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ARTICLE

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

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Abstract

Scientific consensus links dietary choices to health outcomes, highlighting the urgency to prioritise healthy food production in food systems. At the EU level, however, defining healthy food and integrating it into food governance remains a challenge, particularly regarding the inclusion of health-related characteristics in food safety assessments. While the EU primarily relies on the risk analysis principle to address food safety concerns, the process still exhibits weaknesses that hinder its direct impact on fostering a healthier food production landscape. This review demonstrates how the risk analysis process, particularly scientific opinions in risk assessment and external factors (economic and political) in risk management, impact food governance and the healthiness of food systems. We find that while external factors play a crucial role in risk management decisions by incorporating non-food safety considerations, they often stem from an imbalance of power favouring major industry and political stakeholders. This imbalance disproportionately influences decision-making, often overshadowing nutritional and health aspects. To address these challenges, we recommend directing research towards filling knowledge gaps and exploring minority scientific findings, and separating external factors from risk management's decision-making process, to ensure that food governance prioritises public health and healthy food production.

Keywords: EU food law; food systems; risk analysis; risk assessment; risk management

I. Introduction

International scientific and health authorities associate diets with health impacts and disease burden.[1] This underscores the urgent need for a food systems overhaul that prioritises healthy food.[2] In the EU, there remain challenges to define healthy food and

[1] IPES-Food, "Unravelling the Food-Health Nexus: Addressing Practices, Political Economy, and Power Relations to Build Healthier Food Systems" (2017) at pp 13 and 40; GBD 2017 Diet Collaborators, "Health Effects of Dietary Risks in 195 Countries, 1990–2017: A Systematic Analysis for the Global Burden of Disease Study 2017" (2019) vol 393 Lancet pp 1958.

[2] GBD 2017 Diet Collaborators (n 1) at pp 1967–8; IPES-Food (n 1) at p 1; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system COM/2020/381 final (European Commission, 2020).

improve food quality and diet-related health at the production level.[3] Notably, health-related characteristics of food remain largely unaddressed by EU food governance.[4]

At the heart of EU food governance lies a comprehensive legal framework that aims to foster healthier food systems. This includes legislative and non-legislative sources of law and food policies. Among these sources, the General Food Law (GFL)[5] is a main legislative instrument that stands as the overarching framework for EU food law. It introduces the risk analysis principle to assess food safety risks and inform management (decision-making) of these risks.[6] While the GFL aims for risk analysis to be scientific in a food safety sense, it also includes other non-safety (external) factors in decision-making.[7] The effects of this mixed input of scientific (food safety) and external factors on food quality are disputed.

In previous research on risk analysis, Szajkowska studied the EU's consideration of external factors in food safety decision-making.[8] The study found that the EU considers a wide range of external factors, including consumer preferences and economic concerns, when setting food safety standards. This can lead to standards that are looser or stricter than what safety-oriented science alone would recommend. It also found that the role of socio-economic assumptions in food safety measures is not always clear and is often hidden behind scientific language or uncertainty.[9] To improve risk governance, Szajkowska recommended a clear formulation of how scientific and external factors interact in policy-making.[10] Ely and Sterling also explored the socio-economic dimension of external factors affecting risk assessment.[11] They found that the inclusion of socio-economic factors must be proportional to the severity of the risk, meaning that lower food risks call for less detailed assessments of socio-economic factors, and vice-versa.[12] They considered that the overall process is subject to political oversight.[13] By comparison, Dreyer and Renn considered different types of participation in framing, assessment, evaluation and management of risk, with focus on external socio-political factors.[14] They recommended that public participation be made a permanent part of governance, with open access for the public and input from key stakeholders at the framing and evaluation stages.[15] De Boer examined the use of risk assessment in EU food law, specifically how

[3] Sonia S Anand and others, "Food Consumption and Its Impact on Cardiovascular Disease: Importance of Solutions Focused on the Globalized Food System" (2015) 66 Journal of the American College of Cardiology 1590; Garrett Brown, Gavin Yamey and Sarah Wamala, *The Handbook of Global Health Policy* (Wiley–Blackwell 2014); GBD 2017 Diet Collaborators (n 1) at pp 1967–8; David Wallinga, "Today's Food System: How Healthy Is It?" (2009) 4 Journal of Hunger & Environmental Nutrition 251.

[4] IPES-Food (n 1) at p 9.

[5] 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–GFL).

[6] Art 6 GFL.

[7] ibid.

[8] Anna Szajkowska, "Food Safety Governance from a European Perspective: Risk Assessment and Non-Scientific Factors" in Otto Hospes and Irene Hadiprayitno (eds), *EU multi-level regulation, in Governing food security: Law, politics and the right to food* (Wageningen Academic Publishers 2010) at p 226.

[9] ibid.

[10] ibid.

[11] Adrian Ely and Andrew Sterling, "The Process of Assessment" in Marion Dreyer and Ortwin Renn (eds), *Food Safety Governance: Integrating Science, Precaution and Public Involvement* (Springer-Verlag Berlin Heidelberg 2009).

[12] ibid at p 68.

[13] ibid.

[14] Marion Dreyer and Ortwin 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).

[15] ibid at p 120.

transparency and independence issues affect the outcome of these assessments.[16] To address these concerns, De Boer recommended to anchor the role of nutritional sciences in current EU food legislation through systematic approaches to risk assessment.[17]

This prior research on risk analysis in EU food governance has addressed transparency issues, isolated external economic and political factors and associated each one of them with the societal factor,[18] and focused on the risk assessment step of risk analysis.[19] Additionally, legislative initiatives have addressed transparency challenges in risk assessment and risk communication.[20] However, risk assessment still exhibits weaknesses, and a legislative gap in risk management persists, failing to address critical transparency and independence (from risk assessment) concerns. Addressing these shortcomings is essential.

Therefore, this paper does not delve into risk communication, but rather prioritisses the challenges in risk assessment and risk management. This decision stems from the acknowledgement that risk analysis is an interactive process, where constant interaction between risk assessors and risk managers is vital to the success and acceptance of the entire scientific assessment process, especially when scientific facts are believed to be frequently ignored.[21] We therefore focus on strengthening the risk assessment and risk management infrastructure.

A comprehensive review exploring legislative sources of law relating to risk analysis, particularly risk assessment and risk management, is needed. Additionally, the combined effects of economic and political factors on risk analysis outcomes, particularly in the risk assessment and risk management steps, remain unexplored in the literature.

To tackle these gaps in legislative developments and in the literature, the paper reviews the risk analysis process with a focus on risk assessment and risk management. It examines the influence of safety-oriented scientific factors and other external factors on legislative and policy developments, and how they can impact food governance and lead to healthier food systems. Part II presents a theoretical background of food governance and how it is affected by two factors: the science-policy interface and regulatory capture. Part III explores the EU risk analysis process used to integrate scientific evidence and external factors in risk management leasing to legislative and policy developments. It focuses on the legislative framework in which this happens, and specifically identifies challenges in risk assessment and risk management. Part IV discusses the findings, including recommendations to tackle identified shortcomings of risk analysis.

II. Food governance at the nexus of science, policy and regulatory capture

1. What is food governance?

Food governance and food systems are emerging topics, with many attempts to define them in literature.[22] Kooiman et al. describe food governance as processes and practices

[16] Alie de Boer, "Scientific Assessments in European Food Law: Making It Future-Proof" (2019) 108 Regulatory Toxicology and Pharmacology 104437.

[17] ibid.

[18] Szajkowska (n 8); Ely and Sterling (n 11); Dreyer and Renn (n 14).

[19] Szajkowska (n 8); de Boer (n 16).

[20] 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.

[21] Yann Devos and others, "Conducting Fit-for-Purpose Food Safety Risk Assessments" [2019] EFSA Journal.

