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ARTICLE

The Role of Heuristics and Biases in the Choice of Risk Triggers for Novel Foods and GMOs in the European Union

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Abstract

In the European Union (EU), novel foods and Genetically Modified Organisms (GMOs) are subject to long and costly authorisation procedures and post-marketing requirements. The regulatory frameworks applicable to novel foods and GMOs come into effect based on perceived factors of risk. These "risk triggers" are characteristics of novel foods and GMOs which differentiate them from traditional foods, creating a presumption of risk. Within the EU, consumer acceptance of genetically modified foods and novel foods like insects or cultivated meat is shaped by heuristics and biases, mainly focusing on the "novelty" and "unnaturalness" of these products, resulting in a predominantly negative perception. This paper investigates the close connection between cognitive biases identified in consumer perception literature and the implementation of specific risk triggers in the regulation of novel foods and GMOs in the EU. It subsequently raises concerns about the appropriateness of these risk triggers in forming a presumption of risk for these innovative products.

Keywords: GMOs; novel foods; risk regulation

I. Introduction

Despite their potential to mitigate the negative effects of population growth, climate change, biodiversity loss, and environmental degradation,[1] novel foods and genetically modified organisms (GMOs) face severe regulatory burdens in the European Union (EU). Novel foods and GMOs are legally presumed to be risky and are subject to strict requirements, namely pre-market approval, mandatory labelling and traceability requirements.[2] Scholars have criticised these regulatory measures for slowing down

[1] AA Adenle and others, "Two Decades of GMOs: – How Can Modern Biotechnology Help Meet SDGs" (2020) Science, Technology and Innovation for Sustainable Development Goals: Insights from Agriculture, Health, Environment and Energy 401; A Parodi and others, "The Potential of Future Foods for Sustainable and Healthy Diets" (2018) 1 Nature Sustainability 782.

[2] A Lähteenmäki-Uutela and others, "Alternative Proteins and EU Food Law" (2021) 130 Food Control 108336. J Vapnek, K Purnhagen and B Hillel, "Regulatory and Legislative Framework for Novel Foods" in *Food Formulation* (John Wiley & Sons, Ltd 2021) 285–308, https://doi.org/10.1002/9781119614760.ch14.

the innovation process in the EU food sector[3] and for delaying the realisation of the benefits these innovations can bring.[4]

Foods are categorised as novel foods and GMOs when they exhibit particular features that warrant regulatory oversight in the eyes of the legislators, the "risk triggers." Risk triggers are thus characteristics of innovative products and/or processes identified by the legislator as factors of risk that differentiate innovations from comparable, traditional alternatives.

Risk triggers and subsequent regulatory requirements are determined by legislators and policymakers taking into consideration several factors. First, the legislation's objectives to protect human health, the environment, and consumer interests, along with ensuring the functioning of the internal market: authorisation procedures are designed to assess and manage the potential harm posed by those products that are presumed to be risky. Second, the disruptive potential of novel foods and GMOs could provoke hostility from established industries, which might lobby against their widespread adoption. For example, the dairy and meat sectors oppose the use of terms like "steak," "milk," and "butter" for plant and fermentation-based alternatives to animal products.[5] Third, legislators and policymakers consider the perception of these products by the general public.[6] Consumers' acceptance of novel foods and GMOs is shaped by emotions, personal attitudes, and cultural and social identity, which lead to the formation of heuristics, mental shortcuts humans instinctively use to make decisions under uncertainty, and related biases.[7] Heuristics and biases subsequently affect consumers' willingness to adopt novel foods and GMOs.[8]

This paper investigates the close connection between cognitive biases identified in consumer perception literature and the implementation of particular risk triggers in the regulation of novel foods and GMOs in the EU. It subsequently raises concerns about the appropriateness of these risk triggers in forming a presumption of risk for these innovative products.

1. Structure of the paper

In the first section, I introduce the role that heuristics and biases play in decision-making, and shed light on which heuristics and biases affect the general public's perception of novel foods and GMOs according to literature.

