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Food-Borne Endocrine-Disruption: An EU Risk Governance Perspective

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Abstract

Exposure to endocrine disrupting chemicals is linked to negative health impacts, including non-communicable diseases such as obesity, cardiovascular diseases and cancer. This disease burden compromises consumer safety and costs the European Union an estimated €163 billion per year. Given these stakes, the importance of effectively regulating EDCs in food is paramount. Yet regulators face difficult challenges: scientific uncertainty, the ubiquity of EDCs in food products, and pressure from economic and political interests all complicate legislative responses. From a risk regulation perspective, the core problem is how to protect public health from EDC risks in food amidst these uncertainties and constraints. This paper addresses the problem by examining the current EU regulatory framework for managing EDCs in the food supply chain, identifying gaps and weaknesses, and proposing improvements to better safeguard public health. From this risk regulation perspective, the paper highlights the benefits of ensuring regulatory action keeps pace with scientific evidence, leveraging the General Food Law Regulation for a comprehensive approach to EDCs, and developing sector-specific EDC regulation across the food supply chain.

Keywords: endocrine disruption; EU; food law; risk analysis; risk regulation

I. Introduction

Endocrine-disrupting chemicals (EDCs) pose a significant threat to public health in the EU, contributing to a substantial burden of disease and disability, with estimated annual healthcare costs reaching €163 billion.[1] These chemicals interfere with hormonal systems, affecting metabolism,[2] reproductive health,[3] and neurodevelopment.[4] Emerging research also suggests that EDC exposure may influence dietary nutrition and play a role in the increasing prevalence of obesity and related non-communicable diseases (NCDs).[5] While

[1] Leonardo 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.

[2] Yolanda Gálvez-Ontiveros and Others, "Endocrine Disruptors in Food: Impact on Gut Microbiota and Metabolic Diseases" (2020) 12 Nutrients 1158.

[3] Maria De Falco and Others, "Editorial: Endocrine Disrupting Chemicals in Reproductive Health, Fertility, and Early Development" (2024) 15 Frontiers in Endocrinology 1478655.

[4] Viviana Ramírez and Others, "Role of Endocrine Disrupting Chemicals in Children's Neurodevelopment" (2022) 203 Environmental Research 111890.

[5] Radhika Gupta and Others, "Endocrine Disruption and Obesity: A Current Review on Environmental Obesogens" (2020) 3 Current Research in Green and Sustainable Chemistry 100009.

dietary modifications can help reduce some health risks,[6] minimising EDC exposure is a crucial disease prevention strategy that requires strong regulatory measures.[7]

Despite existing EU regulations that restrict EDCs in pesticides and biocides, these measures are insufficient to mitigate risks across the entire food supply chain. Many potential EDCs remain unregulated in food production, packaging and processing, leaving gaps in consumer protection. Given the growing recognition of EDC-related health risks, it is crucial to examine how the EU's food governance framework – specifically its risk regulation mechanisms – can be strengthened to control foodborne EDC exposure and contribute to reducing NCD rates more – effectively.

1. Endocrine-disrupting chemicals in food: links to non-communicable diseases

EDCs are external substances that interfere with the normal functioning of the hormone system in living organisms, potentially leading to harmful effects in the individual, their descendants, or even entire populations.[8] They are different from endocrine active substances, which can interact or interfere with normal hormonal action but without leading to adverse health effects.[9] In food products, ECDs can be introduced through contamination or intentional addition during food processing. Contamination occurs across all food categories (e.g., eggs, fresh vegetables, meat, etc.),[10] and originates from pesticide residues[11] or food packaging materials.[12] Processed foods – especially high-fat items packaged in plastic – are particularly susceptible to EDCs leaching, as many EDCs are lipid-soluble (e.g., phthalates and Bisphenol A (BPA)).[13] Food processing also contributes to EDC exposure through the intentional addition of artificial additives, dyes and sweeteners used to enhance flavour, colour or preservation.[14] Major substances of concern include BPA, phthalates, tartrazine, erythrosine and perfluoroalkyl substances (PFAS), all of which have been linked to hormonal disruption and adverse health effects.[15]

Minimising food-borne EDC exposure is vital, given their significant links to NCDs.[16] Research suggests that beyond diet and calorie intake, EDCs play a crucial but underexplored

[6] GA Corbett and Others, "Nutritional Interventions to Ameliorate the Effect of Endocrine Disruptors on Human Reproductive Health: A Semi-Structured Review from FIGO" (2022) 157 International Journal of Gynecology & Obstetrics 489.

[7] Å Bergman and Others, "The Impact of Endocrine Disruption: A Consensus Statement on the State of the Science" (2013) 121 Environmental Health Perspectives a104.

[8] WHO International Programme for Chemical Safety, "Global Assessment of the State-of-the-Science of Endocrine Disruptors" (2002) at p 1.

[9] EFSA, "Endocrine Active Substances" (14 February 2023) available at <https://www.efsa.europa.eu/en/topics/topic/endocrine-active-substances> (last accessed 17 February 2025).

[10] R Mukherjee and Others, "Endocrine Disruptors–'Food' for Thought" (2021) 74 Proceedings of the Zoological Society 432.

[11] Ibid.

[12] LC Pedroso de Paula and C Alves, "Food Packaging and Endocrine Disruptors" (2023) 100 Jornal de Pediatria S40.

[13] X-L Cao, "Phthalate Esters in Foods: Sources, Occurrence, and Analytical Methods" (2010) 9 Comprehensice Reviews in Food Science and Food Safety 21.

[14] Anand Paramasivam and Others, "Additives in Processed Foods as a Potential Source of Endocrine-Disrupting Chemicals: A Review" (2024) 14 Journal of Xenobiotics 1697.

[15] Ibid.

[16] Thaddeus Schug and Others, "Endocrine Disrupting Chemicals and Disease Susceptibility" (2011) 127 The Journal of Steroid Biochemistry and Molecular Biology 204; T Zoeller and Others, "Endocrine-Disrupting Chemicals and Public Health Protection: A Statement of Principles from The Endocrine Society" (2012) 153 Endocrinology 4097.

role in obesity and associated metabolic disorders such as diabetes.[17] EDCs are also associated with other NCDs, including cardiometabolic disorders[18] and cancer,[19] and pose specific risks to vulnerable populations, such as developmental issues in infants[20] and infertility in women.[21] Moreover, some health effects of EDC exposure can be passed down to future generations through epigenetic changes, altering gene expression without modifying the DNA sequence.[22] All these long-term, transgenerational risks highlight the pressing need for stronger regulatory measures to limit EDC exposure in food and protect both current and future generations.

2. EDC regulation: what has the EU done so far?

The EU is active on the matter and has made progress in regulating EDCs through legislation on plant protection products (the Plant Products Protection Regulation – PPPR),[23] biocides (the Biocidal Products Regulation – BPR),[24] and chemicals (Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation – REACH).[25] The European Commission has evaluated in a 2016 Communication various approaches to establish scientific criteria for identifying EDCs in pesticides and biocides.[26] It was followed by a more refined 2018 Communication outlining essential steps to address EDCs, including applying a uniform definition across all legislation, screening existing laws and supporting research.[27] However, a 2019 report requested by the European Parliament found that food additives and food contact materials regulations lag behind in defining EDCs, providing

[17] R Chamorro-Garcia and Others, "Ancestral Perinatal Obesogen Exposure Results in a Transgenerational Thrifty Phenotype in Mice" (2017) 8 Nature Communications 2012; JJ Heindel and Others, "Obesogens: A Unifying Theory for the Global Rise in Obesity" (2024) 48 International Journal of Obesity 449.

[18] F Rancière and Others, "Bisphenol A and the Risk of Cardiometabolic Disorders: A Systematic Review with Meta-Analysis of the Epidemiological Evidence" (2015) 14 Environmental Health 46–9.

[19] E Filippone and Others, "Endocrine Disruptors in Food, Estrobolome and Breast Cancer" (2023) 12 Journal of Clinical Medicine 3158.

[20] O Ercan and G Tarcin, "Overview on Endocrine Disruptors in Food and Their Effects on Infant's Health" (2022) 2 Global Pediatrics 100019.

[21] AB Silva and Others, "The Role of Endocrine Disruptors in Female Infertility" (2023) 50 Molecular Biology Reports 1069.

[22] F Xin, M Susiarjo and M Bartolomei, "Multigenerational and Transgenerational Effects of Endocrine Disrupting Chemicals: A Role for Altered Epigenetic Regulation?" (2015) 43 Seminars in Cell & Developmental Biology 66.

[23] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309/1 (Plant Protection Products Regulation – PPPR); Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, OJ L 101/33.

[24] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167/1 (Biocidal Products Regulation – BPR).

[25] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 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, OJ 2015 L 396/1 (REACH Regulation).

