# Regulating Food Innovations in the EU: An Analysis of the Novel Food Regulation

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# Table of contents

Table of contentsi
List of abbreviationsvii
Abstract (English)viii
Abstract (Deutsch)x
Chapter 1 General Introduction
1. Introduction and background14
1.1. The regulation of novel foods in the EU
1.2. Innovation in EU food policies and in the Novel Food Regulation
1.3. The Novel Food Regulation and consumer perception of novel foods
2. Objectives of the dissertation and research questions
2.1. Research questions
2.2. Alternative proteins as a case study for novel foods regulation
3. Theoretical framework
3.1. Innovative regulations to regulate innovations: the concept of legal disruption24
3.2. Factors influencing the adoption of a regulatory framework
3.3. Design thinking principles for the regulation of innovation
4. Methodological approaches
5. Structure of the dissertation
Chapter 2 Risk Triggers as Innovation Triggers? Risk analysis and innovation's promotion
under the Novel Food Regulation
Abstract
1. Introduction
1.1. Methodology and structure of the chapter
2. Regulation of food Innovations in the EU: objectives of the legislation
2.1. Risk regulation in the EU

3. Legal place of innovation in the EU       40         3.1. Innovation in the EU legal framework       40         3.2. Innovation as an objective of the NFR       43         4. Risk triggers in the Novel Food Regulation       45         4.1. Novelty       45         4.2. Unnaturalness       47         5. Appropriateness of risk triggers       48         5.1. The use of "novelty" as risk trigger       49         5.2. The use of "unnaturalness" as risk trigger       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.1. Overview of biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       69         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3. Limitations	2.2. Objectives of the NFR	. 40
3.1. Innovation in the EU legal framework       40         3.2. Innovation as an objective of the NFR       43         4. Risk triggers in the Novel Food Regulation       45         4.1. Novelty       45         4.2. Unnaturalness       47         5. Appropriateness of risk triggers       48         5.1. The use of "novelty" as risk trigger       49         5.2. The use of "unnaturalness" as risk trigger       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions. 64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation o	3. Legal place of innovation in the EU	. 40
3.2. Innovation as an objective of the NFR       43         4. Risk triggers in the Novel Food Regulation       45         4.1. Novelty       45         4.2. Unnaturalness       47         5. Appropriateness of risk triggers       48         5.1. The use of "novelty" as risk trigger       49         5.2. The use of "unnaturalness" as risk trigger       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3.1. Overview of included studies       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74	3.1. Innovation in the EU legal framework	. 40
4. Risk triggers in the Novel Food Regulation       45         4.1. Novelty       45         4.2. Unnaturalness       47         5. Appropriateness of risk triggers       48         5.1. The use of "novelty" as risk trigger       49         5.2. The use of "unnaturalness" as risk trigger.       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions.       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74	3.2. Innovation as an objective of the NFR	. 43
4.1. Novelty       45         4.2. Unnaturalness       47         5. Appropriateness of risk triggers       48         5.1. The use of "novelty" as risk trigger       49         5.2. The use of "unnaturalness" as risk trigger.       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions.       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3. Limitations       76	4. Risk triggers in the Novel Food Regulation	. 45
4.2. Unnaturalness       47         5. Appropriateness of risk triggers       48         5.1. The use of "novelty" as risk trigger       49         5.2. The use of "unnaturalness" as risk trigger.       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3. I imitations       76	4.1. Novelty	. 45
5. Appropriateness of risk triggers       48         5.1. The use of "novelty" as risk trigger       49         5.2. The use of "unnaturalness" as risk trigger       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3. Limitations       76	4.2. Unnaturalness	. 47
5.1. The use of "novelty" as risk trigger       .49         5.2. The use of "unnaturalness" as risk trigger.       .50         6. Conclusions       .51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a       Systematic Review         Systematic Review       .53         Abstract       .54         1. Introduction       .54         1.1. Objectives of the systematic review       .57         2. Methodology       .58         2.1. Search strategy       .58         2.2. Eligibility criteria and data extraction       .60         3. Results       .61         3.1. Overview of included studies       .61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       .64         3.3. Heuristics and biases linked to novel foods       .69         4. Discussion       .72         4.1. Consumer perception and the regulation of novel foods       .73         4.2. Public debate on the regulation of insects and cultivated meat       .74         4.3. Limitations       .76	5. Appropriateness of risk triggers	. 48