[3] AA Baicu and ME Popa, "Effects on the Competitiveness of Food Businesses of the New Novel Food Regulation." (2016) 12 Journal of EcoAgriTourism 168; M Holle, "Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example" in H Bremmers and K Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing 2018); G Tagliabue and K Ammann, "Some Basis for a Renewed Regulation of Agri-Food Biotechnology in the EU" (2018) 31 Journal of Agricultural and Environmental Ethics 39; J Wesseler and N Kalaitzandonakes, "Present and Future EU GMO Policy" in L Dries and others (eds), *EU Bioeconomy Economics and Policies: Volume II* (Springer International Publishing 2019).

[4] M Herrero and others, "Innovation Can Accelerate the Transition towards a Sustainable Food System" (2020) 1 Nature Food 266; R Mazac and others, "Incorporation of Novel Foods in European Diets Can Reduce Global Warming Potential, Water Use and Land Use by over 80%" (2022) 3 Nature Food 286; S Sforza, "Food (In)Security: The Role of Novel Foods on Sustainability" in L Scaffardi and G Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis*. (Springer International Publishing 2022), 59–79. https://doi.org/10.1007/978-3-031-13494-4_4.

[5] F Southey, "'Vegan Cheese' Banned but 'Veggie Burger' Still on the Table, Votes European Parliament" (*Food Navigator*, 23 October 2020) <https://www.foodnavigator.com/Article/2020/10/23/Vegan-cheese-banned-but-veggie-burger-still-on-the-table-votes-European-Parliament>

[6] E Faccio and LGN Fovino, "Food Neophobia or Distrust of Novelties? Exploring Consumers' Attitudes Toward GMOs, Insects and Cultured Meat" (2019) 9 Applied Sciences 4440.

[7] JS Lerner, Y Li, P Valdesolo, and KS Kassam, "Emotion and Decision Making" (2015) 66 Annual Review of Psychology 1, 799–823.

[8] M Siegrist and C Hartmann, "Consumer Acceptance of Novel Food Technologies" (2020) 60 Nature Food 1, 343–50, https://doi.org/10.1038/s43016-020-0094-x.

Afterwards, I illustrate the general principles of the legal framework applicable to novel foods and GMOs in the EU and investigate the use of risk triggers in their regulation, focusing on "novelty" and "unnaturalness."

Finally, I explore the link between heuristics and biases identified in consumer perception literature, and the use of "novelty" and "unnaturalness" as risk triggers in the regulatory framework applicable to novel foods and GMOs in the EU. I then discuss whether such risk triggers constitute suitable indicators of risk and whether they are appropriate for regulating food innovations.

II. Heuristics and biases in consumer perception of novel foods and GMOs

1. Heuristics and biases

Heuristics are mental shortcuts used to solve problems and guide our minds to make decisions under uncertainty.[9] Heuristic theory is based on the dual process of decision-making, in which "System 1" is an instinctive, not mentally demanding response to the situation, and, by contrast, "System 2" is the process of evaluating all data and information to make informed choices through effortful mental activities.[10]

Heuristics are the base of "System 1" thinking. Considering that making optimal decisions under uncertainty is, at best, improbable, the role heuristics play does not necessarily have to be negative. It would be impossible to always consider all relevant data and information.[11] For this reason, mental shortcuts are essential for responding to information overload.[12] Unfortunately, heuristics can sometimes promote long-term biases, systematic errors in thinking that interfere with our decision-making and influence our perception of risk.[13] Taking as an example a flight booking: a photo or a report of an airplane crash might influence the perceived risk of flying more than any statistics showing that airplanes are safer than cars. This would ultimately prompt us to decide to use a car, a result of the "availability heuristic".[14] Heuristics and subsequent biases are generated by emotions, personal attitudes, membership in social groups, and cultural and social identity, and are context dependent.[15]

2. Consumer perception of GMOs and novel foods

Despite some fluctuations over the years,[16] consumer perception of GMOs in the EU has never been positive.[17] Even if scientific evidence has consistently proved that GMOs do not pose adverse effects on human health and/or the environment, GMOs trigger emotional responses based on ethics and risk aversion towards potential long-term effects.[18] In particular, the general public has difficulties in perceiving the benefits of GMOs for food

[9] A Tversky and D Kahneman, "Judgment under Uncertainty: Heuristics and Biases" (1974) 185 Science 1124.

[10] D Kahneman, *Thinking, Fast and Slow* (1st edition, Farrar, Straus and Giroux 2013).

[11] GB Moskowitz, *Social Cognition: Understanding Self and Others* (A Tesser, Ed., 2005). Guilford Press.