[26] European Commission, "Staff Working Document Impact Assessment: Defining Criteria for Identifying Endocrine Disruptors in the Context of the Implementation of the Plant Protection Products Regulation and Biocidal Products Regulation, COM(2016) 350 Final, SWD(2016) 212 Final."

[27] European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Towards a Comprehensive European Union Framework on Endocrine Disruptors, COM(2018) 734 Final" paras 7, 8, 18 and 23–7.

guidance, establishing tests and managing risks.[28] The European Parliament addressed these concerns in a subsequent 2019 Resolution urging the Commission to take stronger action to regulate EDCs.[29] The Resolution specifically demanded a comprehensive and effective approach to regulating EDCs by treating them with the same level of concern as carcinogenic, mutagenic and reprotoxic substances; adopting a clear definition of EDCs across all EU legislation; incorporating specific provisions in relevant product regulations; accelerating the development of EDC identification tests; and considering the combined effects of exposure to multiple EDCs.[30]

The EU took several steps to address these challenges, particularly in the food sector. This included continuous work to refine criteria for identifying EDCs in pesticides, biocides, food additives and contaminants, through the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA).[31] It also included a risk-preventive approach to address EDCs. Horizon Europe, the EU's research and innovation program, has dedicated funding to study EDCs, their impact on health, and to develop better risk assessment methods.[32] The initiative aimed to improve risk assessment, management and communication by generating better data and a clearer understanding of the links between EDC exposure and health effects.[33]

The European Green Deal[34] also addressed EDCs under the Farm to Fork Strategy[35] and the One Substance–One Assessment (OSOA) approach.[36] The Farm to Fork Strategy aimed to review import tolerances for hazardous substances used in plant protection, including EDCs.[37] However, this objective was limited in scope, and the policy failed to address EDCs in the EU food supply. The current OSOA framework is more focused on hazardous chemicals such as EDCs, targeting streamlined chemical safety assessments through greater coherence, efficiency and transparency.[38] It includes proposals to enhance the scientific contributions of competent EU agencies, enhance inter-agency cooperation and establish a centralised data platform for chemicals.[39] These reforms are designed to improve the efficiency, consistency and scientific integrity of chemical assessments, with particular relevance for substances such as EDCs, which often fall under multiple legal frameworks (e.g., food, cosmetics, medical devices), causing regulatory inconsistencies. Finally, to further increase transparency around EDCs, the EU made available public

[28] B Demeneix and R Slama, "Endocrine Disruptors: From Scientific Evidence to Human Health Protection" (2019) Policy Department for Citizens' Rights and Constitutional Affairs at 13.

[29] European Parliament, "Resolution on Towards a Comprehensive European Union Framework on Endocrine Disruptors (2019/2683(RSP)) OJ C 34/100."

[30] Ibid.

[31] EFSA (n 9).

[32] Horizon Europe, "Health Impacts of Endocrine-Disrupting Chemicals: Bridging Science-Policy Gaps by Addressing Persistent Scientific Uncertainties" (2023).

[33] Ibid.

[34] European Commission, "Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – The European Green Deal COM/2019/640 Final."

[35] European Commission (2020), "Farm to Fork Strategy: For a Fair, Healthy and Environmentally Friendly Food System."

[36] European Commission, "Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment COM(2020) 667 Final, 14 October 2020."

[37] European Commission (2020) (n 35) 19.

[38] European Council, "Chemicals Assessment: Council Adopts Mandate for Forthcoming Negotiations with the European Parliament" (2024) available at <https://www.consilium.europa.eu/en/press/press-releases/2024/06/14/chemicals-assessment-council-adopts-mandate-for-forthcoming-negotiations-with-the-european-parliament/> (last accessed 5 May 2025).

[39] Ibid.

resources such as the ED Lists[40] and the REACH Candidate List of substances of very high concern[41] providing information on identified and evaluated EDCs.

Despite ongoing efforts to regulate EDCs, a major challenge remains: the absence of a comprehensive regulatory system that translates scientific evidence on EDC exposure into consistent rules across the entire food supply chain. Specifically, the lack of a clear and transparent risk regulation framework continues to hinder effective regulation, highlighting the need for a stronger, science-based approach – a concern consistently emphasised in the literature.

3. Risk-based vs hazard-based approaches to EDC regulation in the literature

In current EU regulation, only biocides and pesticides have a legal framework for EDCs, while other food-related sectors across the supply chain – such as food additives and food contact materials – lack clear definitions, mandatory testing and clear approaches to regulation, weakening enforcement.[42] To broaden and strengthen this regulatory framework, the literature suggests two approaches to regulating EDCs across sectors: a risk-based regulation and hazard-based regulation.

On the one hand, risk-based regulation assesses and manages risks based on the likelihood and severity of harm, considering factors such as exposure level and affected populations.[43] Some have emphasised the advantages of risk-based approaches for regulating EDCs at both EU and global levels, highlighting the need and current efforts to develop testing and assessment strategies.[44] Others critiqued the EU for leaning toward a hazard-based approach rather than a risk-based one in its regulation of EDCs, recommending a more rigorous, weight-of-evidence, risk assessment framework that considers exposure, potency and biological plausibility to better inform regulatory decisions.[45]

On the other hand, the hazard-based approach to regulating EDCs bans substances based solely on their intrinsic harmful properties: if a substance can cause harm, it is banned, regardless of exposure levels.[46] Research supporting this approach recommends focusing on scientific hazard identification, similar to carcinogen classification,[47] meaning recognising EDCs as a distinct hazard category. Proponents argue that a global shift to hazard-based regulation is needed to prioritise public health.[48] They strongly reject the risk-based approach, which assumes harm occurs only above certain thresholds, citing evidence that EDCs can cause harm at very low doses and have non-monotonic effects, particularly endangering vulnerable groups such as foetuses and children.[49] Because

[40] Endocrine Disruptor Lists, "The ED Lists" available at <https://edlists.org/the-ed-lists> (last accessed 8 April 2024).

[41] ECHA, "Candidate List of Substances of Very High Concern for Authorisation" available at <https://echa.europa.eu/candidate-list-table> (last accessed 17 February 2025).

[42] R Slama and B Demeneix, "An Overview of the EU Regulation on Endocrine Disruptors" (2019) 3 Environmental Epidemiology 373.

[43] B Demeneix and Others, "Thresholds and Endocrine Disruptors: An Endocrine Society Policy Perspective" (2020) 4 Journal of the Endocrine Society bvaa085.

[44] M Hecker and H Hollert, "Endocrine Disruptor Screening: Regulatory Perspectives and Needs" (2011) 23 Environmental Sciences Europe 1–14.

[45] Lorenz R Rhomberg and others, "A Critique of the European Commission Document, 'State of the Art Assessment of Endocrine Disrupters'" (2012) 42 Critical Reviews in Toxicology 465.

[46] J-P Bourguignon and Others, "Science-Based Regulation of Endocrine Disrupting Chemicals in Europe: Which Approach?" (2016) 4 The Lancet Diabetes & Endocrinology 643, at p 643.

[47] Bourguignon and Others (n 46); C Kassotis and L Trasande, "Endocrine Disruptor Global Policy" in LN Vandenberg and JL Turgeon (eds), *Advances in Pharmacology*, vol 92 (Academic Press 2021) p 1–34.

[48] Kassotis and Trasande (n 47).

[49] Demeneix and Others (n 43).

thresholds cannot be reliably established for EDCs, hazard-based regulation is seen as scientifically necessary.[50] Critics of risk-based methods also oppose including potency – a risk concept – in hazard assessment, arguing it introduces economic bias and undermines precautionary principles.[51] They maintain that hazard identification must remain science-driven and independent of risk considerations to preserve the EU's precautionary EDC policy framework.[52] While initially applied to pesticides and biocides, researchers argue industry opposition has delayed broader implementation of the hazard-based approach to regulating EDCs.[53]

Despite the ranging opinions on how to approach EDCs, the literature appears to be more in favour of the hazard-based approach. Additionally, the literature review and the review of recent EU actions on EDC regulation highlight one idea: There is a significant regulatory gap in EU food law, with uneven protection against EDCs across the food supply chain. To address this gap, we critically examine how the EU's food governance framework regulates EDCs in the food supply chain and propose legal reforms to better protect public health. First, we frame this analysis within food risk governance, examining EDC regulatory challenges, the role of the Science-Policy Interface (SPI) in informing EU legislative developments, and the role of risk analysis in addressing decision-making challenges in EDC regulation (Part II). Next, we review the current EU legal framework on endocrine disruption in the food supply chain, focusing on legislation that directly and indirectly addresses EDCs, and exploring the General Food Law Regulation (GFL)[54] as a framework for broadening regulation (Part III). Finally, drawing on these findings, we discuss how the EU can enhance its risk governance framework based on three recommendations: leveraging risk analysis, the GFL and a hazard-based approach in sector-specific regulations (Part IV).