[22] Otto Hospes and Anke Brons, "Food System Governance: A Systematic Literature Review" in Amanda Kennedy and Jonathan Liljeblad (eds), *Food Systems Governance* (2016); Aogán Delaney and others, "Governance of Food Systems across Scales in Times of Social-Ecological Change: A Review of Indicators" (2018) 10 Food Security;

adopted to solve societal problems and create opportunities by bringing together civil, public and private actors.[23] Van Bers et al. define it as a system of rules, organisations and people that influence how food is produced, distributed and consumed.[24] Liverman and Kapadia consider that governance goes beyond governmental functions, to include the role of markets, traditions and networks, and non-state actors such as firms and civil society.[25] Similarly, Dreyer and Renn consider that governance englobes a wide range of stakeholders, including political decision-makers, scientists, economic actors and civil society representatives.[26]

A common point to all definitions is that food governance links together the many actors found in food systems to provide food that is adequate to current societal and environmental changes.[27] However, there still is no common vision to tackle this objective. While authors and health authorities agree that current food systems are not healthy,[28] there is no consensus as to the root causes and solutions to this problem.[29] As a result, the debate remains at the stage of selecting the right approach to transform food systems.[30] Recent literature indicates a shift towards integrated approaches, with a focus on the interactions between food production, processing and consumption.[31]

In the 2001 While Paper on European Governance, the European Commission describes five principles of good governance: openness, participation, accountability, effectiveness and coherence.[32] These principles are essential for establishing more democratic governance and reinforcing the principle of proportionality. This means that policymakers should choose the appropriate level of governance and instruments to achieve their objectives, and carefully consider whether public action is necessary and whether the measures chosen are proportionate to the objectives.[33]

Both literature and Union approaches to governance share a common pillar: complex decision-making processes that aim to address and solve problems.[34] One of these processes is science-based policymaking. It plays an important role in decision-making by

Caroline van Bers and others, "Advancing the Research Agenda on Food Systems Governance and Transformation" [2019] Current Opinion in Environmental Sustainability; HLPE, "Nutrition and Food Systems: A Report by the High Level Panel of Experts on Food Security and Nutrition" (2017) Report #12.

[23] Jan Kooiman and others, "Interactive Governance and Governability: An Introduction" (2008) 7 The Journal of Transdisciplinary Environmental Studies 2, at p 2.

[24] Caroline van Bers and others, "Transformation in Governance towards Resilient Food Systems" (2016) Working Paper at p 10.

[25] Diana Liverman and Kamal Kapadia, "Food Systems and the Global Environment: An Overview" in John Ingram, Polly Ericksen and Diana Liverman (eds), *Food Security and Global Environmental Change* (Earthscan 2010) at p 20.

[26] Dreyer and Renn (n 14) at p 112.

[27] Kelly Parsons and Corinna Hawkes, "Connecting Food Systems for Co-Benefits: How Can Food Systems Combine Diet-Related Health with Environmental and Economic Policy Goals?" (2018) Policy Brief 31 at p 11; Rafaele Vignola, Peter Oosterveer and Chris Béné, "Conceptualising Food System Governance and Its Present Challenges" [2021] Wageningen University at pp 6-7.

[28] IPES-Food (n 1).

[29] Christophe Béné and others, "When Food Systems Meet Sustainability – Current Narratives and Implications for Actions"(2019) 113 World Development 116.

[30] Vignola, Oosterveer and Béné (n 27) at p 7.

[31] ibid at pp 5 and 19; Melissa Leach and others, "Food Politics and Development" (2020) 134 World Development 105024; Ruerd Ruben, Jan Verhagen and Christine Plaisier, "The Challenge of Food Systems Research: What Difference Does It Make?" (2019) 11 Sustainability 171; Christophe Béné and others, "Understanding Food Systems Drivers: A Critical Review of the Literature" (2019) 23 Global Food Security.

[32] European Commission, "COM(2001) 428 - European Governance; A White Paper" at p 8.

[33] ibid at p 9.

[34] Béné and others (n 29); Rutger Schilpzand and others, "Governance Beyond the State: Non-State Actors and Food Systems" in John Ingram, Polly Ericksen and Diana Liverman (eds), *Food Security and Global Environmental Change* (Earthscan 2010).

using scientific evidence and involving multiple actors and stakeholders (policymakers, scientists, industry and the public) to inform public policy decisions.

2. Two models of science-based policymaking

Millstone describes two main models of science-based policymaking: the technocratic and decisionist models. In the *technocratic* model, objective science is the only direct informant to policymaking when addressing risk.[35] In the *decisionist* model, external factors are assigned a role in informing decision-making, as scientific representations of risk are never free of external influences (societal, economic, political, etc.).[36] The current risk analysis process developed in the GFL is based on the decisionist model.[37]

The inclusion of external factors in the decisionist model is seen as liberating from flaws in the technocratic model, namely that scientific representation of risk is often based on assumptions and uncertainties.[38] However, the decisionist model is criticised for designating decision-makers as spokespersons for the scientific community's work, when they do not always prioritise scientific evidence in their decisions.[39] Moreover, decision-makers are accused of appealing to "sound science" as the justification for their decisions and as an escape from accountability.[40] They do not directly manipulate scientific facts but rather refer to external factors that force unaccounted-for leniency in the decision-making process and enhance certain aspects of risk assessment while hiding others.[41]

Millstone argues that the separation of science and politics in the decisionist model hides flaws in the governance system, leading to inconsistencies in both the application of the model and among different policies.[42] Nevertheless, the decisionist model still plays a major role in the current food governance structure through the science-policy interface (SPI).

3. The science-policy interface (SPI) at the core of food governance

The SPI is a platform that facilitates interactions and mediation between science and policy to support well-informed decision-making in food governance.[43] It assigns a major role to scientific evidence in food governance generally, and risk analysis specifically, by integrating independent scientific interactions into decision-making processes.[44]

However, the SPI is highly impacted by external factors that make it difficult to navigate for both policy-makers and scientists.[45] Two main difficulties arise: first, decision-

[35] Erik Millstone, "Science, Risk and Governance: Radical Rhetorics and the Realities of Reform in Food Safety Governance" (2009) 38 Research Policy 624, at pp 624-5.

[36] ibid at p 626.

[37] ibid at pp 625–6; National Research Council of the National Academies, *Science and Decisions: Advancing Risk Assessment* (National Academies Press (US) 2009) at p 15.

[38] Sheila S Jasanoff, "Contested Boundaries in Policy-Relevant Science" (1987) 17 Social Studies of Science 195; Erik Millstone, Erik Brunner and Sue Mayer, "Beyond 'substantial Equivalence'" (1999) 401 Nature 525.

[39] Millstone (n 35) at p 626.

[40] Patrick Van Zwanenberg and Erik Millstone, "BSE: Risk, Science and Governance" (2005) 58 Journal of Antimicrobial Chemotherapy 303.

[41] Millstone (n 35) at p 626.

[42] ibid at p 634.

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

[44] Brajesh K Singh and others, "Enhancing Science–Policy Interfaces for Food Systems Transformation" (2021) 2 Nature Food 838, at p 2; 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).

[45] OECD, "Scientific Advice for Policy Making: The Role and Responsibility of Expert Bodies and Individual Scientists," vol 21 (2015) 21 at p 11.

makers have to consider and balance the interests of many stakeholders, such as scientists, industry, NGOs and consumers.[46] Second, scientific knowledge is often associated with uncertainties that make its communication and translation into policy much more difficult.[47]

Addressing these challenges is necessary considering the broad role played by scientific knowledge in food governance, including risk analysis, innovation, technical competences, competitive strategies and learning.[48] The significant weight of science, the influence of external factors, and the importance of balancing the interests and responsibilities of all stakeholders make this a complex task. Regulatory capture further complicates this task.