5.2. The use of "unnaturalness" as risk trigger.       50         6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a       53         Abstract       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3. Limitations       76	5.1. The use of "novelty" as risk trigger	. 49
6. Conclusions       51         Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a       53         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3. Limitations       76	5.2. The use of "unnaturalness" as risk trigger	. 50
Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a         Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions.       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3 Limitations       76	6. Conclusions	. 51
Systematic Review       53         Abstract       54         1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3 Limitations       76	Chapter 3 Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a	ı
Abstract541. Introduction541.1. Objectives of the systematic review572. Methodology582.1. Search strategy582.2. Eligibility criteria and data extraction603. Results613.1. Overview of included studies613.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions643.3. Heuristics and biases linked to novel foods694. Discussion724.1. Consumer perception and the regulation of novel foods734.2. Public debate on the regulation of insects and cultivated meat744.3 Limitations76	Systematic Review	. 53
1. Introduction       54         1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3 Limitations       76	Abstract	. 54
1.1. Objectives of the systematic review       57         2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3 Limitations       76	1. Introduction	. 54
2. Methodology       58         2.1. Search strategy       58         2.2. Eligibility criteria and data extraction       60         3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3 Limitations       76	1.1. Objectives of the systematic review	. 57
2.1. Search strategy582.2. Eligibility criteria and data extraction603. Results613.1. Overview of included studies613.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions643.3. Heuristics and biases linked to novel foods694. Discussion724.1. Consumer perception and the regulation of novel foods734.2. Public debate on the regulation of insects and cultivated meat744.3 Limitations76	2. Methodology	. 58
<ul> <li>2.2. Eligibility criteria and data extraction</li></ul>	2.1. Search strategy	. 58
3. Results       61         3.1. Overview of included studies       61         3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions       64         3.3. Heuristics and biases linked to novel foods       69         4. Discussion       72         4.1. Consumer perception and the regulation of novel foods       73         4.2. Public debate on the regulation of insects and cultivated meat       74         4.3 Limitations       76	2.2. Eligibility criteria and data extraction	. 60
<ul> <li>3.1. Overview of included studies</li></ul>	3. Results	. 61
<ul> <li>3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions 64</li> <li>3.3. Heuristics and biases linked to novel foods</li></ul>	3.1. Overview of included studies	. 61
<ul> <li>3.3. Heuristics and biases linked to novel foods</li></ul>	3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions	. 64
<ul> <li>4. Discussion</li></ul>	3.3. Heuristics and biases linked to novel foods	. 69
<ul> <li>4.1. Consumer perception and the regulation of novel foods</li></ul>	4. Discussion	. 72
4.2. Public debate on the regulation of insects and cultivated meat	4.1. Consumer perception and the regulation of novel foods	.73
4.3 Limitations 76	4.2. Public debate on the regulation of insects and cultivated meat	. 74
	4.3. Limitations	. 76
5. Conclusions	5. Conclusions	. 77

Appendix: List of articles included in the review	79
Chapter 4 The role of heuristics and biases in the choice of risk triggers for novel	foods and
GMOs in the European Union	109
Abstract	
1. Introduction	
1.1. Structure of the chapter	
2. Heuristics and biases in consumer perception of novel foods and GMOs	
2.1. Heuristics and biases	
2.2. Consumer perception of GMOs and novel foods	113
3. Risk triggers in the legal framework applicable to GMOs and novel foods in	the EU 116
3.1. Legal Framework applicable to GMOs and novel foods in the EU	116
3.2. Risk triggers for novel foods and GMOs: "novelty" and "unnaturalness"	117
4. The use of "novelty" and "unnaturalness" as risk triggers	
4.1. The adoption of "novelty" and "unnaturalness" as risk triggers	
4.2. Better risk triggers for better regulation?	
5. Conclusions	
Chapter 5 Regulatory Barriers and Incentives for Alternative Proteins in the Euro	pean Union
and Australia-New Zealand	
Abstract	
1. Introduction	
2. Methodology	
2.1. Doctrinal legal analysis	
2.2. Qualitative interviews	
3. The novel food frameworks in the EU and AUSNZ	
3.1. The EU Novel Food Regulation	134
3.2. The AUSNZ novel food framework	139
4. Results of the qualitative interviews	144
4.1. Regulatory barriers in the authorisation procedures	144