II. EU food governance: a risk regulation framework hinging on scientific evidence

In this paper, we understand food governance as the system of rules, organisations and stakeholders that shape how food is produced, distributed and consumed.[55] This includes the EU food law framework as well as the influence of markets, traditions and non-state actors such as businesses and civil society. A core element of EU food governance is its risk regulation framework, which enables policymakers to assess and manage food-borne hazards in a structured and transparent way. Risk regulation is embedded in the GFL, where risk analysis ensures a science-based approach to food safety and public health protection.[56]

Risk analysis bridges scientific knowledge with regulatory decision-making, ensuring that food safety measures are both evidence-based and proportionate. It consists of three interconnected steps: risk assessment, where EFSA conducts a scientific evaluation of food safety hazards and issues an expert opinion[57]; risk management, where the European

[50] Ibid.

[51] Bourguignon and Others (n 46).

[52] R Slama and Others, "Scientific Issues Relevant to Setting Regulatory Criteria to Identify Endocrine-Disrupting Substances in the European Union" (2016) 124 Environmental Health Perspectives 1497.

[53] Bourguignon and Others (n 46) 644.

[54] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L31/1 (General Food Law Regulation – GFL).

[55] C van Bers and Others, "Transformation in Governance towards Resilient Food Systems" (2016) Working Paper.

[56] Preambles (9) and (32) and Art 6 GFL.

[57] Art 3(11) and 22 GFL.

Commission and European Parliament translate EFSA's opinions into regulatory measures while also considering other legitimate factors (e.g., political, economic and social concerns)[58]; and risk communication, which ensures transparency by disseminating information on risks and regulatory decisions to the public.[59]

The effectiveness of risk analysis depends on the strength of the science-policy interface. As risk analysis underpins EU food risk governance, a well-functioning SPI is essential for translating complex scientific data into actionable policy measures. This is particularly relevant for EDC regulation, which is impacted by multi-dimensional challenges. In this section, we explore these challenges within the EU food governance framework, the actionable role of the SPI in contributing to stronger, evidence-based regulation of EDCs, and how risk analysis can leverage this for stronger EDC regulation.

1. Multi-factorial challenges impacting EDC regulation

Regulating EDCs in EU food law faces numerous challenges. The most significant ones are scientific uncertainty and political-economic factors, both leading to regulatory hurdles. First, the considerable scientific uncertainty in studying EDC effects is due to complex human exposures, imprecise measurements and unpredictable effects.[60] Establishing safe exposure levels is further complicated by uncertainties surrounding low-dose and mixture effects, and difficulties in proving causality.[61] Current regulatory efforts often focus on a limited range of endocrine pathways, potentially overlooking other mechanisms of harm[62] Standard testing often fails to provide enough data to identify EDCs or trigger further investigation, especially for data-poor substances.[63] Generating additional data is hindered by limitations in testing methods and procedures.[64] Furthermore, interpreting non-apical endpoints (biological markers that indicate activity but lack clear correlations with population-level adverse effects) and accounting for species sensitivity variations pose significant challenges for scientific risk assessment.[65] These uncertainties necessitate a more comprehensive approach to EDC regulation, encompassing broader pathways, improved EDC-specific data and integration of this data in risk regulation processes.

Second, regulating EDCs in EU food supply has faced significant political-economic challenges, primarily due to industry lobbying and trade concerns that can hinder regulation.[66] Major chemical and food packaging companies have actively lobbied EU institutions to weaken or delay restrictions on substances such as BPA and titanium dioxide, arguing that bans would be economically disruptive.[67] A notable case is the EU's

[58] Art 3(12) GFL.

[59] Art 3(13) GFL.

[60] D-H Lee and D Jacobs, "Methodological Issues in Human Studies of Endocrine Disrupting Chemicals" (2015) 16 Reviews in Endocrine & Metabolic Disorders 289.

[61] Bergman and Others (n 7).

[62] Z-C Dang and Others, "Endocrine Disrupting Chemicals within EU Legal Frameworks: Environmental Perspective" (2016) National Institute for Public Health and the Environment at 23–31 (RIVM Letter report 2016-0145).

[63] Ibid.

[64] Ibid.

[65] Ibid.

[66] S Horel, "A Toxic Affair: How the Chemical Lobby Blocked Action on Hormone Disrupting Chemicals" (Corporate Europe Observatory 2015).

[67] C Crawford-Brown, "Coordinated Lobbying Campaign Targeted European PFAS Regulation: Reports" (*Food Packaging Forum*, 20 January 2025) available at <https://foodpackagingforum.org/news/coordinated-lobbying-campaign-targeted-european-pfas-regulation-reports> (last accessed 5 March 2025); Corporate Europe Observatory, "Endocrine Disruptors: How Corporations and Their Scientists Have Put Public Health in Harm's Way" (2017) available at <https://corporateeurope.org/en/food-and-agriculture/2017/09/endocrine-disruptors#> (last accessed 5 March 2025).

debate over the criteria for identifying EDCs, where industry pressure caused years of delay, ultimately resulting in a final set of criteria criticised for imposing high burdens of proof and containing loopholes that could hinder effective regulation.[68] Similarly, France's unilateral ban on BPA in all food contact materials sparked EU concerns over internal market disruptions, with the European Commission considering legal action against France for undermining trade rules,[69] before finally banning BPA itself years later.[70] Efforts to ban PFAS chemicals in food packaging have been met with strong industry lobbying and resistance from Germany, a major chemical producer.[71] Additionally, global chemical production and trade also raise concerns.[72] For instance, countries such as Canada and Brazil have lobbied the EU to ensure that EDC limits do not restrict agricultural imports.[73] This resistance stems from concerns about the potential economic impacts of restricting or banning widely used chemicals, creating tension between economic interests and public health protection.

These scientific and political–economic challenges contribute to regulatory delay. The European Commission was legally required to define criteria for identifying EDCs in pesticides by 2013, but missed the deadline, citing the complexity of the science, and the need for further consultation.[74] This insistence on complete scientific certainty slowed decision-making at a critical early stage. Meanwhile, intensified lobbying from industry further reinforced regulatory inaction.[75] In response to this delay, Sweden filed a legal challenge against the Commission in 2014, arguing that the failure to adopt EDC criteria violated EU law.[76] In 2015, the EU General Court ruled in Sweden's favour, confirming that the Commission had unlawfully delayed its obligation.[77] This ruling ultimately forced the Commission to act on defining EDC criteria. However, even when the criteria were adopted in 2017, they reflected years of industry and political influence, applying only to known disruptors with definitive evidence and excluding many suspected EDCs.[78] Further loopholes allowed certain EDCs to remain approved if exposure was deemed negligible, weakening the regulation's impact. This is particularly evident in pesticides, where EDC

[68] Corporate Europe Observatory (n 67).

[69] G Stieger, "France vs. EU: Ban on BPA in FCMs" (*Food Packaging Forum*, 24 May 2018) available at <https://foodpackagingforum.org/news/france-vs-eu-ban-on-bpa-in-fcms> (last accessed 5 March 2025).

[70] European Commission, "Commission Adopts Ban of Bisphenol A in Food Contact Materials" available at <https://food.ec.europa.eu/food-safety-news-0/commission-adopts-ban-bisphenol-food-contact-materials-2024-12-19_en> (last accessed 4 March 2025).

[71] Crawford-Brown (n 67).

[72] Christopher Kassotis and Others, "Endocrine-Disrupting Chemicals: Economic, Regulatory, and Policy Implications" (2020) 8 Lancet Diabetes Endocrinology 719; L Trasande and Others, "Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union" (2015) 100 The Journal of Clinical Endocrinology and Metabolism 1245.

[73] Corporate Europe Observatory (n 67).

[74] C Wagner, "EC Misses EDC Criteria Deadline" (*Food Packaging Forum*, 7 January 2014) available at <https://foodpackagingforum.org/news/ec-misses-edc-criteria-deadline> (last accessed 6 March 2025).

[75] See TTIP trade negotiations between the United States and the EU on broad EDC bans causing trade barriers, and the Commission's delayed action on the matter to launch an economic impact assessment that aligned with industry demands (Horel [n 66] 4, 14).

[76] *Kingdom of Sweden v European Commission, Case T-521/14, Judgment of the General Court (Third Chamber) of 16 December 2015*; G Stieger, "EDCs: Sweden Wins Court Case against European Commission" (*Food Packaging Forum*, 2015) available at <https://foodpackagingforum.org/news/edcs-sweden-wins-court-case-against-european-commission> (last accessed 6 March 2025).

[77] *Kingdom of Sweden v European Commission* (n 78).