4. Regulatory capture and its effects on food governance

Regulatory capture is the practice of industries influencing the governance system to favour their own interests over public interest.[49] The traditional view of regulatory capture is that the public sector responds to political pressure from industry lobbying.[50]

However, new ways of capture have emerged, such as controlling the science and ethics that fuel public policy,[51] and avoiding criticism of unhealthy production by partnering with health actors.[52] Some argue that these new techniques give the industry power within and through the regulatory system, rather than just over it.[53] This suggests that economic and political actors are main drivers of decision-making, rather than being only external factors. Others believe that these accusations are too harsh and that some producers are genuinely switching to healthier alternatives.[54] Despite well-developed economic theories on capture, industry involvement in the decision-making process remains poorly substantiated.[55]

Our brief review of the food governance structure shows that it is a complex and interconnected system that is influenced by science, policy and regulatory capture. The decisionist model, which is under the SPI umbrella, sets the framework for translating scientific evidence and external factors into law. This framework is essential for addressing the current and future nutrition challenges of food systems, especially with regard to nutrition-related risks.[56]

In this framework, a science-based risk analysis method is a key tool for informing food governance decisions. The method allows policymakers to develop food policies that

[46] ibid.

[47] ibid.

[48] Dreyer and Renn (n 14) at pp 11–2.

[49] Jean-Jacques Laffont and Jean Tirole, *A Theory of Incentives in Procurement and Regulation* (The MIT Press 1993); Andrea Saltelli and others, "Science, the Endless Frontier of Regulatory Capture" (2022) 135 Futures 102860.

[50] Saltelli and others (n 49) at p 9; George J Stigler, "The Theory of Economic Regulation" (1971) 2 The Bell Journal of Economics and Management Science 3.

[51] Saltelli and others (n 49) at p 9.

[52] Jennifer Lacy-Nichols and Owain Williams, "'Part of the Solution': Food Corporation Strategies for Regulatory Capture and Legitimacy" (2021) 10 International Journal of Health Policy and Management 845.

[53] Raphael Lencucha, "Situating Food Industry Influence: Governance Norms and Economic Order Comment on 'Part of the Solution': Food Corporation Strategies for Regulatory Capture and Legitimacy'" [2022] International Journal of Health Policy and Management <https://www.ijhpm.com/article_4270.html> accessed 18 April 2023.

[54] Luke N Allen, "Trust, but Verify Comment on 'Part of the Solution': Food Corporation Strategies for Regulatory Capture and Legitimacy'" [2022] International Journal of Health Policy and Management.

[55] Lacy-Nichols and Williams (n 52); Ernesto Dal Bó, "Regulatory Capture: A Review" (2006) 22 Oxford Review of Economic Policy 203; Saltelli and others (n 49).

[56] Joachim von Braun and Matthias Kalkuhl, "International Science and Policy Interaction for Improved Food and Nutrition Security: Toward an International Panel on Food and Nutrition (IPFN)" (2015) ZEF Working Paper Series, No. 142, University of Bonn, Center for Development Research (ZEF), Bonn at p 10.

promote public health and protect consumers from nutrition-related risks. However, the interactions between the different steps of risk analysis are complex.

III. Risk analysis in EU food governance: Legislative framework, challenges and adopted solutions

1. Risk analysis as a GFL principle

The GFL is the cornerstone that establishes common definitions, objectives and general principles of the EU food regulatory framework.[57] It clearly expresses a core objective to base its decision-making processes on scientific evidence with the assistance of independent institutions protecting human health.[58]

To do this, the GFL adopts a risk analysis model consisting of three steps: risk assessment, risk management and risk communication.[59] Risk assessment is the scientific evaluation of the safety hazards and risks associated with food.[60] This is done by the European Food Safety Authority (EFSA).[61] Risk management is the process of evaluating and implementing measures to reduce or eliminate food safety risks, taking into account EFSA's scientific Opinions and other factors such as the societal, economic or political implications of different risk management options.[62] This is done by the European Commission and Parliament. Risk communication is the process of sharing information about risk assessment findings and risk management decisions with the public.[63] This is done by the European Commission and EFSA.

The risk analysis model is based on the principle that food law should be science-based.[64] Risk assessment is the core element of this model, as it ensures that human health protection is prioritised through scientific evidence. Health and nutrition components constitute a major part of this scientific approach, as per Article 22 describing EFSA's mission.

Article 6 describes the scientific process that EFSA follows. It puts the preservation of health at the centre of this science-based governance and mentions that food law should always be based on risk analysis, except when inappropriate.[65] Risk assessment should be science-based, independent, objective and transparent.[66] Risk management should be based on risk assessment results and 'other factors legitimate to the matter under consideration,' to achieve the general objectives of food law established in Article 5.[67] This structure ensures that food safety decisions are based on sound scientific evidence and that scientific input (risk assessment) is separated from political decision-making (risk management). In the article, we refer to 'other factors legitimate to the matter under consideration' as external legitimate factors, or external factors.

Article 5 states that food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests.

[57] European Commission, "The General Food Law: Fitness Check" (2018) <https://food.ec.europa.eu/system/files/2018-01/gfl_fitc_infographic_2018_en.pdf> accessed 1 September 2022.
[58] Preambles (9) and (32) GFL.
[59] Art 6 GFL.
[60] Art 3(11) GFL.
[61] Preamble (33) and Art 22 GFL.
[62] Art 3(12) GFL.
[63] Art 3(13) GFL.
[64] European Commission, "The General Food Law: Fitness Check" (n 57) accessed 1 September 2022.
[65] Art 6(1) GFL.
[66] Art 6(2) GFL.
[67] Art 6(3) GFL.

Overall, the risk analysis model is a robust and effective system that ensures the safety of food. However, it presents major shortcomings stemming from transparency and independence issues, and limits to scientific evidence.

2. *Addressing risk assessment and risk management shortcomings: Legislation, EFSA, and recommendations in the literature*

Risk assessment procedures are discussed and evaluated in legislative, academic and civil society capacities.

In a legislative context, the Commission launched in 2012 the REFIT programme to continuously review, improve and simplify EU legislation.[68] The GFL's 2018 REFIT evaluation found that while the GFL has generally achieved its core objective of protecting human health, there are two fundamental shortcomings in the risk assessment process: independence and transparency issues stemming from strong links between risk assessment and risk management.[69] These issues impact the quality of scientific output, the efficient identification of emerging risks, and the acceptability of EFSA's scientific contribution, which compromises the GFL's objective to guarantee a high level of human health protection.[70]

Risk assessment procedures are also criticised in literature on two fronts. First, transparency and independence issues are also flagged.[71] Second, safety and health assessments are perceived as time consuming and inconsistent[72] because they are often faced with inconclusive or lacking scientific evidence.[73] EFSA's efforts to improve risk assessment were aligned with these academic opinions, and it released guidance documents to tackle, incorporate and communicate such uncertainties.[74]

Risk assessment is also brought to public attention in the framework of the Glyphosate case. The 2017 renewal of Glyphosate's EU authorisation (followed by another 2023 draft implementing regulation for authorisation renewal)[75] was controversial due to the different conclusions reached by EFSA and IARC on its carcinogenicity.[76] This raised concerns about the transparency and independence of the risk assessment process and led

[68] European Commission, "REFIT – Making EU Law Simpler, Less Costly and Future Proof" <https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof_en> accessed 13 February 2023.

[69] European Commission, "Commission Staff Working Document: The Refit Evaluation of the General Food Law (Regulation (EC) No 178/2002) (SWD(2018) 38 Final)" at p 78–9.

[70] ibid at p 78.