4.2. Communication between applicants and regulatory authorities	45
4.3. Political influence in the authorisation procedure and role of traditional sectors 14	46
4.4. Suggestions for improving the EU and AUSNZ frameworks14	48
5. Discussion	49
6. Limitations	51
7. Conclusion	52
Acknowledgments15	53
Chapter 6 Data Protection under the Novel Food Regulation: valuable instrument or barrier Innovation? Insights from the insect sector	to 55
Abstract	56
1. Introduction	56
1.1. Objectives and methodology15	57
2. Data protection under the Novel Food Regulation15	58
2.1. Data protection and innovation	59
3. Categorisation of insects as novel foods	63
4. Data protection in the insect sector	64
4.1. Potential consequences of the data protection clause in the insect sector	64
4.2. Potential future developments	66
5. Conclusion	67
Chapter 7 Design thinking principles in the regulation of novel foods in the European Union and Singapore: A comparison	1 69
Abstract	70
1. Introduction	70
2. Theoretical framework and methodology	73
2.1. Design thinking theory	73
2.2. Design thinking as a lens to analyse regulation	74
3. The novel food regulatory frameworks in the EU and Singapore	75
3.1. The authorisation procedure for novel foods in the EU	75

3.2. The authorisation procedure for novel foods in Singapore	177
4. Design thinking principles in the authorisation procedures for novel foods in the E	U and
Singapore	178
5. Discussion	185
5.1. Regulatory achievements in the EU and Singapore: the case study of alternativ	'e
proteins	185
5.2. Different perceptions among innovators: design thinking principles in the	
authorisation procedures	187
5.3. EU framework's ability to encourage innovation	190
6. Conclusion	192
Chapter 8 General discussion and conclusions	195
1. Introduction	196
2. Answering the research questions	196
3. Contributions to the field	204
3.1. Academic contributions	204
3.2. Practical contributions	205
4. Limitations	206
5. Recommendations for future research	207
6. The regulation of novel foods: an uncertain future	209
References	211
Bibliography	211
Online resources	231
Legislation policy documents and scientific guidances	236
European Union legislation	236
Australia New Zealand legislation and guidenee decuments	230
Australia-New Zealand legislation and guidance documents	241
Singapore legislation and guidance documents	243
Funding declaration	245
About the author	247

Personal profile	
List of publications	
Attended events	
Eidesstattlichen Erklärungen	

# List of abbreviations

ACNF	Advisory Committee on Novel Foods
AUSNZ	Australia – New Zealand
EFSA	European Food Safety Authority
EU	European Union
FRESH	Future Ready Food Safety Hub
FSANZ	Food Standards Australia New Zealand Agency
GDP	Gross Domestic Product
GFL	General Food Law
GMOR	Regulation 1829/2003 on genetically modified food and feed
GMOs	Genetically Modified Organisms
NFR	Novel Food Regulation
NPBTs	New Plant Breeding Techniques
PAFF Committee	Standing Committee on Plants, Animals, Food and Feed" ()
SFA	Singapore Food Agency
SMEs	Small and medium enterprises
TFEU	Treaty on the Functioning of the European Union

## Abstract (English)

Within the European Union (EU), Regulation (EU) No 2283/2015 on novel foods (hereinafter: Novel Food Regulation) is the primary legislative framework governing innovation in the food sector. Novel foods are defined as foods not used for human consumption to a significant degree within the Union before 15<sup>th</sup> May 1997 that can be classified into one of the ten novel food categories. The Novel Food Regulation covers some of the most promising and debated new food ingredients and production processes, such as insect-based foods and cultivated meat. When products are classified as novel foods, they are subject to a pre-market authorisation procedure which aims to demonstrate their safety, that the intended use of the novel food does not mislead the consumers, and that the novel food. The authorisation procedure consists of a risk assessment conducted by the European Food Safety Authority and a final political approval handled by the European Commission and the EU Member States.