[12] S Dale, "Heuristics and Biases: The Science of Decision-Making" (2015) 32 Business Information Review 93.

[13] P Slovic and E Peters, "Risk Perception and Affect" (2006) 15 Current Directions in Psychological Science 322.

[14] VS Folkes, "The Availability Heuristic and Perceived Risk" (1988) 15 Journal of Consumer Research 1, 13–23, https://doi.org/10.1086/209141.

[15] Lerner and others, supra n 7.

[16] MC Ichim, "The More Favorable Attitude of the Citizens toward GMOs Supports a New Regulatory Framework in the European Union" (2021) 12 GM Crops & Food 18.

[17] LJ Frewer and others, "Consumer Response to Novel Agri-Food Technologies: Implications for Predicting Consumer Acceptance of Emerging Food Technologies" (2011) 22 Trends in Food Science & Technology 442.

[18] J Mohorčich and J Reese, "Cell-Cultured Meat: Lessons from GMO Adoption and Resistance" (2019) 143 Appetite 104408.

uses.[19] The opposition towards GMOs has been linked to the intuitive appeal of anti-GMO messages, explained in part by cognitive processes such as the fear of unnatural products and emotions like disgust.[20] The aversion is further fuelled by anti-biotech advocates and their negative (visual) portrayals of GMOs.[21]

On the contrary, assessing public perception of novel foods as a whole is difficult, because of how diverse novel food categories are. One market segment, however, includes a large number of novel foods, whose number is deemed to increase in the future: the alternative protein sector. Alternative proteins are meant to substitute traditional animal protein sources and are produced from plants or animal cells, or by way of fermentation.[22] For example, cultivated meat, products of precision fermentation, and insects.[23] Studies on alternative proteins represent the majority of the literature evaluating consumer perception of novel foods, focusing mainly on insects and cultivated meat.[24] Factors that negatively affect the perception of novel foods are disgust, food neophobia, and perception of unnaturalness.[25] On the contrary, familiarity is related to higher consumer acceptance.[26]

Siegrist and Hartmann[27] point to disgust sensitivity, neophobia, and cultural factors as the main emotions and personality traits affecting the perception of gene technology and novel foods. They cluster them into three heuristic cues: the "affect heuristic," the "natural-is-better heuristic" and the "trust heuristic."

Under the effect of the "affect heuristic," people rely on emotions derived from single traits or attached to images to judge risks and benefits associated with novel foods and GMOs. For example, the feeling of disgust that insects cause drives consumers to reject products that contain them, despite the nutritional and environmental benefits that the consumption of insects might bring. The affect heuristic leads to a "status quo bias," the tendency to reject changes, and to the preference for familiar products.[28]

The "natural-is-better heuristic" postulates that the perceived level of naturalness of a food product points to its health benefits and overall quality, leading to a misconception of nature, which is thought of as pure, safe and benign.[29] Biological hazards like bacterial

[19] G Gaskell and others, "GM Foods and the Misperception of Risk Perception" (2004) 24 Risk Analysis: An Official Publication of the Society for Risk Analysis 185.

[20] S Blancke and others, "Fatal Attraction: The Intuitive Appeal of GMO Opposition" (2015) 20 Trends in Plant Science 414.

[21] KA Clancy and B Clancy, "Growing Monstrous Organisms: The Construction of Anti-GMO Visual Rhetoric through Digital Media" (2016) 33 Critical Studies in Media Communication 279.

[22] Good Food Institute, "Defining Alternative Proteins" (GFI, n.d.) <https://gfi.org/defining-alternative-protein/#:~:text=Alternative%20proteins%20are%20proteins%20produced,costing%20the%20same%20or%20less>

[23] Y Akhtar and MB Isman "10 – Insects as an Alternative Protein Source" (2018) in RY Yada (ed), *Proteins in Food Processing* (Second Edition, Woodhead Publishing). Despite being animals, insects are often classified as alternative proteins because of their poor history of consumption in Western countries and their lower environmental impact compared with traditional animal proteins.

[24] A Monaco and others, "Consumers' Perception of Novel Foods and the Impact of Heuristics and Biases: A Systematic Review" (2024) 196 Appetite 107285, https://doi.org/10.1016/j.appet.2024.107285; C Hartmann and M Siegrist, "Consumer Perception and Behaviour Regarding Sustainable Protein Consumption: A Systematic Review" (2017) 61 Trends in Food Science & Technology 11.