[71] Aleš Bartl, "REFIT of Food Legislation: An Opportunity to Discuss Implementation and Enforcement Issues" (2015) 10 EFFL 84; Alie de Boer and Aalt Bast, "Stakeholders' Perception of the Nutrition and Health Claim Regulation" (2015) 66 International Journal of Food Sciences and Nutrition 321; Bas J Blaauboer and others, "Considering New Methodologies in Strategies for Safety Assessment of Foods and Food Ingredients" (2016) 91 Food and Chemical Toxicology 19.

[72] de Boer (n 16) at pp 2-3; Blaauboer and others (n 71).

[73] Karin GM Lenssen, Aalt Bast and Alie de Boer, "Clarifying the Health Claim Assessment Procedure of EFSA Will Benefit Functional Food Innovation" (2018) 47 Journal of Functional Foods 386; Hans Verhagen and Henk van Loveren, "Status of Nutrition and Health Claims in Europe by Mid 2015" (2016) 56 Trends in Food Science & Technology 39.

[74] Diane Benford and others, "Guidance on Uncertainty Analysis in Scientific Assessments" (2018) 16 EFSA Journal e05123; Julien Etienne and others, "Final Report: Clear Communications and Uncertainty" (2018) 15 EFSA Supporting Publications 1412E.

[75] European Commission, Draft Commission Implementing regulation for 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.

[76] EFSA, "Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate" (2015) 13 EFSA Journal 4302; IARC, "IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides" (2015).

to calls for reform through the European Citizens' Initiative to ban glyphosate and protect people and the environment from toxic pesticides.[77]

All these factors underlining shortcomings in risk assessment are addressed in legislation by the Transparency Regulation, and in literature by recommendations for systematic methods in risk assessment and recommendations to address shortcomings of risk management.

a. The Transparency Regulation for addressing risk assessment shortcomings: A key legislative instrument

In 2019, the Transparency Regulation[78] amended the GFL and other secondary food regulations. It aimed to increase transparency, independence, accountability and sustainability in EFSA's risk assessment process, to improve decision-making on food safety matters.[79] The Regulation set a preambular goal to underline the separation between risk assessment, risk management and risk communication to increase the independence of the assessment process and limit industry involvement.[80]

Article 1 of the Transparency Regulation addresses this goal by: requiring industry-led studies and information submitted to EFSA to be electronically published and accessible to consumers; making available to the public ongoing consultations about authorisation applications for regulated products; broadening EFSA's authority by requiring it to be informed of all industry-led studies and information, and to commission further verification of evidence used in its risk assessment process, based on the Commission's requests; requiring Commission experts to perform fact-finding missions to verify compliance with testing and research standards in both Member States and third countries; and altering EFSA's governance structure by adding representatives of all Member States to its Management Board and aiming to increase Member States participation in drafting EFSA Opinions.

The Transparency Regulation's amendments to the GFL promote EFSA transparency and independence by making all information publicly accessible and separating risk assessment from risk management. The literature also addresses these issues, specifically through recommendations for systematic risk assessment methods.

b. Systematic Methods for Addressing Risk Assessment Shortcomings: Recommendations from the Literature

EFSA faces a challenging task in risk assessment, due to the large and complex amounts of scientific data involved.[81] While it developed a standardised system of tools and resources to ensure fast processing and consistent results, its methodology is criticised for exacerbating transparency and independence issues.[82] This is because EFSA only conveys

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

[78] 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.

[79] Preambles (4), (12) and (18), and Art 8a GFL.

[80] Preambles (8), (12), and (24) GFL.

[81] EFSA, "Assessment Tools and Resources" <https://www.efsa.europa.eu/en/science/tools-and-resources#> accessed 12 February 2023.

[82] EFSA, "Methodology" <https://www.efsa.europa.eu/en/topics/topic/methodology> accessed 12 February 2023; Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009, OJ L 132/5.

findings that have "the weight of evidence," while mostly disregarding minority findings.[83] This is particularly concerning when it comes to the assessment of foods' health benefits and safety hazards, which are often controversially accompanied by biased and unqualified industry input.[84]

To contribute to better transparency in risk assessment, the systematic method is proposed. The method represents an exhaustive summary of all available scientific evidence, including minority findings, and processes them according to a pre-determined strategy.[85] Through this rigorous approach to assessment, scientists can better link their results to existing scientific evidence and established scientific principles.[86] However, a major disadvantage is that systematic reviews are lengthy and time consuming.[87]

EFSA research indicates a consensus that systematic reviews would present great benefits regarding transparency and support to decision-making, specifically in matters of public health.[88] EFSA has developed a comprehensive and standardised model for conducting systematic reviews to reduce the risk of excluding potentially relevant data from food safety assessments.[89] However, these methodologies are specifically relative to food and feed safety, namely for the assessment of risks and hazards of chemical, biological and physical nature, and exclude nutrition and health issues in food governance.[90]

Risk analysis does not only present transparency and independence issues at the risk assessment stage. These issues also affect risk management.

c. Risk management shortcomings and recommendations in the literature to address them

Risk management relative to food governance presents several shortcomings. These include transparency issues causing barriers to public input, absence of portals where information is shared, decision-makers relying on information that is not publicly available, experts with questionable legibility, the occasional exclusion of scientific risk assessment in decision-making, and limited obligation to justify decisions.[91] This results in lack of consistency in performance and quality of decisions.[92] Also, risk management is criticised for being focused on tackling risks deriving from the consumption of select substances, rather than the general health impacts of such productions, which inhibits the ability to protect human health.[93] Finally, approval processes are too slow, causing scientific evidence to lose its momentum and decisions to be based on outdated science.[94]

[83] Vittorio Silano, "Science, Risk Assessment and Decision- Making to Ensure Food and Feed Safety in the European Union" (2009) 4 EFFL 400, at p 403; Henri 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 Academic Publishers 2010) at p 172.

[84] de Boer (n 16) at p 5.

[85] Mark Petticrew and Helen Roberts, *Systematic Reviews in the Social Sciences: A Practical Guide* (Blackwell Publishing 2006) at p 90.

[86] ibid at pp 3–4.

[87] de Boer (n 16) at p 5.

[88] AM O'Connor and others, "Implementation of Systematic Reviews in EFSA Scientific Outputs Workflow" (2012) 9 EFSA Supporting Publications 367E, at p 9.

[89] European Food Safety Authority (EFSA), "Application of Systematic Review Methodology to Food and Feed Safety Assessments to Support Decision Making - EFSA Guidance for Those Carrying out Systematic Reviews" (2010) 8 1637, at p 55.

[90] European Food Safety Authority (EFSA) (n 89).

[91] European Risk Forum, 'Risk Management and the EU's Administrative State: Implementing Law through Science, Regulation and Guidance' (2019) at p 7.

[92] ibid at p 6.

[93] European Risk Forum (n 91).

[94] de Boer (n 16); MH Zwietering, "Risk Assessment and Risk Management for Safe Foods: Assessment Needs Inclusion of Variability and Uncertainty, Management Needs Discrete Decisions" (2015) 213 International Journal of Food Microbiology 118.

There are efforts to pinpoint shortcomings of the risk management process and tackle them in a general Union framework.[95] However, these efforts do not specifically address food governance or the translation of assessed risks into management decisions, and have so far been minimal.[96] Additionally, lack of institutional responsibility aiming to identify and resolve these issues leads to poor management decisions, especially in the absence of systematic mechanisms to do so[97] and external factors that might sometimes be too powerful.