Both policy documents and academic literature emphasise that novel foods can play a significant role in the EU's transition towards more sustainable food systems. The production of novel foods such as cultivated meat is expected to require fewer resources than traditional foods while also diminishing negative externalities in terms of environmental impact and animal welfare.

This dissertation investigates whether the Novel Food Regulation proportionally balances the promotion of innovation in the food sector and its established objectives of ensuring the functioning of the internal market and protecting human health and safety. The dissertation contributes to academic scholarship by recognising the promotion of innovation as an implicit objective of the Novel Food Regulation, thereby offering a new perspective to research in the field. The research is based on a mixed method approach, which extends a normative doctrinal legal and comparative analysis of the novel food framework in the EU, adopting an interdisciplinary perspective at the intersection of law, psychology, and behavioural economics, which enriches the understanding of the interplay between consumer biases, lawmakers' intentions and regulatory barriers. Finally, the dissertation proposes to incorporate design thinking principles in the novel food framework to balance the promotion of innovation in the food sector with the established objectives of the legislation.

The first part of this research explores the factors that prompt the application of the Novel Food Regulation. These factors are referred to as "risk triggers" and are defined as characteristics of products and processes which constitute a presumption of risk for novel foods, triggering regulatory supervision. "Novelty" and "unnaturalness" are recognised as the primary risk triggers for the regulation of novel foods. While these triggers aim to safeguard consumers and the environment, neither "novelty" nor "unnaturalness" can be related to an immediate threat to human health and safety. Nevertheless, when foods are considered novel or unnatural, they are classified as novel foods and are subject to the authorisation procedure.

The dissertation then draws a connection between the risk triggers in the regulation and the psychological factors shaping consumer perception of novel foods. Emotions such as disgust and fear, personality traits like food neophobia and perceived unnaturalness, and socio-cultural norms lead to the formation of negative heuristics and biases in consumers. The "affect", the "natural-is-better" and the "trust" heuristics are identified as the primary heuristic cues in consumer literature affecting consumer acceptance of novel foods. The thesis explores how similar heuristic mechanisms and biases also influence the choice of "novelty" and "unnaturalness" as risk triggers, directly affecting the individual judgment of lawmakers and through societal pressure, leading to overinclusive and restrictive regulations.

The last part of the dissertation investigates the regulatory barriers introduced by the Novel Food Regulation and advances proposals to enable the development and adoption of food innovations in the EU, using alternative proteins as a case study. The broad scope of the framework, the lengthy and costly authorisation procedures, the lack of rewards for innovators, and the uncertain and hostile stance of several EU governments negatively affect the perception of the EU novel food framework among innovators. Through semi-structured interviews with stakeholders and considering best practices from other jurisdictions, namely Singapore and Australia-New Zealand, the thesis advances proposals for modifying the EU framework, centred on the inclusion of design thinking principles into the novel food authorisation procedures.

### **Abstract (Deutsch)**

Innerhalb der Europäischen Union (EU) bildet die Verordnung (EU) Nr. 2283/2015 über neuartige Lebensmittel, bekannt als "Novel Food Verordnung", den primären rechtlichen Rahmen für Innovationen im Lebensmittelsektor. Als neuartige Lebensmittel werden solche definiert, die vor dem 15. Mai 1997 in der Union nicht in nennenswertem Umfang für den menschlichen Verzehr verwendet wurden und die in eine der zehn Kategorien neuartiger Lebensmittel eingeordnet werden können. Die Novel Food Verordnung umfasst einige der vielversprechendsten und umstrittensten neuen Nahrungsquellen und Produktionsprozesse, wie etwa Lebensmittel auf Insektenbasis und kultiviertes Fleisch. Produkte, die als neuartige Lebensmittel eingestuft werden, unterliegen einem Zulassungsverfahren vor dem Inverkehrbringen, das darauf abzielt, ihre Sicherheit nachzuweisen. Das Zulassungsverfahren besteht aus einer Risikobewertung durch die Europäische Behörde für Lebensmittelsicherheit sowie einer abschließenden politischen Genehmigung durch die Europäische Kommission und die EU-Mitgliedstaaten.