[78] PAN Europe, "Hormone Disrupting Pesticides (EDCs)" (24 May 2023) available at <https://www.pan-europe.info/eu-legislation/hormone-disrupting-pesticides-edcs> (last accessed 6 March 2025).

restrictions are applied less stringently than for other hazardous chemicals such as carcinogens and reproductive toxicants.[79] The result was a decade-long delay in banning harmful substances, with the first actual pesticide bans under the new criteria only occurring in 2023.[80]

These multi-factorial challenges reinforce one another in a self-perpetuating loop, causing significant stagnation in EDC regulation in the food sector. Stalled legal developments contribute to scientific and political uncertainty, which in turn delays regulatory action, preventing meaningful progress. Breaking free from this inertia requires a comprehensive and integrated response that not only strengthens regulatory frameworks but also addresses the underlying gaps in scientific knowledge and risk assessment methodologies. Increased research into EDC exposure and health impacts is essential for developing more effective, evidence-based regulations, reducing the ambiguity that industry and political actors often exploit to delay action. However, science alone is not enough – regulation must evolve to reflect the complexities of EDC exposure, long-term effects and cumulative risks while ensuring harmonised and enforceable legal standards. A science-based approach is key to navigating these challenges, but for it to drive meaningful regulatory progress, scientific evidence must be effectively translated into policy and action. It is here that the science-policy interface plays a pivotal role, bridging the gap between research and regulation to ensure that scientific insights inform effective risk governance rather than becoming another point of contention or delay.

2. *Bridging science and policy: the crucial role of the SPI in EDC risk regulation*

A fundamental component of food risk governance is science-based decision-making. This approach necessitates collaboration among various stakeholders, including policymakers, scientists, industry representatives and the public, to ensure that policies are informed by the most reliable evidence and are effectively implemented.[81] Science-based decision-making relies on the science-policy interface – a process that facilitates the communication and application of scientific knowledge to inform policy, helping ensure that independent research is effectively integrated into regulatory frameworks and contributes to more transparent, responsive and evidence-based risk governance.[82]

Overall, the design of SPIs depends on individual country contexts and existing institutional arrangements.[83] In the EU, the SPI is legally given shape through the comitology procedure, a framework that enables EU Member States to oversee the European Commission's implementation of EU legislation.[84] This process involves committees composed of representatives from each Member State, who review and provide input on draft implementing measures proposed by the Commission.[85] In this decision-making framework, the SPI provides strong scientific evidence on which these

[79] A Kortenkamp and Others, "EU Regulation of Endocrine Disruptors: A Missed Opportunity" (2016) 4 The Lancet Diabetes & Endocrinology 649.

[80] PAN Europe (n 78).

[81] UN Environment, "Strengthening the Science-Policy Interface: A Gap Analysis."

[82] BK Singh and Others, "Enhancing Science–Policy Interfaces for Food Systems Transformation" (2021) 2 Nature Food 838; IPFSS Expert Group, European Commission, "Recommendations to the United Nations' Food Systems Summit Scientific Group from the European Commission's High-Level Expert Group to Assess Needs and Options to Strengthen the International Science Policy Interface for Food Systems Governance" (2021).

[83] "Guidance on Strengthening National Science–Policy Interfaces for Agrifood Systems" available at <https://www.fao.org/3/cd3125en/online/cd3125en.html> (last accessed 13 March 2025).

[84] European Commission, "Comitology" available at <https://commission.europa.eu/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts/comitology_en> (last accessed 13 March 2025).

[85] Ibid.

decisions are made; its contribution highlights 'the common trust in science and expertise, not only as a means to facilitate decision-making but also as a source of legitimacy.'[86] A major initiative supporting this idea is the Commission's high-level expert group, which emphasises the importance of the SPI in leading to safer food systems.[87]

In the case of EDCs, the SPI plays a particularly crucial role in strengthening regulatory decision-making. It serves as a mechanism to focus on available (and encourage future) scientific data, translating it into concrete policy measures – helping define what should be regulated, to what extent and on what basis.[88] While comitology is an end-step where decisions are implemented legally, it all begins with the GFL's risk analysis process.[89]

3. EDC risk analysis: enhancing the influence of scientific assessments in risk management

In this section, we use the SPI as a key mechanism to inform and guide EDC regulation. To do this, we focus on the risk assessment and risk management steps of risk analysis, as they are directly involved in evaluating food-borne risks and informing regulatory decisions. We specifically examine EFSA's central role in risk assessment and transparency challenges in risk management.

The risk analysis process generally involves EFSA as the EU's designated risk assessor, operating under mandates issued by the European Commission. EFSA provides independent risk assessments on EDCs in the food chain, which inform EU risk managers responsible for regulatory decisions. However, EFSA's assessments have at times appeared inconsistent, concluding that no risks exist despite growing concerns from other scientific bodies or public sources. For example, despite early concerns about BPA in food contact materials,[90] EFSA initially deemed the substance safe.[91] Only after sustained scientific and public pressure[92] did it reassess BPA, eventually concluding that it posed serious health risks[93] and prompting a swift Commission ban.[94] Similarly, after assessing evidence on glyphosate and repeated calls for a ban,[95] EFSA did not identify any critical areas of concern that would justify such action.[96] Industry interests and influence are widely viewed as key factors behind these delays and cautious assessments.[97] These examples highlight the complex tension between science, regulation and industry interests, where

[86] C Robert, "The Political Use of Expertise in EU Decision-Making: The Case of Comitology Cécile Robert," p 15.

[87] European Commission, "High Level Expert Group to Assess the Needs, Potential, Feasibility and Approach for International Platform for Food Systems Science (IPFSS) (E03739)."

[88] M Dreyer and O Renn, "A Structured Approach to Participation" in Marion Dreyer and Ortwin Renn (eds), *Food Safety Governance: Integrating Science, Precaution and Public Involvement* (Springer-Verlag Berlin Heidelberg 2009) at pp 11–12.

[89] Art 6 GFL.

[90] Environmental Working Group, "Timeline: BPA from Invention to Phase-Out" (22 April 2008) available at <https://www.ewg.org/research/timeline-bpa-invention-phase-out> (last accessed 3 April 2025).

[91] EFSA, "Scientific Opinion on the Risks to Public Health Related to the Presence of Bisphenol A (BPA) in Foodstuffs" (2015) 13 EFSA Journal 3978.

[92] FS Vom Saal and LN Vandenberg, "Update on the Health Effects of Bisphenol A: Overwhelming Evidence of Harm" (2021) 162 Endocrinology bqaa171.

[93] EFSA, "Bisphenol A in Food Is a Health Risk" (2023) available at <https://www.efsa.europa.eu/en/news/bisphenol-food-health-risk> (last accessed 4 March 2025).

[94] European Commission (n 70).

[95] European Commission, "European Citizens' Initiative: Ban Glyphosate and Protect People and the Environment from Toxic Pesticides" (2017).

[96] F Álvarez and Others, "Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate" (2023) 21 EFSA Journal e08164.

[97] "Glyphosate in the EU up to 2034? Danger to Health and Environment and Violation of Citizens Will" (*PAN Europe*, 2023) available at <https://www.pan-europe.info/press-releases/2023/09/glyphosate-eu-2034-danger-health-and-environment-and-violation-citizens-will> (last accessed 6 May 2025).

delayed or conflicting assessments can undermine consumer protection and erode trust in regulatory science. More importantly, they suggest a reluctance to issue scientific opinions against the use of certain substances, raising questions about the transparency and independence of EFSA's assessment processes and the criteria underpinning its conclusions.

While EFSA plays a crucial role in risk assessment, its effectiveness ultimately depends not only on the independence and transparency of its findings, but also on how risk management decisions respond to those findings. Ensuring that science drives regulation requires a transparent, structured risk analysis process that separates scientific evidence from external influences and builds public trust.[98] Independence and transparency must be present at two key levels: in how scientific evidence is processed and conclusions are drawn, and in how those conclusions inform risk management decisions.

This is reinforced in EU food law through the Transparency Regulation,[99] which amended the GFL and several secondary food laws to enhance transparency, independence, accountability and sustainability in EFSA's risk assessment process. The Regulation identifies, as a key objective, a clearer separation between risk assessment, risk management and risk communication to strengthen the independence of scientific advice and limit undue industry influence.[100] To achieve this, Article 1 of the Regulation introduced a range of procedural reforms. These include requirements for the electronic publication of industry-submitted studies and data used in EFSA assessments; public access to ongoing consultations on authorisation applications; and the obligation for industry to notify EFSA of all commissioned studies. It also empowers EFSA, upon request from the Commission, to commission verification studies and introduces fact-finding missions by Commission experts to assess research standards in both Member States and third countries. In addition, EFSA's governance was reformed by expanding its Management Board to include representatives from all Member States, thereby increasing their involvement in the development of scientific opinions.