3. External factors influencing risk management: Mechanisms and implications

In the risk analysis process, science only influences the risk assessment step. The subsequent risk management step can consider other external legitimate factors in its decision-making process. We review the legislative provisions that allow such impacts with a focus on external political and economic factors.

a. Incorporating external factors into the legislative framework of risk analysis

The GFL is the umbrella regulation that introduces external factors in risk analysis. It gives the Commission the discretion to consider risk assessment results and external legitimate factors when making risk management decisions.[98]

However, the legislative inclusion of external factors cannot be studied in isolation and must be considered in the context of what evidence is legally-binding or not. On the one hand, scientific factors are in the form of EFSA Opinions that play a central role in the risk assessment process[99] but are not legally binding.[100] On the other hand, there are legal provisions that justify and allow including external factors in the decision-making process.[101] This creates tension between the need to protect human health through non-legally binding scientific evidence, and the protection of other interests, such as societal, economic or political ones. These are addressed in the GFL and in secondary legislation.

Article 5 GFL refers to one major objective of food law: the protection of human health. However, the Article also introduces economic objectives for fair trade and free movement.[102] These objectives automatically implicate several stakeholders and factors in risk management decisions, as enacted by Article 6. This structure impacts the application of risk assessment Opinions in risk management.

Secondary legislation that addresses EFSA's role in the risk analysis process also mentions objectives other than the health objective in the framework of each regulation. They consider that scientific risk assessment cannot always provide all the required information for a risk management decision.[103] They also indicate that decisions should be

[95] European Risk Forum (n 91).

[96] Sevasti Chatzopoulou, Nélida Leiva Eriksson and Dennis Eriksson, "Improving Risk Assessment in the European Food Safety Authority: Lessons from the European Medicines Agency" (2020) 11 Frontiers in Plant Science.

[97] European Risk Forum (n 91) at p 6 and 8.

[98] Art 6(3) GFL.

[99] Art 6(2)(3) GFL.

[100] Alberto Alemanno and Stephanie Mahieu, "The European Food Safety Authority Before European Courts" (2008) 5 European Food and Feed Law Review 320, at p 325.

[101] Art 6(3) GFL.

[102] Arts 5(1) and (2) GFL.

[103] Preamble (29) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404/9 (Nutrition and Health Claims Regulation–NHCR) (European Union); Preamble (14) Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ 2008 L354/1; Art 12(1) Regulation (EU) 2015/2283 of the European Parliament and of the Council of

based on both EFSA Opinions and other legitimate factors relevant to the matter under consideration,[104] such as societal, economic, traditional, ethical and environmental ones.[105] In the case where the decision in question is not in accordance with EFSA's Opinion, an explanation for this misalignment must be provided by the Commission.[106]

GFL and secondary legislation provisions highlight two main rules of risk analysis in food law. First, science is at the core of the risk management process.[107] Second, it is not the only factor, and external legitimate factors also play a role in risk management.[108] However, there remains a controversy as to how and to what extent external factors can interfere in decision-making.[109] We specifically address political and economic factors in risk management's decision-making process.

b. Political and economic factors: External influences on risk analysis

EFSA's Scientific Opinions have priority in informing risk management decisions, but can be complemented by societal, economic, traditional, ethical, environmental, or other factors when necessary. While such external factors play a role in balancing the interests of the food sector's many stakeholders, these stakeholders often have different interests than consumer health interests.[110] We focus on political and economic factors because they are interlinked and represent the most powerful alliance of all external factors,[111] and because a review of these two factors combined in a risk analysis context remains outstanding in the literature.

Political and economic actors have an objective to eliminate barriers to the free movement of food and protect consumers' interests.[112] However, the involvement of these two factors is highly controversial, as they come with major benefits and shortcomings. On the one hand, they play a major role in risk analysis by helping avoid scientific coercion (scientific evidence being the only informant of food law), hyper-awareness of identified risk, and diminished democratic and political participation of citizens.[113] On the other hand, they are criticised for dominating the food system, competing with other less powerful actors that aim to improve the nutritional quality of foods, and setting objectives

25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327/1 - NFR; Art 7(1) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ 2003 L 268/1 (GMOR Regulation).

[104] Art 17(1) NHC; Art 3(4), Regulation (EC) No 1331/2008.

[105] Preamble (14), Regulation (EC) No 1331/2008; Preamble (7) 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); Preamble (6) 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).

[106] Art 17(1) NHC; Arts 7(1) and 19(1) GMO Regulation.

[107] Art 6(2)(3) GFL.

[108] ibid. (n 103-107).

[109] Szajkowska (n 8) at p 202.

[110] Per Pinstrup-Andersen, "Nutrition-Sensitive Food Systems: From Rhetoric to Action" (2013) 382 The Lancet 375, at p 375; Per Pinstrup-Andersen and Derrill Watson, *Food Policy for Developing Countries: The Role of Government in Global, National, and Local Food Systems* (Cornell University Press 2011).

[111] Stuart Gillespie and others, "The Politics of Reducing Malnutrition: Building Commitment and Accelerating Progress" (2013) 382 Lancet 552; Bernd van der Meulen, "Science Based Food Law" (2009) 4 EFFL 58, at p 59.

[112] Art 34 TFEU and Art 5 GFL.

[113] Rolf Lidskog, "Scientised Citizens and Democratised Science. Re-Assessing the Expert-Lay Divide" (2008) 11 Journal of Risk Research 69.

that mainly benefit industry stakeholders, especially since political stakeholders are accused of being financially aligned with industry stakeholders.[114]

Shortcomings of political and economic participation in risk management have two major consequences. They contribute to "negotiable elements," and set a "reasonable level of risk" standard in risk analysis.

i. 'Negotiable elements' and recommendations to address them through research. Goverde finds that decision-making in nutritional sciences is affected by "negotiable elements," such as economic and political interests.[115] These are impactful when pressing research projects are halted by inconclusive scientific evidence, leading to negotiations between scientists to agree on a majority opinion.[116] A scientist's opinion must be centred around scientific data, but the legislative recognition and inclusion of external legitimate factors open several doors for the involvement of these external negotiable elements in the decision-making process.

To address negotiable elements, the International Panel of Experts on Sustainable Food Systems (IPES-Food) highlights the importance of government-funded scientific research in understanding and interpreting the health impacts of food systems.[117] However, governments are retracting their support for research,[118] while private industry interests have become more active in the field.[119] This privatisation of research interests presents one main disadvantage: the industry selects research projects to fund[120] and results to share[121] based on possibilities for profit, thus sometimes ignoring issues of high public interest and raising ethical, transparency, independence and accountability issues.[122] This high level of industry involvement suggests that economic and political stakeholders play a larger role than the one described in EU legislation as "other factors legitimate to the matter." The Transparency Regulation does not address these issues since it aims to verify compliance with research standards[123] but has no control over the choice of research topics and how their results are shared and discussed in the literature.

The other main consequence of political and economic participation in risk management is that they result in a "reasonable level of risk" standard in risk analysis.

ii. The "reasonable level of risk" standard and recommendations to address it through a "nutrition sensitive approach". Pinstrup-Andersen believes that the association between political and industry stakeholders leads to a decision-making approach that prioritises financial gain by accepting a "reasonable level of risk."[124] This expression appears to set a minimum standard for the nutritional quality of food and does not seem to address risks associated with long-term consumption of unhealthy diets and deriving non-communicable diseases

[114] Gillespie and others (n 111); Pinstrup-Andersen (n 110); Pinstrup-Andersen and Watson (n 110).

[115] Goverde (n 83) at p 174.

[116] ibid.

[117] IPES-Food (n 1) at p 58.

[118] Dana Dalrymple, 'International Agricultural Research as a Global Public Good: Concepts, the CGIAR Experience and Policy Issues' (2008) 20 Journal of International Development 347; Alessandro Muscio, Davide Quaglione and Giovanna Vallanti, 'Does Government Funding Complement or Substitute Private Research Funding to Universities?' (2013) 42 Research Policy 63.