Politische Dokumente und wissenschaftliche Literatur betonen, dass neuartige Lebensmittel eine wichtige Rolle beim Übergang der EU zu nachhaltigeren Lebensmittelsystemen spielen können. Die Produktion neuartiger Lebensmittel wie kultiviertes Fleisch erfordert voraussichtlich weniger Ressourcen als herkömmliche Lebensmittel und reduziert negative externe Effekte hinsichtlich Umweltbelastung und Tierschutz.

Diese Dissertation untersucht, ob die Novel Food Verordnung die Förderung von Innovationen im Lebensmittelsektor im Einklang mit ihren etablierten Zielen, nämlich der Sicherstellung des Funktionierens des Binnenmarktes sowie des Schutzes der menschlichen Gesundheit und Sicherheit, ausgewogen berücksichtigt. Die Dissertation leistet einen Beitrag zur akademischen Forschung, indem sie die Innovationsförderung als Ziel der Novel Food Verordnung anerkennt und dadurch eine neue Perspektive für die Forschung in diesem Bereich bietet. Die Forschung basiert auf einem Mixed-Method-Ansatz, der die normative, doktrinäre und vergleichende Analyse des Rechtsrahmens für neuartige Lebensmittel in der EU erweitert und dabei eine interdisziplinäre Perspektive an der Schnittstelle von Recht, Psychologie und Verhaltensökonomie einnimmt. Dies ermöglicht ein vertieftes Verständnis für das Zusammenspiel zwischen Verbraucherurteilen, den Absichten der Gesetzgeber und regulatorischen Hürden. Abschließend schlägt die Dissertation vor, Design-Thinking-Prinzipien in das neuartige Lebensmittelrahmenwerk zu integrieren, um die Förderung von Innovationen im Lebensmittelsektor mit den festgelegten Zielen der Gesetzgebung in Einklang zu bringen.

Der erste Teil dieser Forschung untersucht die Faktoren, die zur Anwendung der Novel Food Verordnung führen. Diese Faktoren werden als "Risikotriggers" bezeichnet und als Merkmale von Produkten und Prozessen definiert, die eine Vermutung eines Risikos für neuartige Lebensmittel begründen und somit eine regulatorische Überwachung auslösen. "Neuheit" und "Unnatürlichkeit" werden als die primären Risikotriggers für die Regulierung neuartiger Lebensmittel anerkannt. Obwohl diese Triggers darauf abzielen, Verbraucher und Umwelt zu schützen, können weder "Neuheit" noch "Unnatürlichkeit" mit einer unmittelbaren Bedrohung der menschlichen Gesundheit und Sicherheit in Verbindung gebracht werden. Dennoch werden Lebensmittel, die als neu oder unnatürlich gelten, als neuartige Lebensmittel eingestuft und unterliegen den Zulassungsverfahren.

Die Dissertation stellt dann eine Verbindung zwischen den Risikotriggers in der Regulierung und den psychologischen Faktoren her, die die Verbraucherwahrnehmung neuartiger Lebensmittel prägen. Emotionen wie Ekel und Angst, Persönlichkeitsmerkmale wie Lebensmittelneophobie und wahrgenommene Unnatürlichkeit sowie sozio-kulturelle Normen führen zur Bildung negativer Heuristiken und Vorurteile bei den Verbrauchern. Die "Affect-Heuristik", die "Natürlich-ist-besser-Heuristik" und die "Vertrauensheuristik" werden als die primären heuristischen Anhaltspunkte in der Verbraucherforschung identifiziert, die die Akzeptanz neuartiger Lebensmittel beeinflussen. Die Arbeit untersucht, wie ähnliche heuristische Mechanismen und Vorurteile auch die Wahl von "Neuheit" und "Unnatürlichkeit" als Risikotriggers beeinflussen und dadurch das individuelle Urteil der Gesetzgeber sowie durch gesellschaftlichen Druck zu überinklusiven und restriktiven Vorschriften führen.