[25] H Tuorila and C Hartmann, "Consumer Responses to Novel and Unfamiliar Foods" (2020) 33 Current Opinion in Food Science 1.

[26] Monaco and others, supra n 24.

[27] Siegrist and Hartmann, supra n 8.

[28] S Eidelman and CS Crandall, "Bias in Favor of the Status Quo" (2012) 6 Social and Personality Psychology Compass, 270–281. https://doi.org/10.1111/j.1751-9004.2012.00427.x.

[29] G Tagliabue, "Nature as a Totem, "GMOs" as a Contemporary Taboo" (2016) 18 North American Journal of Psychology 283; BP Meier, AJ Dillard and CM Lappas, "Naturally Better? A Review of the Natural-Is-Better Bias" (2019) 13 Social and Personality Psychology Compass.

contamination are perceived as far less threatening than potential, nonproven, bad outcomes of artificial manipulations like gene editing.

The "trust heuristic" substitutes the conscious assessment of the innovation with the level of trust towards the source of the innovation. An example is the intuitive preference for products developed by local companies or young start-ups over those from multinational corporations with global presence. When approaching and processing information, particularly when the issues at stake are culturally controversial, people subject to the "trust heuristic" tend to be conditioned by the "framing effect," according to which decisions are taken based on how information is presented,[30] and to a "confirmation bias," which builds up a certain position by considering only information and data in line with their a priori considerations.[31]

III. Risk triggers in the Legal Framework applicable to GMOs and Novel Foods in the EU

1. Legal Framework applicable to GMOs and Novel Foods in the EU

Regulation (EU) 2015/2283[32] on novel foods (from here on referred to as the "Novel Food Regulation" or NFR) defines novel foods as foods that were not used for human consumption to a significant degree within the EU before 15 May 1997, and that fall under at least one of the novel food categories.[33] Examples include insects and cultivated meat, plant extracts and products of fermentation.

GMOs, on the other hand, are defined in Directive (EC) 2001/18 on the release into the environment of genetically modified organisms as "*organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.*"[34]

In the EU, the NFR and Regulation (EC) 1829/2003[35] on the placing on the market of genetically modified food and feed (the "GMOR") are the two pieces of legislation that regulate the market entrance of novel foods and foods produced from or containing GMOs. Together, they cover almost all innovative food sources.

Article 114 of the Treaty on the Functioning of the European Union provides the legal base for the NFR and the GMOR;[36] Accordingly, they both aim at protecting human health, the environment, and consumer interests, along with ensuring the functioning of the internal market.

[30] J-J Igartua and L Cheng, "Moderating Effect of Group Cue While Processing News on Immigration: Is the Framing Effect a Heuristic Process?" (2009) 59 Journal of Communication 4, 726–49, https://doi.org/10.1111/j.1460-2466.2009.01454.x.

[31] RS Nickerson, "Confirmation Bias: A Ubiquitous Phenomenon in Many Guises" (1998) 2 Review of General Psychology 2, 175–220. https://doi.org/10.1037/1089-2680.2.2.175.

[32] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 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, 11.12.2015, 1–22.

[33] Ibid., Art. 3(2).

[34] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC – Commission Declaration, p. OJ L 106. Art. 2(2).

[35] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, 1–23.

[36] Treaty on The Functioning of The European Union, OJ C 202 7.6.2016, p. 47. Art. 114 (ex. Art. 95 of the Treaty Establishing the European Community).

The NFR and the GMOR follow the principle of risk analysis, as stipulated in Article (6)(1) of Regulation (EC) No 178/2002[37] laying down the general principles and requirements of food law. Thus, both the NFR and the GMOR require pre-market approval for products within their scope. The objective is to ensure that a science-based risk assessment, carried out independently by the European Food Safety Authority (EFSA), is coupled with a risk management process overseen by political authorities.[38] The latter are supposed to make decisions based on EFSA's opinion, relevant legal provisions, the precautionary principle and other legitimate factors.[39] The authorisation procedures guarantee that novel foods and GMOs pose no additional risks compared to conventional food products before they are allowed entry into the market. This is essential for ensuring the safety of these products for human consumption and for protecting the interests of consumers.