[119] IPES-Food (n 1) at p 58.

[120] J Piesse and C Thirtle, 'Agricultural R&D, Technology and Productivity' (2010) 365 Philosophical Transactions of the Royal Society B: Biological Sciences 3035.

[121] Gary Sacks and others, 'The Characteristics and Extent of Food Industry Involvement in Peer-Reviewed Research Articles from 10 Leading Nutrition-Related Journals in 2018' (2020) 15 PLOS ONE e0243144; Lenard I Lesser and others, 'Relationship between Funding Source and Conclusion among Nutrition-Related Scientific Articles' (2007) 4 PLOS Medicine e5.

[122] IPES-Food (n 1) at p 58.

[123] Art 61(a) GFL, as amended by Art 1, Transparency Regulation.

[124] Pinstrup-Andersen (n 110) at p 375.

(NCDs).[125] In fact, the relationship between diet and health is often overlooked, with the focus being limited to acute safety risks.[126]

To address unhealthy diets and increased NCD risks, Pinstrup-Andersen recommends aligning nutrition and economic objectives, as such an association would compel political stakeholders to assign a larger role to nutrition in food systems.[127] He describes this as a cost-effective, sustainable and preventive "nutrition-sensitive" approach to food systems.[128] This approach aims to change industry behaviour and invest in a healthier food output instead of the current medical therapy trends[129] used to cure the long-term effects of unhealthy diets.

There is criticism about political and economic factors overshadowing other concerns in food production, namely shaping nutrition research, guidelines and standards based on the industry's own interests. Despite this criticism, the industry has successfully produced safe, convenient and tasty foods at a low cost. However, and although such food quality factors are certainly desirable, they should not overshadow the need to address the negative impacts of food production on health. This is today's challenge, and it necessitates a multifactorial and synergistic approach to food production that tackles the complexities of current food systems.[130] We adopt this perspective in our discussion.

IV. Discussion and recommendations

We reviewed the risk analysis process to examine the influence of scientific and external legitimate factors on legislation and policy developments, and how they can impact food governance and lead to healthier food systems. Our findings show that although legislative texts aim for risk assessment to be the main informant of risk management, external factors also play a role in decision-making.

External factors, specifically economic and political ones, play an important role in risk management by bringing non-scientific issues to attention, such as costs, benefits and public acceptability of risks and decisions, and mitigating the impact of a purely scientific approach. However, these factors can also overshadow nutrition and health concerns, as economic and political actors are accused of often being too powerful[131] and using their influence to achieve their own financial objectives.[132]

As a result, economic and political factors play – or at least have the potential to play – a larger role in risk management than is suggested in legislation. This stems from legislative principles that provide a window of opportunity for such inclusions and do not delimit a clear framework for health inside of which risk analysis happens, which we address in Part 1. It also stems from independence and transparency challenges in the risk analysis process, and an imbalance of power in favour of certain stakeholders, which we address in Part 2.

[125] Jill McCluskey and Johan Swinnen, 'The Media and Food-Risk Perceptions' (2011) 12 EMBO Reports 624.

[126] ibid.

[127] Pinstrup-Andersen (n 110) at p 375; Gillespie and others (n 111).

[128] Pinstrup-Andersen (n 110) at p 376.

[129] see "Too Much Medicine" (*BMJ*) <https://www.bmj.com/too-much-medicine> accessed 21 July 2023; Sarah Downer and others, "Food Is Medicine Research Action Plan" (2022); Michele Checchini and others, "Tackling of Unhealthy Diets, Physical Inactivity, and Obesity: Health Effects and Cost-Effectiveness" (2010) 376 Lancet 1775.

[130] Dariush Mozaffarian and others, "Role of Government Policy in Nutrition—Barriers to and Opportunities for Healthier Eating" (2018) 361 The BMJ; Dariush Mozaffarian, Irwin Rosenberg and Ricardo Uauy, "History of Modern Nutrition Science—Implications for Current Research, Dietary Guidelines, and Food Policy" (2018) 361 BMJ.

[131] Gillespie and others (n 111).

[132] IPES-Food (n 1) at p 58.

1. Including a "health" perspective in the risk analysis principle

a. How do the GFL and future legislative developments present risk analysis in a health framework?

The GFL assigns the protection of human health to the risk analysis process (Article 6). In this process, safety-oriented scientific evidence is the basis of risk assessment, and risk assessment is the basis of risk management. However, this is not a straightforward flow, as the last provision of Article 6 adds "other factors legitimate to the matter" to be considered in risk management's decision-making.

Article 5 is the basis of Article 6, stating that food law should achieve one or more of the objectives of health protection and consumers' interests, including fair practices in food trade and the free movement of food products. This ambiguous provision suggests that only the protection of either health or consumer interests is required and is enough. At best, it suggests that economic interests (consumer interests, fair trade practices and free movement of food products) are also a priority that can only be held back by health concerns. This raises the question of where health stands in the risk analysis equation. Is it the basis, or a by-product to be maintained? What aspects of health does the law want to protect? And does the current risk analysis process address these health concerns?

This brief analysis of Articles 5 and 6 indicates that while the protection of health is a major objective of risk analysis, it is not the only one. This might subject it to trade-offs, especially when scientific Opinions, which address the protection of health, and external legitimate factors, which address the protection of other interests, both play a role in the decision-making process.

While the GFL is the main legislative instrument that addresses dietary health, the sustainability dialogue also tackles the concept of health and aims to strengthen its legislative presence in a sustainability framework. For instance, and although it is still at a very embryonic stage and its proposal has been further delayed,[133] the EU framework for sustainability in food systems (FSFS) is a new comprehensive initiative that will address sustainability in EU food law.[134] One of the FSFS's major legislative contributions is that it proposes to introduce a food system law with an intent to align existing food law with new sustainability principles and objectives.[135] Specifically, the FSFS is expected to include a new social dimension of sustainability defined as all aspects that pertain to healthy diets[136] and the right of access to such diets.[137]

The newly FSFS will institute two key advancements that address the health aspect of food: a principle of transparency and a sustainability assessment process.[138] While these advancements would constitute significant contributions to the health framework, they would also raise questions about the relationship between the FSFS and the GFL. Specifically, the dynamics between the FSFS's transparency principle and the GFL's transparency (stemming from the Transparency Regulation as an amending regulation to the GFL), as well as the dynamics between the FSFS's sustainability assessment concept and the GFL's risk assessment process, would merit further investigation.

[133] European Public Health Alliance, 'Joint Call to the Commission to Not Backtrack on the Work on Food Systems' (26 October 2023) <https://epha.org/joint-call-to-the-commission-to-not-backtrack-on-the-work-on-food-systems/> accessed 13 December 2023.

[134] European Commission, 'Sustainable EU Food System – New Initiative' (2021) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13174-Sustainable-EU-food-system-new-initiative_en> accessed 13 September 2023.

[135] Health and Food Safety Directorate General, 'Ad-Hoc Meeting of the Advisory Group on Sustainability of Food Systems on a Legislative Framework for a Union Sustainable Food System (FSFS)'.

[136] European Commission, 'Legislative Framework for a Union Sustainable Food System - Advisory Group Meeting'.

[137] Health and Food Safety Directorate General (n 135).

[138] ibid.

It is important to determine whether the FSFS's principles and processes would align with the GFL's, how they would impact each other, which one would be dominant, and how this would affect risk analysis, particularly with regard to the roles of EFSA Opinions and external factors in risk management. While the impacts of the FSFS is a question for future research, we must first address the current GFL approach to external factors in risk management.

b. How does the GFL address external factors in risk management?