Der letzte Teil der Dissertation untersucht die durch die Novel Food Verordnung eingeführten regulatorischen Barrieren und macht Vorschläge, um die Entwicklung und Einführung von Lebensmittelinnovationen in der EU zu ermöglichen, wobei alternative Proteine als Fallstudie verwendet werden. Der weite Geltungsbereich des Rahmens, die langwierigen und kostspieligen Zulassungsverfahren, das Fehlen von Anreizen für Innovatoren und die unsichere und feindselige Haltung mehrerer EU-Regierungen beeinträchtigen die Wahrnehmung des neuartigen Lebensmittelrahmens der EU unter Innovatoren negativ. Durch halbstrukturierte Interviews mit Stakeholdern und unter Berücksichtigung bewährter Verfahren aus anderen Rechtsordnungen, nämlich Singapur und Australien-Neuseeland, entwickelt die Dissertation

Vorschläge zur Anpassung des EU-Rahmens, unter Einbeziehung von Design-Thinking-Prinzipien in die Zulassungsverfahren für neuartige Lebensmittel.

# Chapter 1

# **General Introduction**

#### 1. Introduction and background

On August 5, 2013, 200 journalists, academics, and scientists gathered in London for a historic event. For the first time ever, people had the opportunity to taste hamburgers made not from traditionally farmed beef, but from lab-grown cells. In the months leading up to the event, Mark Post and his team at the University of Maastricht had grown animal muscle tissue from stem cells, ultimately producing the two burgers. The cells were collected from a Dutch cow called Marte, who survived the process. This first public tasting of lab-grown meat potentially marked the beginning of a new era in meat consumption, one where animals may no longer be necessary to produce food.<sup>1</sup>

In 2020, the company Eat Just received regulatory approval in Singapore to sell chicken nuggets containing a small amount of lab-grown chicken cells.<sup>2</sup> These nuggets, served in local restaurants, became the first commercially available products derived from cultivated cell tissue. By May 2024, the product had reached retail stores, allowing consumers to cook lab-grown chicken at home for the first time.<sup>3</sup>

The emergence of new food sources is driven by the growing demand for sustainable, nutritious, and diverse options, and it is one of the most exciting developments in the food industry.<sup>4</sup> However, innovative products and processes also raise several questions. Influential authors like Michael Pollan, Marion Nestle, and Carlo Petrini have heightened public awareness and scepticism around industrial food production, criticising its effects on public health and the environment.<sup>5</sup> New food sources such as cultivated meat trigger the same concerns that have

<sup>&</sup>lt;sup>1</sup> Paul Shapiro, *Clean Meat* (Gallery Books, 2018). Chapter 3 provides a historically accurate description of the development of the first cultivated meat burger.

<sup>&</sup>lt;sup>2</sup> Mike Ives, 'Singapore Approves a Lab-Grown Meat Product, a Global First' (*The New York Times*, 2 December 2020) <a href="https://www.nytimes.com/2020/12/02/business/singapore-lab-meat.html">https://www.nytimes.com/2020/12/02/business/singapore-lab-meat.html</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>3</sup> Anay Mridul, 'Cultivated Meat in Your Freezer? Available, Lah! In Singapore' (*Green Queen*, 16 May 2024) <a href="https://www.greenqueen.com.hk/eat-just-good-meat-cultivated-chicken-retail-hubers-butchery-singapore/">https://www.greenqueen.com.hk/eat-just-good-meat-cultivated-chicken-retail-hubers-butchery-singapore/</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>4</sup> For an overview of the genealogy of the food innovations' sector and its objectives and promises, see Larissa Zimberoff, *Technically Food: Inside Silicon Valley's Mission to Change What We Eat* (Abrams Press, 2021).

<sup>&</sup>lt;sup>5</sup> For a partial bibliography of the cited authors, refer to Marion Nestle and Michael Pollan, *Food Politics: How the Food Industry Influences Nutrition and Health* (Revised and expanded tenth anniversary edition, University of California Press, 2013); Carlo Petrini, *Slow Food Nation: Why Our Food Should Be Good, Clean, and Fair* (Rizzoli Ex Libris, 2013); Michael Pollan, *The Omnivore's Dilemma: A Natural History of Four Meals* (Penguin Press, 2006).

dominated the public debate over genetically modified organisms, and they could face the same widespread opposition.<sup>6</sup> Regulatory authorities worldwide are being called upon to weigh in on the safety concerns and the potentially revolutionary benefits of these innovations, enabling them to play a key role in the shift towards sustainable food systems. Finding this balance is critical for gaining consumer acceptance and facilitating their adoption.