2. Risk triggers for novel foods and GMOs: "novelty" and "unnaturalness"

Products become subject to the NFR and the GMOR when some of their features and characteristics serve as "risk triggers." Risk triggers can be derived by examining the definitions and relevant provisions of the legal frameworks. In the eyes of the legislators, the presence of risk triggers potentially undermines the primary objectives of ensuring food safety, protecting human health and the environment, and safeguarding consumer interests. Hence, risk triggers prompt the enforcement of the legislation.

When considering definitions and regulatory provisions, "novelty" and "unnaturalness" emerge as the primary risk triggers for novel foods and GMOs, serving as the key factors that distinguish them from comparable, traditional food products.[40]

Novel foods are foods not consumed to a significant degree within the Union before 15 May 1997. Novel foods are considered risky because they were not consumed before 1997 in the EU. The fact that they are novel on the EU market constitutes a risk factor in itself. The EU definition is particularly restrictive. For example, in Singapore, the definition of novel foods does not include a geographical limitation to determine whether a novel food was consumed by a significant population before,[41] while in Australia–New Zealand, foods without a history of consumption in the jurisdiction are considered novel foods and are subject to the authorisation procedure only when they require an assessment of public health and safety considerations against specific indicators included in the definition.[42]

Alongside "novelty," "unnaturalness" is also used as a trigger in the novel foods framework. The "traditional foods from third countries," despite falling within the novel food definition, enjoy a facilitated "notification procedure" instead of the full "authorisation procedure."[43] The "notification procedure," in absence of duly justified safety objections from the EFSA or the Member States, requires significantly less time to

[37] 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 L 31, 1.2.2002, p. 1–24.

[38] Ibid., Art 6.

[39] Ibid.

[40] AT Christiansen, MM Andersen and K Kappel, "Are Current EU Policies on GMOs Justified?" (2019) 28 Transgenic Research 267; H-G Dederer, "Confédération Paysanne and Others v. Premier Ministre and Ministre De L'Agriculture, De L'Agroalimentaire Et De La Forêt (C.J.E.U.)" (2019) 58 International Legal Materials 1281; A Monaco and KP Purnhagen, "Risk Triggers as Innovation Triggers? Risk Analysis and Innovation's Promotion under the Novel Food Regulation" (2022) 17 European Food and Feed Law Review.

[41] Singapore Food Agency, "Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients" (2023) <https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-foods-and-novel-food-ingredients.pdf>.

[42] FSANZ – Food Standards Australia New Zealand, Australia New Zealand Food Standards Code – Definitions used throughout the Code – Standard 1.1.2 2023 [F2023C00752].

[43] Monaco and Purnhagen, supra n 40.

place products on the market. Such preferential treatment is granted only to foods with an history of safe use in a third country, derived from primary production and that can be classified into one of the novel food categories (ii), (iv), (v), (vi).[44] Primary production is defined as: "*the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.*"[45] The logic behind the "traditional food category" is to facilitate the placing on the market of products of plant and animal origin commonly consumed in third countries,[46] which fall under the affected novel food categories, excluding novel foods developed using new technological processes. For example, novel foods falling under the categories "food with a new or intentionally modified molecular structure" or "food consisting of, isolated from or produced from cell culture or tissue culture," which presume the use of modern and artificial production techniques, cannot be classified as traditional foods, even when they could hypothetically demonstrate a history of consumption in third countries.

Similarly, the definition of GMOs establishes that only those organisms whose genome has been modified in a way that cannot occur naturally should be subject to the framework. The use of "unnaturalness" as a risk trigger does not consider the specific properties of the GMOs. Artificial intervention is considered a presumption of risk in itself, particularly when the intervention does not fit into traditional processes familiar to the majority of the population.[47] For this reason, manipulation of the genome through hybridisation is acceptable, while lab modification of the genome is not, a false belief based on a misunderstood and unscientific conception of what "genetically modified organisms" means.[48]

In addition to "unnaturalness," "novelty" is used as a risk trigger also in the GMO framework. An example is the regulatory debate over new plant breeding techniques (NPBTs). These revolutionary techniques, such as CRISPR-Cas9, have been developed in the past decade and allow for a simple and precise modification of a plant's DNA. NPBTs are subject to the GMO framework, despite firm opposition from the scientific community,[49] since NPBTs show similarities with traditional mutagenesis techniques, which are exempted from the application of the GMO framework.[50] Their regulatory treatment was

[44] The novel food categories excluded from the scope of the "traditional foods from third countries" definition are: (i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997; (iii) food consisting of, isolated from or produced from material of mineral origin; (vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances; (viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph; (ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where: a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph or they contain or consist of engineered nanomaterials; and (x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC.