The GFL does not address how and to what extent external factors can interfere in risk management. This leads to some controversy, as external factors could potentially have more impact power than scientific Opinions. For example, political factors could influence risk management decisions when a government is under pressure from industry groups to approve a particular substance or technology, even if there is scientific evidence of a risk. An example of economic factors influencing risk management is when a government is concerned about the economic impact of banning a particular substance or technology, such as job losses or disruptions to supply chains.

The consideration of external factors in risk management decision-making is not necessarily a bad thing. In some cases, it may be necessary to weigh the scientific evidence against other factors, such as the economic impact of a decision. However, it is important to be systematic and transparent about how these external factors are considered and to ensure that they do not outweigh the scientific evidence.

To underline the importance of transparency, specifically when external factors are involved, we go back to the glyphosate case. The upcoming 2023 renewal of the 2017 authorisation of glyphosate has stirred some additional civil society concerns[139] in light of another EFSA conclusion in favour of the renewal.[140] The concerns are countered by EFSA[141] and the Commission's draft implementing regulation for the renewal.[142] In this ongoing debate, two main issues arise. First, we have already flagged IARC's conflicting carcinogenicity conclusions on glyphosate.[143] Second, the Commission's webpage documenting stakeholder activities relating to the renewal of glyphosate mentions that the Commission is "legally obliged to take account of the conclusion adopted by EFSA."[144] However, the document fails to mention that the Commission is not legally bound to act upon these conclusions in the direction set by EFSA, as EFSA Opinions are not legally binding. This omission raises major transparency concerns. Why, in this specific case, does the phrasing of the Commission's legal obligations create the misleading impression that it is legally required to implement EFSA Opinions in its decisions? Are there external factors influencing the decision on the renewal? If so, what are these factors, and whose interests

[139] Pesticide Action Network Europe and others, 'Letter to Commissioner Kyriakides on Stopping the Reapproval of Glyphosate Due to Major Deficiencies in Carcinogenicity Assessment' (2023) <https://food.ec.europa.eu/system/files/2023-10/pesticides_renew_glyphosate_cso-to-comm_statement_20230907.pdf> accessed 21 November 2023.

[140] European Food Safety Authority (EFSA) and others, 'Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate' (2023) 21 EFSA Journal e08164.

[141] EFSA and ECHA, 'Reply Letter to Request for a Statement on the Carcinogenicity Assessment of Glyphosate Following Criticism by European Civil Society Organisations' (2023) at p 7 <https://food.ec.europa.eu/system/files/2023-10/pesticides_renew_glyphosate_echa-efsa-statement_20231005-00635.pdf> accessed 21 November 2023.

[142] European Commission Draft Commission Implementing regulation for 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 (n 75).

[143] IARC (n 76).

[144] European Commission, 'Glyphosate' (2023) <https://food.ec.europa.eu/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en> accessed 21 November 2023.

do they protect? Furthermore, how effective is the Transparency Regulation if it does not shed light on the deliberations behind risk management decisions?

It is important to regulate the ways in which external factors impact risk management, especially since its decisions affect not only the way that health is represented in legislation, and by extension, in food systems, but also the credibility of decision-makers. In this next part, we discuss our recommendations to address shortcomings in the risk analysis process, specifically in risk assessment and risk management.

2. Improving risk analysis through directive research and more transparency and independence

Transparency and independence issues in risk analysis were addressed at several levels, including legislative (Transparency Regulation), institutional (EFSA guidance and methodologies) and academic (recommendations for systematic reviews and nutrition-oriented approaches) levels. However, there remain transparency and independence issues relating to the involvement of external factors and their influence on decision-making.

For a fair and proportional participation of scientific and external factors, we address these issues at two levels: directing research to support recommendations for systematic methods in risk assessment, and focusing on transparency and independence in risk management by separating external factors from the risk management process.

a. Directive research to support systematic methods in risk assessment

To address health risks, EFSA processes scientific evidence into Opinions at the risk assessment stage, so that decisions can be made to address this risk. However, these Opinions reflect majority decisions and often disregard minority findings.[145] Including all scientific data in an Opinion is complicated due to diverse evidence, views and uncertainty that make it difficult to communicate clear and concise Opinions that will eventually lead to efficient actions.[146] Also, the risk assessment process aims to unify results, not underline differences, which is why it minimises the effect of variants through a scientific consensus that facilitates final decision-making.[147]

Opinions are further influenced by industry involvement in research.[148] This prevents transparent assessment of health impacts in food systems, and influences risk identification, assessment and management. Specifically, it can include industry-hired researchers critiquing inconvenient evidence to spread doubt and pushing policy actions to focus on changing consumer behaviour rather than tackling diet-related health from a production perspective.[149]

The issue is addressed in De Boer's recommendation to base EFSA's work on systematic methods.[150] Systematic methods used to assess risk involve a broad spectrum of scientific information, including data, evidence and uncertainties. Consequently, a detailed systematic assessment makes it inappropriate to disregard "systematic" results when providing an Opinion, and risk assessment takes on paramount importance and cannot be overlooked.

[145] Silano (n 83) at p 403; Goverde (n 83) at p 172.

[146] OECD (n 45) at pp 11, 20 and 21.

[147] ibid at pp 20–1.

[148] Genna Reed and others, 'The Disinformation Playbook: How Industry Manipulates the Science-policy Process—and How to Restore Scientific Integrity' (2021) 42 Journal of Public Health Policy 622.

[149] IPES-Food (n 1) at p 59.

[150] de Boer (n 16).

There are two main advantages to this approach. First, it would anchor systematic evidence without the need to make it legally binding, as making scientific evidence legally binding would lead to scientific dictatorship arguments where science is the only informant of law. Second, it would preserve the advantages of mitigating a strong scientific presence with external factors at the risk management stage.

We use the example of nitrates and nitrites to illustrate this. While nitrates and nitrites are authorised for cured meats and other perishable products[151] for safety purposes,[152] they may lead to carcinogenic nitrosamines.[153] EFSA recommends continuing to follow the already established acceptable daily intakes (ADIs) it regards as "sufficiently protective," but also recommends additional studies.[154] Controversially, IARC classifies nitrates and nitrites as Group 1 carcinogens.[155] We question the different conclusions and recommendations that EFSA would have drawn if a systematic review of evidence had been used and included minority, but maybe more conclusive, evidence of carcinogenicity, and if such a method might have led to a conclusion more in line with IARC's. Although economic and political actors would theoretically only play a role in risk management, we also question whether they also played a role in risk assessment,[156] for instance, in EFSA's recommendation to limit protective measures to ADIs and additional research, and in who will conduct this research.

Research is the basis of scientific evidence, and by extension regulatory developments. It must be objective, ethical and beneficial to the public good.[157] However, the food industry's involvement in research is often criticised for its unethical practices, specifically in selecting topics and sharing results.[158] To counteract this, a systematic approach to scientific and political discussions can preserve scientific integrity.[159] It offers a major advantage by limiting the actions of specific actors and imposing a holistic vision of food systems. The idea is not to exclude the industry from research, as it brings a valuable perspective, but to diversify the implicated actors, to include not only political, economic, industry and scientific ones, but also consumers and other minor actors.[160]

Recommendation 1: Focusing on research as a main contributor to systematic methodologies of risk assessment. Specifically, the main goal is to promote nutritional research. This is because as evidenced by EFSA guidance on systematic methodologies, the current role of nutritional sciences in food law is far from being systematic.[161] Whether EFSA methods are fit for nutritional assessments, namely, to assess the impacts of the nutrition factor on food quality and health, has yet to be addressed. This starts with research.

[151] Parts D and E, Annex II, 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) (n 105).

[152] EFSA (2017), 'EFSA Explains Risk Assessment: Nitrites and Nitrates Added to Food' at p 1.

[153] ibid at pp 1–3.