These amendments strengthen EFSA's transparency and independence and help clarify the division between risk assessment and risk management functions. Nevertheless, it is argued that despite these improvements, risk management remains opaque,[101] with scientific opinions often being weighed against powerful political or economic factors.[102] This can lead to inconsistent decisions and weakened health protections when external pressures override scientific evidence and delay regulation, highlighting the need to strengthen transparency at every stage of risk analysis beyond what the Transparency Regulation currently provides.

To address these concerns, it has been proposed to separate scientific assessments from external factors within risk management by introducing an independent "external factors assessment" conducted by a designated authority.[103] This authority would review and

[98] M Petticrew and H Roberts, *Systematic Reviews in the Social Sciences: A Practical Guide* (Blackwell Publishing 2006); AM O'Connor and Others, "Implementation of Systematic Reviews in EFSA Scientific Outputs Workflow" (2012) 9 EFSA Supporting Publications 367E; Alie de Boer, "Scientific Assessments in European Food Law: Making It Future-Proof" (2019) 108 Regulatory Toxicology and Pharmacology 104437.

[99] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, OJ L 231/1 – Transparency Regulation.

[100] Preambles (8), (12) and (24) Ibid.

[101] H Goverde, "Food Politics: Science and Democracy in the Dutch and EU Food Polity" in Otto Hospes and Irene Hadiprayitno (eds), *Governing Food Security: Law, Politics and the Right to Food* (Wageningen, Netherlands, Wageningen Academic Publishers 2010) at 177.

[102] M El Gemayel, "The Role of Risk Analysis in EU Food Governance: Balancing Scientific Food Safety Factors and External Factors That Inform Risk Management for Healthier Food Systems" (2025) 16 European Journal of Risk Regulation 149.

[103] Ibid., pp 168–9.

provide non-binding opinions on external considerations – such as political, economic, societal and environmental factors – similar to how EFSA conducts scientific risk assessments. Under this structure, risk management would first evaluate EFSA's scientific opinion before separately considering the external factors assessment, ensuring a clear distinction between scientific evidence and other influences.[104] By isolating and documenting all decision-making inputs, this framework strengthens independence, prioritises scientific integrity, enhances transparency and traceability, and ensures a balanced yet not overly politicised approach. In doing so, it leverages the SPI in risk analysis.

A structured and transparent risk analysis process is essential for an effective SPI and strong EDC regulation. However, legislative coherence on EDCs is equally necessary to ensure uniform application across all stages of the food supply chain. Building on these insights, the next section explores how EU food law can strengthen EDC regulation through a harmonised legal framework.

III. EDCs in current EU law: strengthening legislation

In this section, we examine the EU's legal approach to EDCs as substances that negatively impact human health through food consumption. First, we focus on EU legislation that explicitly addresses EDCs and that impacts the food supply chain.[105] Second, we review regulations that aim to protect consumers from harmful chemicals in the food supply chain, without explicitly referencing EDCs. Finally, we examine the GFL framework to explore how it can be leveraged to broaden the scope of EDC regulation throughout the entire food supply chain.

1. A direct regulation of EDCs in agriculture and chemical products legislation

The EU currently addresses EDCs as substances with adverse health effects on humans in three regulations: the Plant Protection Products Regulation, the Biocidal Products Regulation and the REACH Regulation.

The Plant Protection Products Regulation establishes the framework for the authorisation and use of plant protection products in the EU, aiming to balance agricultural needs with the protection of human health and the environment.[106] The regulation is based on the precautionary principle, allowing for restrictive measures if scientific uncertainty or inconclusive evidence suggests potential harm to human health, animal health, or the environment.[107] The regulation includes specific provisions on endocrine disruption. One of the approval criteria for active substances used in plant protection products is that they must not have endocrine-disrupting properties that may cause adverse effects in humans or non-target organisms.[108] Additionally, as some low-risk substances are sometimes authorised,[109] the Regulation considers that an active substance cannot be considered as low risk if it is deemed to be an endocrine disruptor,[110] thus adopting a hazard-based approach to EDCs.

[104] Ibid.
[105] Demeneix and Slama (n 28) at 68.
[106] Art 1(1) PPPR.
[107] Art 1(4) PPPR.
[108] Art 23(1)(b) PPPR.
[109] Art 22 PPPR.
[110] Annex II(5) PPPR.

The Biocidal Products Regulation aims to harmonise the rules governing biocidal products across the EU while ensuring a high level of protection for human health, animal health and the environment.[111] The regulation follows the precautionary principle, allowing for preventive action even in cases of scientific uncertainty to safeguard public health, particularly for vulnerable groups.[112] Under the BPR, active substances cannot be approved or authorised for market use if they are identified as endocrine disruptors that may cause "adverse effects in humans."[113] This provision ensures that substances with endocrine-disrupting properties are restricted to minimise potential health risks, also adopting a hazard-based approach to EDCs.

To improve the regulatory framework for EDCs, the European Commission conducted an impact assessment to evaluate the effects of different criteria for identifying and regulating EDCs under the PPPR and the BPR, affecting new and ongoing applications.[114] The assessment recommended adopting the WHO definition[115] of EDCs in EU legislation to ensure a scientifically sound basis for regulation.[116] It also evaluated both risk-based and hazard-based approaches for EDC regulation,[117] concluding that although a general hazard-based approach for EDCs would be maintained, some exceptions would rely on a risk-based approach assessment if exposure is low.[118] The introduction of a risk-based approach aimed to enhance regulatory clarity and consistency while balancing scientific, legal and economic considerations.

This initiative resulted in two key regulations: an amendment to the PPPR[119] and a Delegated Regulation under the BPR.[120] Both adopt the WHO definition of endocrine disruptors and establish criteria for identifying EDCs based on adverse effects caused by endocrine mechanisms, assessed through a weight-of-evidence approach.[121] As a result, the same chemical may be banned under one regulation but allowed with restrictions under the other, because the PPPR and BPR have distinct scopes and evaluation criteria. Consequently, EDCs on the list of endocrine disruptors[122] are not automatically banned, as exceptions can be made under specific conditions.[123]

The amendments to EU pesticide and biocide regulations have been criticised as a missed opportunity to strengthen protection against EDCs.[124] Instead of maintaining a

[111] Art 1(1) BPR.

[112] Ibid.

[113] Arts 5(1)(d) and 19(4)(d) BPR.

[114] European Commission, "Staff Working Document Impact Assessment: Defining Criteria for Identifying Endocrine Disruptors in the Context of the Implementation of the Plant Protection Products Regulation and Biocidal Products Regulation, COM(2016) 350 Final, SWD(2016) 212 Final" (n 26).

[115] WHO International Programme for Chemical Safety (n 8).

[116] European Commission, "Staff Working Document Impact Assessment: Defining Criteria for Identifying Endocrine Disruptors in the Context of the Implementation of the Plant Protection Products Regulation and Biocidal Products Regulation, COM(2016) 350 Final, SWD(2016) 212 Final" (n 26) s 4.1.

[117] Ibid., 6.1.

[118] Ibid., 5.4.2 and 5.4.3.

[119] Commission Regulation (EU) 2018/605 (n 23).

[120] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council, OJ L 301/1.

[121] Section A(1), Annex, Commission Delegated Regulation (EU) 2017/2100; and 3.6.5., Annex II(1), PPPR, as amended by Commission Regulation (EU) 2018/605.

[122] Endocrine Disruptor Lists (n 40).

[123] European Commission, "Communication from the Commission to the European Parliament and the Council on Endocrine Disruptors and the Draft Commission Acts Setting Out Scientific Criteria for Their Determination in the Context of the EU Legislation on Plant Protection Products and Biocidal Products COM(2016) 350 Final (Brussels, 2016) 11."; Dang and others (n 62) at p 21.

[124] Kortenkamp and Others (n 79).

strict hazard-based ban on EDCs, the changes introduced risk-based exemptions, allowing approval if exposure is considered negligible.[125] The amendments also increased the burden of proof for classifying EDCs, making regulation harder.[126] This shift enables continued used of harmful EDCs such as glyphosate[127] and chlorpyrifos[128] in agriculture, despite evidence of irreversible health effects,[129] and undermines protections against low-dose effects that a hazard-based approach is designed to address.

Finally, the EU also regulates EDCs under the REACH Regulation, a cornerstone of EU chemical management. REACH mandates the registration and safety assessment of chemicals manufactured, marketed, used, or imported in the EU, applying the precautionary principle to minimise risks.[130] Recognising the adverse health effects of EDCs, REACH includes them among substances requiring authorisation before market placement.[131] EDCs can be classified as Substances of Very High Concern and added to the Candidate List, which may lead to further restrictions, including bans or usage limitations.[132] While REACH has a broad scope across multiple sectors, it excludes food ingredients, additives and flavourings,[133] which fall under the GFL Regulation and related food legislation.[134]

While the PPPR, BPR and REACH Regulation set out specific rules for certain chemicals, they do not comprehensively address risk across the entire food supply chain. First, they focus primarily on the agricultural stage, whereas EDCs can be introduced through production, processing, or packaging. Second, following the shift from a hazard-based approach that immediately restricts identified EDCs, these regulations now allow for limited use under certain conditions, failing to account for potential health risks from EDC mixtures and low-dose exposure in real-world scenarios. Beyond this sector-specific framework, EU food law includes broader provisions aimed at ensuring food safety, and that could include EDCs in their scope.