[45] Regulation (EC) No 178/2002, supra n 37. Art. 3(17).

[46] Holle, supra n 3.

[47] JP Collman, *Naturally Dangerous: Surprising Facts about Food, Health, and the Environment* (University Science Books 2001).

[48] K Ammann, "Genomic Misconception: A Fresh Look at the Biosafety of Transgenic and Conventional Crops. A Plea for a Process Agnostic Regulation" (2014) 31 New Biotechnology 1; Werner Arber, "Genetic Engineering Compared to Natural Genetic Variations" (2010) 27 New Biotechnology 517.

[49] K Purnhagen and J Wesseler, "EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond" (2021) 43 Applied Economic Perspectives and Policy, 1621–1637. https://doi.org/10.1002/aepp.13084.

[50] Directive 2001/18/EC, supra n 34, Art 3. G Tagliabue, "Product, Not Process! Explaining a Basic Concept in Agricultural Biotechnologies and Food Safety" (2017) 13 Life Sciences, Society and Policy 3.

upheld by the Court of Justice of the EU in *Confédération paysanne and Others*,[51] in which the Court interpreted the "mutagenesis exemption" in Article 3 of Directive 2001/18 as covering only traditional mutagenesis techniques developed before 2001. The decision relied on the *"intention of the EU legislature"* to exclude "*novel*" techniques from the scope of the mutagenesis exemption.[52] The exemption is meant to cover only techniques conventionally used before the entry into force of the Directive, implying that NPBTs might pose more significant risks than conventional mutagenesis techniques. This approach has been criticised by the scientific community[53] and is likely to have a negative impact on innovation and growth in the EU.[54]

IV. The use of "novelty" and "unnaturalness" as risk triggers

1. The adoption of novelty and unnaturalness as risk triggers

Several theories point to legal, cultural, political, and economic considerations when explaining regulatory choices. The Institutionalist Theory suggests that policymakers are influenced by the rules, norms, and procedures that define the institutions within which they operate,[55] while the Political Culture Theory emphasises that political behaviour is shaped by shared beliefs and cultural values.[56]

Alternative theories focus more on the psychology of policymakers. From this standpoint, legislators are perceived as ordinary individuals susceptible to the same instincts and beliefs as any other people. While the Public Choice Theory describes legislators as mere pursuers of their self-interest,[57] the Cognitive Psychology Theory highlights the importance of psychological traits and attitudes shaping the decision-making processes of the legislators. According to cognitive psychology, legislators are influenced by biases and heuristics.[58] Authors such as Slovic[59] or Kuran and Sunstein[60] have illustrated how heuristics and biases shape legislators' attitudes towards risks, influencing their decision-making with potentially undesirable and costly consequences for society.

The influence of heuristics and biases on people in charge of decision-making has a huge impact on regulatory choices.[61] They might lead legislators to underestimate certain costs and benefits, or *vice versa*,[62] and to adopt different risk management strategies in

[51] *C-528/16 – Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt Judgment of the Court (Grand Chamber)* [2018] Court of Justice of the European Union EU:C:2018:583.

[52] Ibid., Para 51.

[53] D Eriksson and T Zimny, "Critical Observations on the French Conseil d'État ruling on Plant Mutagenesis" (2020) Nature Plants 6, 1392–1393. https://doi.org/10.1038/s41477-020-00819-4.

[54] J Wesseler, G Kleter, M Meulenbroek, KP Purnhagen, "EU Regulation of Genetically Modified Microorganisms in Light of New Policy Developments: Possible Implications for EU Bioeconomy Investments" (2023) 45 Applied Economic Perspectives and Policy 2, 839–859. https://doi.org/10.1002/aepp.13259.

[55] BG Peters, *Institutional Theory in Political Science, Fourth Edition: The New Institutionalism* (Edward Elgar Publishing 2019).

[56] S Welch, *The Theory of Political Culture* (OUP Oxford 2013).