[154] ibid.

[155] IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, International Agency for Research on Cancer and World Health Organization (eds), *Ingested Nitrate and Nitrite, and Cyanobacterial Peptide Toxins* (International Agency for Research on Cancer ; Distributed by WHO Press 2010) 43–325.

[156] Julie de Yuka, 'Charcuteries nitrées : comment le lobby de la charcuterie industrielle tente de bâillonner Yuka' (*Yuka*, 30 September 2021) <https://yuka.io/nitrites-lobby-charcuterie/> accessed 24 July 2023; Guillaume Coudray, *Nitrites dans la charcuterie : le scandale: Tout savoir pour mieux choisir ce que nous mettons dans nos assiettes.* (HarperCollins 2023).

[157] David B Resnik and Kevin C Elliott, 'The Ethical Challenges of Socially Responsible Science' (2016) 23 Accountability in research 31.

[158] Piesse and Thirtle (n 120); Sacks and others (n 121); IPES-Food (n 1) at p 58.

[159] IPES-Food (n 1) at p. 80; de Boer (n 16) at p 5.

[160] Ibid. (n 1) at p 81.

[161] European Food Safety Authority (EFSA) (n 89).

First, this can be done through addressing bias and complexity in research through multidisciplinary research combining nutritional and health sciences with EU food law. Given the different speeds at which legislation and scientific research advance, a multidisciplinary approach would facilitate urgent changes in policymaking and legislative developments, as well as raise current food safety and quality standards.[162]

Second, this can also be done through steering research topics to focus on filling gaps identified by food governance, especially in nutritional sciences. This is because scientific knowledge of NCD risks is more advanced than nutritional sciences, requiring objective and transparent research to build a defence against NCDs.[163] The EU's Research and Innovation policy[164] can support this, specifically the Food 2030 initiative, which promotes food systems research and governance.[165]

Apart from directive research, we also address transparency and independence issues by focusing on the risk management structure.

b. Separating external factors from decision-making to promote transparency and independence in risk management

Risk management is perceived as a decision-making culture only understood by those directly involved in it.[166] This contrasts with transparency efforts brought by the Transparency Regulation. Moreover, while the Transparency Regulation generally addresses risk analysis, it does not include transparency in risk management. This suggests uneven results in application, as evidenced by the nitrates and nitrites example.

As a result, while scientific Opinions on food safety are the main informants of risk management's decision-making process, other external legitimate factors that are unbound by transparency provisions also play a role. To address these issues, the objective is to subject these external factors to transparency and independence at subsequent steps in the risk analysis process, namely in risk management.

Recommendation 2: Separate external legitimate factors from risk management through what we refer to as an "external legitimate factors assessment," or an "external factors assessment" (in reference to legislation referring to them as "legitimate factors"). The assessment is conducted by a separate authority to be determined. The authority reviews and presents non-legally binding opinions on factors other than scientific food safety-related evidence, similar to EFSA's scientific reviews. Risk management then considers both EFSA's scientific Opinion and other external legitimate factors opinions at the decision-making level.

The proposed structure presents many advantages. First, it isolates all factors that inform decision-making so that risk management is not impacted by them, but rather processes them, which would enhance transparency and independence in the whole risk analysis process. Second, it specifically allows for the independence and separation of external legitimate factors from risk management, thus enhancing transparency at this step specifically, which was so far unaddressed. Third, the assessment process must be structured to incorporate and allocate inputs for all relevant legitimate factors, including ethical, societal, environmental and administrative considerations, thereby mitigating the current overemphasis on political and economic factors. Most importantly, the approach

[162] de Boer (n 16) at p 5.

[163] Mozaffarian and others (n 130); Mozaffarian, Rosenberg and Uauy (n 130); Dariush Mozaffarian and Nita G Forouhi, 'Dietary Guidelines and Health-Is Nutrition Science up to the Task?' (2018) 360 BMJ k822.

[164] 'Research and Innovation – EU Action | European Union' <https://european-union.europa.eu/priorities-and-actions/actions-topic/research-and-innovation_en> accessed 7 May 2023.

[165] European Commission, 'Food 2030 Pathways for Action: Research and Innovation Policy as a Driver for Sustainable, Healthy and Inclusive Food Systems' (2020) at p 14.

[166] Goverde (n 83) at p 177.

also makes it possible for consumer opinions to be included in the decision-making process, and this inclusion is a major objective for better regulation.[167]

The proposed structure faces structural challenges. First, risk assessment is a scientific process,[168] while risk management is a political one.[169] We have argued that the most powerful external impacting factors are economic and political, and since the objectives of those are often aligned, we consider them as one political–economic factor. This makes it difficult to separate political–economic factors from the political process of risk management, especially since this would probably face pushback from stakeholders who benefit from their close association. Second, the independence of scientific entities from politics is perceived as a diluent to accountability,[170] which could increase if another political–economic assessor is added.

Despite these challenges, the separation of external factors from decision-making first and foremost allows transparency and documentation of assessments. In our opinion, this would improve traceability, which would reinforce accountability instead of diluting it.

The idea is not to make scientific evidence and other external factors equal in decision-making, as there already is an existing legal basis that prioritises a science-based food law, but to taper the power of external factors by separating them from risk management and subjecting them to complete transparency.

V. Conclusion

Food governance is a complex and challenging issue, but it is essential to ensure that food systems are healthy, among other desired outcomes. Current food law addresses the challenges of food governance by focusing on a science-based risk analysis method. This method allows legislation and policymakers to weigh the scientific evidence of nutrition-related risks with other factors, such as political and economic considerations. By using a science-based risk analysis method, policymakers can develop food policies that promote public health and protect consumers from nutrition-related risks.

However, the risk analysis model is not without flaws. One concern is that it can lead to a focus on short-term economic and political considerations at the expense of long-term public health goals. Another concern is that it can give too much weight to the interests of powerful stakeholders, such as the food industry or politicians.

To address these issues, it is important to bridge and strengthen the steps of risk analysis, from research to policy, while preserving their independence and showcasing transparency. This can be done by adopting systematic methods in risk assessment, which would grant both scientists and decision-makers easy and reliable access to important scientific evidence. To complement systematic methods, we recommend steering nutritional research towards topics addressing current gaps in scientific knowledge, namely the relationship of nutritional properties of food to NCDs. To strengthen transparency and independence in risk management, we recommend separating external legitimate factors from the risk management process and subjecting them to transparency provisions that include all involved actors.

The sustainability dialogue, particularly the FSFS as an upcoming legal framework, promises changes on many fronts of the current food law and food system. Most importantly, it suggests a plan to reframe the umbrella legislation of food law by bringing new concepts and principles to the GFL. This includes new legal definitions, a sustainability assessment process and a principle of transparency that would most likely reframe the

[167] European Risk Forum (n 91) at p 82.
[168] Art 6(2) GFL.
[169] Art 3(12) GFL.
[170] Millstone (n 35) at p 627.

legislative concept of health and impact the balance between safety risk assessment and external legitimate factors in risk management. We recommend further research on the topic when more information is available.

The article does not discuss the risk analysis process in the context of the Court of Justice of the European Union's (CJEU) judgments. While CJEU judgments have established the importance of transparency and independence in risk assessment, they have also recognised that decision-makers may partially or fully disregard EFSA Opinions, which would be reflected in decision-making and could be subject to judicial review.[171] As the article does not discuss the implications of CJEU judgments for food governance, we also recommend more research on this topic.

Despite its limitations, this article provides a valuable contribution to the understanding of food governance and the role of risk analysis in promoting public health. By adopting the recommendations outlined above, we can contribute to the creation of a food system that is more equitable, sustainable and protective of public health.

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[171] Alemanno and Mahieu (n 100) at p 327.

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