to more uniform levels of protection.

Returning to the main research question, the revision of Regulation (EC) 1935/2004 should prioritize the following to more effectively address EDs in FCMs while contributing to the EU Green Deal's aims of ensuring food safety and protecting public health:

Introducing a new EU FCM regulatory framework is recommended, as the current regulatory framework fails to address FCM safety on a fundamental level. The prospective new regulatory framework should aim to maintain continuity to ease compliance requirements for the industry.

Redirecting focus onto final materials instead of starting substances is recommended to better address EDs in FCMs, but this is challenging due to a multitude of complex substances including NIAS and substances with non-linear effects. To ease this redirection, the administrative burden should be reduced on all actors of the supply chain. Facilitating coherence between FCM and REACH and its linked assessment bodies with harmonized rules could ease assessment and authorization of substances and supports the 'one substance, one assessment' approach. Focusing on the presence of substances during assessment, rather than their migration, would also be a more manageable strategy. Assigning the authorization of tier 3 substances to businesses or Official Controls to delegated bodies is not recommended due to potential conflicts of interest and an increased workload. Introducing a fee system based on company size to conduct authorizations or Official Controls would be more appropriate, in particular for SMEs. Harmonizing material-specific FCM rules at the EU level should be a priority to ease the compliance burden for companies including SMEs, and enhances the consistency of safety standards across all Member States.

Provided that compliance with revised rules increases feasibility, the administrative burden could be reduced, creating more room for further improvements in the regulatory framework. Consistent revenue generated from fees, alongside improved collaboration with other assessment bodies through increased coherence, could expand the expenditure capacity of competent authorities, enabling more room for the establishment of stricter requirements regarding the number of substances assessed and the frequency of sufficient official controls. Moreover, more methods to better address EDs could be developed in collaboration with other sectoral assessment bodies. Strengthening information requirements for businesses, possibly through introducing digital systems or through introducing stricter DoC requirements for all FCMs, could empower businesses at the end of the supply chain to make more informed choices regarding the use of starting materials. Information requirements on high-risk products may require further development, and repercussions in cases of non-compliance enforcement should be clarified .

Once a solid regulatory foundation is established and the presence of EDs is minimized, regulatory focus could shift towards promoting sustainable alternatives and recyclability. However, ensuring food safety and protecting public health by minimizing EDs in FCMs should be prioritized, in line with the listed aims of the EU Green Deal. To conclude, a regulatory FCM framework that prioritizes safety and the reduction of ED presence not only strengthens public health but also enhances safer recycling opportunities, aligning with the EU Green Deal's aims and prioritizing public health of future generations.

6.2 Discussion

This thesis explores how the revision of Regulation (EC) 1935/2004 can better address the presence of EDs in FCMs and thereby contribute to the EU Green Deal's aims of ensuring food safety and protecting public health. After identifying the risks posed by EDs, examining the position of the FCM Regulation within the EU regulatory framework, analyzing its gaps related to fundamental issues, listing consequences for stakeholders and assessing policy initiatives leading to the proposed revision of the FCM Regulation, the conclusion can be drawn as follows: To better address the presence of EDs in FCM, the revision of the FCM Regulation should initially make efforts to reduce the administrative burden for all actors in the supply chain before more demanding and harmonized rules can be effectively implemented. Once this foundation is in place, the more efficient, coherent and defined framework creates space for developing measures directed towards sustainable innovation in the longer term.

In a broader perspective, the outcome of this thesis reflect which policy challenges may be encountered when developing a regulatory framework for complex issues with many uncertainties, where scarce resources must be allocated efficiently due to limited capacity. In the specific context of this thesis, the challenge of developing a regulatory framework for assessing a multitude of complex substances which lack clearly identifiable thresholds is demonstrated. The limited capacity to assess a multitude of complex substances in FCMs has contributed to a fragmented regulatory framework for FCMs, characterized by a lack of coherence and unclear definitions, leading to implications for all actors in the supply chain. The overview that this thesis provides of the current FCM regulatory framework and its impact on stakeholders, may be relevant for policymakers and may support to make more informed decisions about the direction of the FCM Regulation's revision with regard to ED presence.

However, knowledge gaps and limitations with regard to the methodology of this thesis must be acknowledged.

Risks ED exposure: As this thesis has a particular focus on how regulatory aspects contribute to the presence of EDs in FCMs, less emphasis is placed on the exact methodologies used to assess the qualitative and quantitative risks of ED exposure. The use of secondary sources may inhibit the ability to evaluate the quality of the assessments used. Consequently, the extent to which EDs can be considered as a risk may be affected.

Positioning of the EU FCM framework: This thesis aims to provide a comprehensive overview of the EU FCM regulatory framework and its associated measures. However, due to the complexity and interconnectedness of this matter, there may be EU Regulations and Directives that also share a connection with the FCM Regulation but are excluded from this overview. This may affect the ability to effectively evaluate interactions between different Regulations and Directives.

Regulatory gaps: The lack of coherence due to a multitude of material-specific national measures is indicated as a major regulatory gap. Mapping these national measures in detail is considered to be beyond the scope of this thesis. Secondary sources were consulted, in particular the 2016 JRC science report on Non-harmonized FCMs. However, this report may be outdated and does not specifically address EDs in FCMs but provides a general overview. Thus, it is it is difficult to evaluate the exact impact of national measures on the coherence and definition in the EU FCM regulatory framework with the information available. Hence, an emphasis is placed on providing a qualitative overview of the regulatory gaps instead of assessing the impact of each gap in a quantitative manner. This may limit the ability to assess the relative importance of regulatory gaps.

Stakeholders' input: To determine the direction for addressing EDs in FCMs in the proposed revision of the FCM Regulation, stakeholders' input responding to the IIA is considered. However, the overrepresentation of Business Associations responding to the IIA may cause a bias in the results that benefit the interests of the industry. Moreover, since the responses are reactions to the IIA, creativity and alternative approaches may be limited. Additionally, the IIA and thus the stakeholders' input does not specifically concern EDs but addresses the EU FCM framework as a whole, which may cause ineffective consideration of ED-specific concerns.

As a result of these limitations, the conclusions may be influenced by incomplete information and biased input. This may affect the evaluation of the most appropriate direction for the revision of the FCM Regulation with regards to EDs, in line with the EU Green Deal's objectives of ensuring food safety and protecting public health. Nevertheless, this thesis provides a thorough overview to support further policy discussion in line with the EU Green Deal, with the goal of addressing the regulatory challenges associated with EDs in FCMs.

6.3 Scope for Further Research

Further research should contribute to the development of a regulatory framework that reduces the burden of fundamental issues related to EDs in FCMs. These fundamental issues related to the inherent characteristics of EDs in FCMs, such as the complex non-linear character and the multitude of substances present in FCMs that require assessment, will not be entirely eliminated. However, further research could help minimize their impact and enhance the overall effectiveness of the regulatory framework. In line with this argumentation, the following research would be recommended for a potential follow-up thesis:

- An analysis of how EDs are addressed in different Member States (national level) other sectoral regulatory frameworks (EU level) on an international level, with the aim of strengthening coherence and harmonization in line with the ‘one substance, one assessment’ approach.

- Developing a method to weigh and quantify the current limitations of the regulatory framework, as well as for the proposed options for revision, while considering the views of all stakeholders proportionally.

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