[57] E Zamir and R Sulitzeanu-Kenan, "Explaining Self-Interested Behavior of Public-Spirited Policy Makers" (2018) 78 Public Administration Review 579.

[58] RG Noll and JE Krier, "Some Implications of Cognitive Psychology for Risk Regulation" (1990) 19 The Journal of Legal Studies 747; J Rachlinski and C Farina, "Cognitive Psychology and Optimal Government Design" (2002) 87 Cornell Law Review 549.

[59] P Slovic, "Perception of Risk" (1987) 236 Science 280.

[60] CR Sunstein and T Kuran, "Availability Cascades and Risk Regulation" (1999) 51 Stanford Law Review 683.

[61] M Hirsch, "Regulators' Mindsets, Ingroup Favoritism, and the National Treatment Obligation in World Trade Organization Law" (2022) 23 German Law Journal 3, 298–313. https://doi.org/10.1017/glj.2022.27.

[62] JAC Everett, NS Faber and M Crockett, "Preferences and Beliefs in Ingroup Favoritism" (2015) 9 Frontiers in Behavioral Neuroscience <https://www.frontiersin.org/article/10.3389/fnbeh.2015.00015> (last accessed 05 February 2022).

different contexts. One example is the World Trade Organisation (WTO) dispute settlement case between the EU and US over the interpretation of the precautionary principle in the context of GMO regulation. While in international law the precautionary principle stipulates that provisional measures aimed at ensuring a high level of health protection may be adopted when the possibility of harmful effects on health is identified, and scientific evidence on such risks is absent or inconclusive, in the EU, policymakers have often interpreted the precautionary principle as necessitating the demonstration of the absolute absence of any risk.[63]

Assuming a cognitive psychology perspective, heuristics and biases influence the process of creating and applying the law by legislators, either by directly guiding the individual behaviours of the policymakers, or indirectly, by nudging public perception in particular directions.[64] As a result, policymakers are keener to redirect limited resources to issues that are considered critical by public perception or relevant interest groups.[65] Accordingly, the recognition of "novelty" and "unnaturalness" as risk triggers for the regulation of novel foods and GMOs aligns with those biases and heuristics cues, like the "affect" or the "natural-is-better" heuristics, that influence the consumer perception of novel foods and GMOs.

2. Better risk triggers for better regulation?

The equation "novelty and unnaturalness → threat" cannot be immediately invoked: "novelty" and "unnaturalness" do not automatically imply an immediate threat to human health, consumers, or the environment. "Novelty" and "unnaturalness" are intrinsic characteristics of novel foods and GMOs. Their use as risk triggers results in an over-inclusive application of the legislation, which potentially hampers the work of innovators in the EU.[66] Moreover, even when scientific authorities deem the products to be safe, after thorough and robust authorisation procedures, the authorisation of innovations can still be delayed and/or not granted due to the political stances and biases of member states and policymakers.[67] Davison and Ammann[68] highlight how the votes over the final authorisations of GMOs crop almost always align with the *a priori* positions of the member states, ignoring scientific evidence and the EFSA's assessment. Another example is the recent Italian law banning the production and sale of cultivated meat in the country, when not one application has been submitted at the EU level yet.[69]

The NFR and the GMO framework do not explicitly list the promotion of innovation as one of their objectives. While there are grounds to claim that facilitating innovation can be

[63] A Scherzberg, "EU–US Trade Disputes about Risk Regulation: The Case of Genetically Modified Organisms" (2006) 19 Cambridge Review of International Affairs, 1, 121–37, https://doi.org/10.1080/09557570500501853; G Tagliabue, "The Precautionary Principle: Its Misunderstandings and Misuses in Relation to 'GMOs'" (2016), 33 New Biotechnology 4, 437–39, https://doi.org/10.1016/j.nbt.2016.02.007.

[64] RB Korobkin, "The Problems with Heuristics for Law" in G Gigerenzer and C Engel (eds), *Heuristics in the Law* (The MIT Press 2006).

[65] RG Cooper and EJ Kleinschmidt, "Winning Businesses in Product Development: The Critical Success Factors" (1996) 39 Research-Technology Management 18; Sunstein and Kuran, supra n 60.

[66] Baicu and Popa, supra note 3; Holle, supra note 3; Wesseler and Kalaitzandonakes, supra note 3; A Whelan, P Gutti and MA Lema, "Gene Editing Regulation and Innovation Economics" (2020) 8 Frontiers in Bioengineering and Biotechnology.