2. *An indirect regulation of EDCs in food legislation*

Unlike the targeted and textually explicit regulation of EDCs in pesticides and biocides, there are secondary food laws that rely on general safety principles for hazardous substances. Such provisions can regulate EDCs if they fit within their criteria and can be found in legislation on food contact materials, additives, enzymes, flavourings and contaminants.

The Food Contact Materials Regulation[135] ensures that materials intended to come into contact with food do not transfer harmful substances at unsafe levels. Similarly,

[125] N Scholz, "Commission Proposals on Identifying Endocrine Disruptors" (2016) PE 586.629. European Parliamentary Research Service 5.; Art 4(7) and Annex II, 3.6.5, PPPR; Art 5(2) BPR.

[126] Kortenkamp and Others (n 79).

[127] Commission Implementing Regulation (EU) 2023/2660 of 28 November 2023 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011, OJ L 2023/2660.

[128] Commission Regulation (EU) 2020/1085 of 23 July 2020 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products, OJ L 239/7.

[129] Kortenkamp and Others (n 79).

[130] Art 1(2)(3) REACH Regulation.

[131] Art 57(f) REACH Regulation.

[132] Arts 55, 56 and 57(f) REACH Regulation.

[133] Art 2(5)(b) REACH Regulation.

[134] Art 14(5)(a) REACH Regulation.

[135] Regulation (EC) No 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 80/590/EEC and 89/109/EEC, OJ 2004 L 338/4 (Food Contact Materials Regulation).

Commission Regulation (EU) No 10/2011[136] governs plastics used in food packaging, requiring risk assessment and authorisation for monomers and additives.[137] While both regulations seek to prevent harmful chemical migration into food, they lack targeted safeguards against endocrine-disrupting properties specifically, leaving consumers potentially exposed to EDCs from packaging and processing materials.

The Food Additives Regulation (FAR),[138] Food Enzymes Regulation (FER),[139] and Food Flavourings Regulation (FFR),[140] establish rules for the respective use of food additives, enzymes and flavourings to protect human health, consumer interests and fair-trade practices. While food additives must be proven safe and justified by a technological need, the precautionary principle applies only in a general sense, and testing requirements do not explicitly mandate screening for endocrine-disrupting effects.[141] Instead, risk assessments for additives, enzymes and flavourings rely on EFSA scientific opinions, which do not require specific data on endocrine activity.[142] As a result, potential endocrine-disrupting properties of food additives, enzymes or flavourings may go unexamined, highlighting inconsistencies in EU risk assessment across different categories of food-related chemicals.

The new Food Contaminants Regulation[143] updates and consolidates maximum levels for certain contaminants in foodstuffs to protect public health across the EU.[144] It sets limits for contaminants such as dioxins, polychlorinated biphenyls and PFAS in various food products.[145] Although EDCs are not explicitly categorised in the regulation, it still helps to reduce exposure to them by targeting substances with similar harmful effects. If a substance is recognised as harmful due to endocrine-disrupting properties and fits within the listed contaminant categories, it can still be regulated under this framework.

The lack of specific EDC provisions in secondary food law leaves a critical gap, as often food is in contact with materials such as plastics or cans, or is subject to additions or contamination throughout the supply chain. Regulation of EDCs from these sources is slow and lags behind industry changes. While the BPA ban[146] marks a critical milestone, this progress remains limited in scope. Many other substances with potential endocrine-disrupting effects continue to be used in food contact materials and as added food ingredients, while risk assessments and regulation remain pending, highlighting regulatory inertia. For instance, pressure is mounting for the EU to take a group-based

[136] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ 2011 L 12.

[137] Ibid. Preamble (8).

[138] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives OJ L 354/67 (Food Additives Regulation – FAR).

[139] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97, OJ 2008 L 354/7 (Food Enzymes Regulation – FER).

[140] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, OJ 2008 L 354/34 (Food Flavourings Regulation – FFR).

[141] Preamble (7) FAR; Preamble (6) FER; Preamble (7) FFR.

[142] European Food Safety Authority (EFSA), "Data Requirements for the Evaluation of Food Additive Applications" (2009) 7 EFSA Journal 1188; Demeneix and Slama (n 28) 70.

[143] Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006, OJ 2023 L 119 (Food Contaminants Regulation – FCR).

[144] Art 9 FCR.

[145] Annex I FCR.

[146] European Commission (n 70).

approach to banning phthalates[147] (similar to BPA and similar substances ban),[148] which are still used in some food contact materials despite endocrine-disrupting concerns.[149] Also, butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) are synthetic antioxidants, both authorised in specific food categories with set limits.[150] EFSA recently raised the acceptable daily intake for BHT, though high-exposure levels in children may still exceed this threshold.[151] BHA was deemed non-genotoxic in a 2011 EFSA review,[152] but has not been reassessed for endocrine-disrupting effects, despite emerging concerns.[153] Both substances are under review for endocrine disruption under REACH and cosmetics legislation, but not in food.[154] Another example is synthetic food dyes such as Tartrazine (E102), Sunset Yellow (E110) and Erythrosine (E127), which have recently shown endocrine-disrupting potential.[155] These additives remain authorised in the EU with limits and labelling requirements,[156] while EFSA maintains their safety at permitted exposure levels despite assessments not addressing endocrine effects.[157] As evidence grows and questions arise about safe thresholds for such substances, current regulations may not fully reflect the latest scientific understanding from these potential hazards, leading to inconsistent consumer protection.

By contrast to this spotty EDC regulation, current EU food law implements hazard-based elements for certain hazardous substances. For example, Regulation (EC) No 315/93 prohibits placing food on the market if it is injurious to health,[158] including contamination by carcinogens above acceptable limits. The Food Contaminants Regulation enforces this by setting maximum levels for numerous carcinogenic and toxic substances.[159] The PPPR uses cut-off criteria to block approval of substances classified as CMRs or endocrine disruptors.[160] The Food Additives Regulation, Food Enzymes Regulation and Food Flavourings Regulation all require that substances do not pose a safety concern to

[147] Health and Environment Alliance, "Food Contact Materials and Chemical Contamination" available at <https://www.env-health.org/IMG/pdf/15022016_-_heal_briefing_fcm_final.pdf> (last accessed 31 March 2025).

[148] European Commission (n 70).

[149] M Dalamaga and Others, "The Role of Endocrine Disruptors Bisphenols and Phthalates in Obesity: Current Evidence, Perspectives and Controversies" (2024) 25 International Journal of Molecular Sciences 675; H Hlisníková and Others, "Effects and Mechanisms of Phthalates' Action on Reproductive Processes and Reproductive Health: A Literature Review" (2020) 17 International Journal of Environmental Research and Public Health 6811.

[150] Annex II, Food Additives Regulation.

[151] EFSA, "Scientific Opinion on the Re-Evaluation of Butylated Hydroxytoluene BHT (E 321) as a Food Additive" (2012) 10 EFSA Journal 2588.

[152] EFSA, "Scientific Opinion on the Re-Evaluation of Butylated Hydroxyanisole – BHA (E 320) as a Food Additive" (2011) 9 EFSA Journal 2392.

[153] SP Felter, X Zhang and C Thompson, "Butylated Hydroxyanisole: Carcinogenic Food Additive to Be Avoided or Harmless Antioxidant Important to Protect Food Supply?" (2021) 121 Regulatory Toxicology and Pharmacology 104887.

[154] Endocrine Disruptor Lists, "Substances under Evaluation for Endocrine Disruption under An EU Legislation" available at <https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption> (last accessed 28 March 2025).

[155] A Axon and Others, "Tartrazine and Sunset Yellow Are Xenoestrogens in a New Screening Assay to Identify Modulators of Human Oestrogen Receptor Transcriptional Activity" (2012) 298 Toxicology 40; Paramasivam and Others (n 14).

[156] Annex II, Food Additives Regulation.

[157] EFSA, "Scientific Opinion on the Re-Evaluation Tartrazine (E 102)" (2009) 7 EFSA Journal 1331; EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), "Reconsideration of the Temporary ADI and Refined Exposure Assessment for Sunset Yellow FCF (E 110)" (2014) 12 EFSA Journal 3765.

[158] Art 2 Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, OJ 1993 L 37/1.

[159] Preamble (2), FCR.