[67] M Mastroeni, J Mitra, J Tait, "Political Influences on Biotechnology-Based Innovation for European Agriculture: Risk-Assessment and Risk Management" (2021) 33 Technology Analysis & Strategic Management 3, 271–282, https://doi.org/10.1080/09537325.2019.1573983.

[68] J Davison and K Ammann, "New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology" (2017) 8 GM Crops & Food 1, 13–34. https://doi.org/10.1080/21645698.2017.1289305.

[69] F Planchestainer, "Meat Me in Italy: The Italian Ban on Sounding Names and Cell-Cultured Meat" (2024) 66 European Food and Feed Law Review 71.

considered an implicit objective within the NFR,[70] it is evident that EU legislators did not regard innovation promotion as a secondary goal in the GMO framework.[71] However, it can be argued that purposely delaying the benefits that food innovations might bring contradicts the legal basis of the framework, when such innovations can contribute to achieving the legislation´s objectives.[72]

In response to the influence of non-scientific biases in the regulation of novel foods and GMOs, some scholars have argued for a reduction of the role of politics in the authorisation process of innovations.[73] Others have called for "better politics," involving more communication between the public and scientific authorities.[74] Paying more attention to the role of risk triggers can be a good starting point. Risk triggers enable the capture of novel foods and GMOs by the NFR and the GMO regulatory framework. When present, risk triggers initiate the application of the legislation and the related burdens and controversies. Separating risk triggers from biases and emotional perception of consumers could help to reduce both the anxiety of the society and the burden on regulators and innovators. To do so, risk triggers could be identified by focusing on the products rather than the processes from which they are obtained.[75] For example, when determining which genetic modifications should be deemed to be risky and thus fall under the GMO framework a trait-based model could be employed.[76] Similarly, taking inspiration from other jurisdictions like Singapore or Australia–New Zealand, novel foods with a proven history of consumption outside of the EU or that are not deemed to pose particular risks for human consumption could be exempted from the scope of the NFR.

Considering the number of innovations that will enter the food sector in the near future, it is critical to ensure that resources are allocated for the regulation of those products and processes more likely to pose risks for consumers. Adopting efficient and risk-based triggers is a crucial starting point to ensure that the adoption of innovations and the subsequent realisation of their benefits are not unduly delayed.

V. Conclusions

Heuristics are mental shortcuts that help humans make good decisions in uncertain situations. However, these shortcuts can sometimes lead to biases that negatively affect decision-making. Concerning the regulation of novel foods and GMOs, specific heuristics and biases affecting consumer perception of these products and processes are closely related to the factors that initiate the application of the legislation. The close relationship between biases and risk riggers shows how the regulation of innovative products tends to be built on prejudices and biased perceptions, thus affecting the innovation process. Understanding the role of heuristics and biases when dealing with

[70] Monaco and Purnhagen, supra n 40.

[71] Christiansen and others, supra n 40. D Eriksson and S Chatzopoulou, "Responsible Decision-Making for Plant Research and Breeding Innovations in the European Union" (2018) 9 GM Crops & Food 39.

[72] KP Purnhagen, "You Want It Extra CRISPERY? Legal Disruption through New Plant Breeding Technologies in the EU" (2021) Yearbook of European Law, https://doi.org/10.1093/yel/yeab003.

[73] SJ Smyth and others, "Removing Politics from Innovations that Improve Food Security" (2021) Transgenic Research 30, 601–12.

[74] A Raybould, "Improving the Politics of Biotechnological Innovations in Food Security and Other Sustainable Development Goals" (2021) Transgenic Research 30, 613–18. https://doi.org/10.1007/s11248-021-00277-4; LM Poort and others "Restore politics in Societal Debates on New Genomic Techniques" (2022) Agriculture and Human Values 39, 1207–1216. https://doi.org/10.1007/s10460-022-10328-z.

[75] Tagliabue, supra n 50.

[76] K Purnhagen and others, "Options for Regulating New Genomic Techniques for Plants in the European Union" (2023) Nature Plants 9, 1958–1961. https://doi.org/10.1038/s41477-023-01570-2.

novel foods and GMOs is key for designing regulatory systems capable of favouring the innovation process, alongside ensuring the protection of human health, the environment and consumer interests.

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