[160] 3.6.3 Annex II, PPPR.

consumer health at the level of use proposed.[161] This safety clause excludes substances with carcinogenic or genotoxic properties, as these are considered unsafe at any level. While these laws apply a risk-based framework, the exclusion of non-threshold carcinogens or genotoxins reflects hazard-driven decision-making. In practice, such substances are banned because no safe level of exposure can be demonstrated. Thus, hazard leads to exclusion through risk-based reasoning, making the legal framework functionally equivalent to a hazard-based model in these cases – and also underscoring the importance of strengthening both risk analysis and secondary food law for a comprehensive EDC regulation.

These sector-specific food laws focus on carcinogenicity and other hazardous substances, while potential endocrine effects remain loosely addressed. This is largely due to insufficient evidence and the lack of a legal framework for restricting EDCs in food contact materials and food additives. With the lack of mandatory EDC-specific testing requirements, this raises additional concerns that the current safety limits cannot be properly verified or enforced.[162] Without systematic testing and clear legal provisions, oversight remains fragmented and inconsistent.

To overcome these limitations, harmonising EU food law is crucial to ensure a consistent legislative approach to EDCs across all stages of the food supply chain. The next section examines the GFL as the structural foundation for food safety and explores how this framework can be leveraged to establish a unified legal approach to regulating EDCs.

3. The GFL's potential for EDCs regulation

Comprehensively addressing EDCs in all food legislation is essential to minimise health risks across the food supply chain. Within this framework, the GFL Regulation serves as the foundational regulation for protecting human health and consumer interests. It sets out common principles and responsibilities, provides the scientific basis for food safety, and establishes procedures to analyse risk and support decision-making – applicable across all stages of the food chain.[163] In this section, we argue that the GFL's core provisions on food-borne health risks can support the development of EDC regulation, focusing on its definitions of risk, hazard and food safety.

The GFL adopts a scientific, risk-based approach by defining risk, hazard and food unsafety and setting principles to prevent them. It defines risk as 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard,'[164] and hazard as 'a biological, chemical, or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.'[165] These definitions are linked by the concept of "adverse health effects": a hazard has the potential to cause harm, while risk concerns the probability and severity of that harm.[166]

However, the GFL does not define what qualifies as an adverse health effect. By contrast, Annex II(1) of the PPPR explicitly defines endocrine-related adverse effects, including changes in morphology, physiology, growth, development, reproduction, or lifespan in organisms (including humans) and their descendants. While its direct application to the GFL is uncertain, these effects clearly bring EDCs within the scope of the GFL's hazard definition. Given EDCs' potential for harm, and their presence in food, exposure turns this hazard into a risk.

[161] Art 6(1)(a), FAR, Art (6)(a) FER and Art 4(a) FFR.

[162] Demeneix and Slama (n 28) at 61.

[163] Art 1 GFL.

[164] Art 3(9) GFL.

[165] Art 3(14) GFL.

[166] A-A Cioca, L Tušar and T Langerholc, "Food Risk Analysis: Towards a Better Understanding of 'Hazard' and 'Risk' in EU Food Legislation" (2023) 12 Foods 2857.

Article 14 GFL reinforces this by prohibiting food that is "unsafe,"[167] defining it as "injurious to health"[168] or "unfit for human consumption,"[169] and explicitly referencing "long-term" and "cumulative toxic effects," including those on future generations.[170] While usually applied to acute hazards, this framework also covers chronic chemical risks such as EDCs. The reference to "cumulative toxic effects" shows EU law's capacity to address long-term harms. Where evidence shows EDCs in food or contact materials pose such risks, they may be deemed "unsafe" under Article 14.

In fact, Article 14 has been proposed as a legal basis to address EDC contamination in the food supply chain and remove products containing persistent toxic substances (e.g. PFAS) from the market.[171] In the absence of a specific EDC ban, Article 14 allows authorities to restrict or withdraw food products based on scientific evidence or the precautionary principle.[172] Regulators may invoke this general safety mandate to prohibit products containing EDCs – even if they comply with current limits – when new evidence indicates risk.[173] This interpretation positions Article 14 as a legal safety net for emerging hazards such as EDCs.

However, while Article 14 is a powerful tool, reliance on it as a catch-all provision has raised concerns. It places responsibility on the food industry to ensure safety and conduct risk assessments. Yet this broad framework can lead to ambiguity and legal uncertainty, especially where definitions of "unsafe food" are applied beyond well-established parameters.[174] This concern is especially relevant in the regulation of EDCs, where scientific uncertainty and complex risk profiles complicate regulatory clarity. The food industry has often resisted broad EDC regulation,[175] preferring case-by-case evaluations over blanket bans.[176] Industry-led risk assessments have been criticised as biased or inconsistent, downplaying risks and undermining transparency.[177] Others argue that hazard-based bans without detailed assessments may lead to unjustified trade barriers.[178] Over-reliance on Article 14 can result in ambiguity and inconsistent enforcement,[179] underlining the need for clearer, hazard-specific regulation.[180]

Therefore, while Article 14 provides a basis for addressing EDCs in food, it should not be the sole regulatory mechanism. Instead, sector-specific, hazard-based tools are needed to improve precision and legal certainty. Strengthening these frameworks would improve food safety across the supply chain. Our view that GFL provisions could support EDC regulation highlights the complexity of integration – one that requires more than textual

[167] Art 14(1) GFL.
[168] Art 14(2)(a) GFL.
[169] Art 14(2)(b) GFL.
[170] Art 14(4)(a)(b) GFL.
[171] CR Ortega, A Molitorisová and K Purnhagen, "Dangerous Legacy of Food Contact Materials on the EU Market: Recall of Products Containing PFAS" (2024) European Journal of Risk Regulation 1.
[172] Ibid.
[173] "Endocrine Disruptors: A Strategy for the Future That Protects EU Citizens and the Environment" (2018) available at <https://ec.europa.eu/commission/presscorner/detail/en/ip_18_6287> (last accessed 2 April 2025).
[174] B van der Meulen, "Is Current EU Food Safety Law Geared up for Fighting Food Fraud?" (2015) 10 Journal für Verbraucherschutz und Lebensmittelsicherheit 19.
[175] B Aho, "Disrupting Regulation: Understanding Industry Engagement on Endocrine-Disrupting Chemicals" (2017) 44 Science and Public Policy 698.
[176] P Ricci, "Endocrine Disruptors: Improving Regulatory Science Policy" (2015) 13 Dose-Response 1–14.
[177] Aho (n 175).
[178] G Funes, "Endocrine Disruptors: Criteria for Identification and Related Impacts" (Presentation at the EU Conference "Endocrine Disruptors: Criteria for Identification and Related Impacts", Brussels, 1 June 2015).
[179] D Polinski and B van der Meulen, "Unfit for Human Consumption: The Elusive Element in the EU Food Safety Concept of Art 14 GFL" (2021) 16 European Food and Feed Law Review 17.
[180] A Szajkowska, "Regulating Food Law: Risk Analysis and the Precautionary Principle as General Principles of EU Food Law" (Wageningen University and Research 2012) pp 13–14.

amendments. The next section explores how regulatory gaps can be addressed through a three-pronged approach, combining risk analysis methodologies and a comprehensive EDC regulation rooted in the GFL and sector-specific, hazard-based legislative amendments.

IV. Discussion: a comprehensive legislative framework to strengthen EDC risk regulation in EU food law

Our research shows that the EU framework for EDCs in the food supply chain is fragmented and inconsistent, lacking a unified regulatory approach. While some laws – such as those governing pesticides and biocides – include specific criteria to identify and restrict EDCs, others – such as food contact materials, food additives and general food safety regulations – lack explicit provisions, creating legal uncertainty and uneven consumer protection.

This regulatory patchwork is further complicated by the influence of several factors in decision-making. Under the GFL Regulation, risk management decisions are shaped not only by scientific evidence but also by other legitimate factors, such as economic and political interests. In theory, this balancing act aims to generate fair decision-making that benefits all parties. However, in practice, it has delayed or weakened regulatory action, as seen when the European Commission was found in breach of EU law for failing to establish timely EDC criteria[181] – a delay widely attributed to industry lobbying and political pressure.

These challenges underscore the need for a stronger, more harmonised regulatory framework to ensure comprehensive and consistent EDC oversight across the entire food supply chain. A unified approach – covering agriculture, food production, processing, packaging, distribution and retail – would close regulatory gaps and strengthen consumer protections. Recognising this need, both the European Parliament[182] and Commission[183] have called for cross-sector, coordinated action to ensure that food safety regulations effectively manage EDC risks throughout the food supply chain.

To address these gaps, we propose three key recommendations: leverage the SPI to reinforce the role of scientific evidence in risk management; leverage the GFL as the legal foundation for comprehensive EDC regulation; and implement these provisions in a harmonised hazard-based approach in sector-specific (secondary) food law.

1. Recommendation 1: leverage the SPI to reinforce science in risk analysis

A key first step toward strengthening EDC regulation is ensuring that scientific evidence remains the primary driver in risk analysis through risk management decisions. To achieve this, we support the recommendation to explicitly divide the risk management step into two separate phases: review of scientific assessment – where EFSA's independent risk assessment informs regulatory decisions; and review of external factors assessment – where political, economic and societal considerations are reviewed independently.[184]

This recommendation leverages the SPI to ensure that scientific expertise translates effectively into policy without political–economic interests overshadowing public health. It operationalises the "science-policy interface" at two main levels. In the "science" component, EFSA's role as the EU's scientific gatekeeper should be expanded and refined to include long-term, cumulative, mixture and intergenerational exposure assessments, particularly given the growing recognition of cocktail effects – where multiple low-dose

[181] Stieger (n 76).
[182] European Parliament (n 29).
[183] European Commission (n 27).
[184] El Gemayel (n 102).

exposures collectively pose significant health risks. In the "policy" component, two assessments are distinct: EFSA's scientific risk assessment and a separate evaluation of "other legitimate factors" by an independent external body. This body would assess economic, political and societal considerations and issue a non-binding advisory opinion for risk managers to consider separately from EFSA's scientific assessment.

The "policy" component of the SPI is a key common denominator to all EDC risk regulation. This two-step risk management structure enhances transparency, reinforces the integrity of EFSA's scientific role in decision-making, and limits undue "other legitimate factors," namely political and economic influences, on public health protections. Applying this structured approach where risks are pinpointed across the food supply chain – from primary production to retail – ensures that science remains the central pillar of food safety policy, ultimately strengthening consumer protection and regulatory credibility.

To complement this science-based approach, leveraging key GFL provisions on food safety is essential, as it ensures a consistent and comprehensive regulation across the entire food supply chain – bringing us to our second recommendation.

2. Recommendation 2: leverage the GFL for comprehensive EDC regulation

The GFL Regulation provides a broad, "farm-to-fork" safety framework that can be leveraged to comprehensively regulate EDCs. Its general principles and risk analysis approach apply to all stages of food production, processing and distribution, ensuring that the same fundamental safety standards govern them. In this GFL framework, we support recommendations to address EDCs horizontally across sectors[185]: any substance posing a health hazard in food, once recognised and classified through an agreed scientific and policy mechanism, should be assessed and controlled at the appropriate stage of the food chain.

To operationalise this legally, certain prerequisite steps are necessary. specifically, a policy document or harmonised guidance at EU level (e.g., Commission Communication or delegated act), would be required to outline the process through which certain chemicals are identified as having endocrine-disrupting properties. This identification (supported by EFSA scientific opinions) would make them hazardous and unsafe under the GFL, requiring regulation at the appropriate stages of the food supply chain.

In practice, leveraging the GFL would mean explicitly incorporating EDC risk assessment and management wherever necessary in the food supply chain to pinpoint and limit hazards – from controlling EDC residues on crops and animal feed to assessing food additives and packaging materials for endocrine effects, and ensuring that distribution and retail practices do not introduce additional risks. This end-to-end coverage would harmonise currently fragmented regulations, ensuring consumer protection at all stages of the food supply chain.

This complements the previous recommendation to strengthen a science-policy interface, and also underscores the need to address EDCs as health hazards and for a comprehensive approach in secondary food law. To complement this GFL framework, we support a sector-specific regulation that extends the EDC framework from pesticide and biocide regulations (which affect food but fall outside of food law) into secondary food legislation. We argue that risk analysis and a predominantly hazard-based approach in secondary legislation are not mutually exclusive, as processing scientific evidence is central to identifying hazards, and necessary for regulatory frameworks such as food law[186] – bringing us to our third recommendation.

[185] Slama and Demeneix (n 42).
[186] Bourguignon and Others (n 46).

3. Recommendation 3: introduce a hazard-based approach to EDCs in sector-specific regulations

To strengthen risk regulation and public health protection, we support a hazard-based approach to EDCs in sector-specific legislation.[187] This approach would ban or restrict a substance if it is harmful (i.e. classified as a 'hazard'), regardless of factors such as exposure level – meaning that the mere identification of a substance as inherently dangerous is sufficient for regulatory action, even without considering how much of it people are actually exposed to or under what conditions. It ensures stricter regulatory control, reducing tolerance for EDC presence in food and aligning their treatment with other well-established hazardous substances, such as carcinogens, mutagens and reproductive toxins.

The layered legal approach for carcinogens and other high-risk substances shows that the EU already treats them with extreme precaution, offering a precedent for similar treatment of EDCs. Yet, EDCs are not currently addressed under food law in the same way as carcinogens and toxins, leaving a gap in regulatory consistency. To close this gap, the EU should extend this precautionary model to EDCs across the food supply chain through sector-specific regulations. This could include amending the Food Additives Regulation, Food Enzymes Regulation and Food Flavourings Regulation to recognise endocrine-disrupting properties as a ground for exclusion; updating the Food Contaminants Regulation to set legal limits for EDCs that enter food unintentionally (e.g., through environmental pollution or processing); revising the Food Contact Materials Regulation to more explicitly address EDC migration from packaging, processing equipment and storage, with tailored exposure assessments. For instance, these sector-specific regulations could be amended to state that "endocrine-disrupting properties, as identified by agreed scientific criteria, shall be managed with the same level of precaution as carcinogenic, mutagenic, or reprotoxic substances."

The aim is a coherent, legally binding framework in which once a substance is scientifically identified as an EDC, it is formally treated as a health hazard under food law – just like a carcinogen. This classification would then drive risk management decisions, outweighing considerations such as economic cost or technical feasibility. This would re-align food law with the original principles applied to pesticides and biocides, where once a substance is confirmed as an EDC, approval is denied regardless of its benefits. Such alignment would also reduce the excessive burden of proof currently hindering the regulation of EDCs,[188] and prevent any EDCs from slipping through the cracks of regulation.

V. Conclusion

The EU stands at a critical juncture in its approach to EDCs in food law. Although some progress has been made, current efforts remain fragmented and slow due to ongoing gaps in the regulatory framework. To address these gaps and the pressing urgency of regulating EDCs, EU legislators can build on what already exists instead of creating entirely new laws. This can be done through three main steps: strengthening a transparent and a science-based risk analysis, leveraging the GFL framework for ensuring food safety, and adopting a hazard-based approach in existing secondary food legislation to explicitly include and regulate EDCs. This suggested approach would ensure a science-based regulation of EDCs, strengthen regulatory consistency and enhance food quality and safety. Mainly, it would reflect the EU's objective, outlined in the 2019 Resolution, to develop a comprehensive, cross-sector EDC strategy based on scientific evidence and clear legal definitions.[189]

[187] Kassotis and Trasande (n 47); Bourguignon and Others (n 46).
[188] Kortenkamp and Others (n 79).
[189] European Parliament (n 29).

Despite this alignment, a key challenge in advancing EDC regulation is the pressure from global trade dynamics, where less regulation is often favoured to facilitate trade and industry competitiveness.[190] However, weakened standards come at a long-term cost: the continued exposure to EDCs has been linked to rising rates of NCDs, including obesity,[191] cardiometabolic disorders,[192] and cancer.[193] By strengthening EDC regulations, the EU can help reduce public health burdens associated with NCDs, decreasing healthcare and loss of productivity costs, and improving overall quality of life.[194] It can also solidify its global leadership in chemical risk regulation, ensuring that European food is not only safe from acute hazards but also free from long-term chemical threats that may disrupt hormonal health across generations.

This approach aligns with the Farm to Fork Strategy's objective to address hazardous substances, including EDCs, through the review of import tolerances for plant protection products.[195] It also lays the groundwork for expanding this focus into a more comprehensive and protective framework in the EU's food supply chain. However, with the Farm to Fork Strategy having become politically stranded and falling short on many of its action points,[196] the goal of effectively tackling EDCs in EU food policy and legislation remains unmet. Building on the Strategy's original ambition, the 2019 Resolution, the One Substance–One Assessment approach on streamlining chemical safety across EU legislation,[197] and our recommendations, now is the moment to revive and fulfil this commitment with renewed political resolve and broader legislative reach. A stronger, more harmonised, regulatory framework for EDCs would lead to safer food production, improved packaging standards, greater consumer awareness, and ultimately, stronger public health protection.

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[190] Kassotis and Others (n 72); Trasande and Others (n 72).
[191] Chamorro-Garcia and Others (n 17); Heindel and Others (n 17).
[192] Rancière and Others (n 18).
[193] Filippone and Others (n 19).
[194] Bergman and Others (n 7).
[195] European Commission (2020) (n 35) 19.
[196] M El Gemayel and H Schebesta, "Health and Nutrition in Current EU Food Law: A Systematic Review" (2024) 19 European Food and Feed Law Review 119.
[197] European Commission (n 36) 3–4.

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