#### 1.1. The regulation of novel foods in the EU

In the European Union (EU), new food sources are legally categorised as novel foods. Novel foods are defined as foods not used for human consumption to a significant degree within the Union before May 15<sup>th</sup> May 1997, and that can be classified in one of the ten novel food categories.<sup>7</sup> Examples of novel foods include plant-based protein extracts, insects, cultivated meat, algae, nanofoods, and ingredients obtained through precision fermentation.

The regulatory framework applicable to novel foods is shaped by several provisions, which range from labelling law to agricultural law. The most relevant piece of legislation is Regulation (EU) No 2283/2015 on novel foods (hereinafter referred to as the Novel Food Regulation), which regulates the market entry of novel foods.<sup>8</sup> The Novel Food Regulation details the steps of the authorisation procedures for novel foods. The authorisation procedure is based on two distinct and consecutive phases: a risk assessment conducted by the European Food Safety Authority (EFSA) and a risk management step handled by political authorities, the European Commission, and the EU Member States.

<sup>&</sup>lt;sup>6</sup> Joseph Mohorčich and Jacy Reese, 'Cell-Cultured Meat: Lessons from GMO Adoption and Resistance' (2019) 143 Appetite 104408. Refer to sub-chapters 2 and 3 for a complete overview of the similarities between the early stages of genetically modified organisms' development and cultivated meat.

<sup>&</sup>lt;sup>7</sup> 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, p. 1–22. (Hereinafter: NFR). Article 3(2)

<sup>&</sup>lt;sup>8</sup> For a complete overview of the key provisions of the Novel Food Regulation see Jessica Vapnek, Kai Purnhagen and Ben Hillel, 'Regulatory and Legislative Framework for Novel Foods', in Shivani Pathania and Brijesh Tiwari (eds), *Food Formulation* (John Wiley & Sons, Ltd 2021) pp. 285-308; Martin Holle, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing, 2018) pp. 291-330; Julika Lietzow, Claudia Luckert and Bernd Schäfer, 'Novel and Traditional Foods: Novel Food Regulation in the EU' in Franz Reichl and Michael Schwenk (eds), *Regulatory Toxicology* (Springer Berlin Heidelberg, 2020) pp. 1-28.





The authorisation procedure aims to assess that novel foods do not pose a safety risk to human health due to their composition and conditions of use, are as safe as comparable foods and, when they are meant to substitute another food, they do not differ from it in a way that would be nutritionally disadvantageous for the consumers.<sup>9</sup> The Novel Food Regulation finds its legal basis in Article 114(3) of the Treaty of the Functioning of the European Union (TFEU), which states that:

"The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts."<sup>10</sup>

The Novel Food Regulation thus identifies the functioning of the internal market and the protection of human health and safety as its primary goals.<sup>11</sup> This aligns with the traditional focus of EU food law, which developed into a coherent body of legislation following several

<sup>9</sup> NFR (n 7). Article 7

<sup>&</sup>lt;sup>10</sup> Consolidated version of the Treaty on the Functioning of the European Union, OJ C 202, 7.6.2016, p. 1–388. Article 114(3)

<sup>&</sup>lt;sup>11</sup> NFR (n 7). Article 1(2).

food safety crises in the twentieth century.<sup>12</sup> While EU policies increasingly advocate for a more sustainable food system, the Novel Food Regulation does not prioritise innovation as one of its objectives.

#### 1.2. Innovation in EU food policies and in the Novel Food Regulation

In 2019, the European Commission adopted the European Green Deal, a set of policies aimed at achieving climate neutrality in the Union by 2050.<sup>13</sup> The Farm-to-Fork strategy, a component of the European Green Deal focused on making the EU food system more sustainable, fair, and healthy, recognised the importance of research and innovation in accelerating this transition.<sup>14</sup> While the strategy does not explicitly mention novel foods, the European Commission's "Communication on the Farm-to-Fork Strategy" identifies alternative protein as a "*key area of research*".<sup>15</sup>

Alternative proteins include all protein sources other than those from traditional animal farming, such as plant-based products, fermentation-derived products, and lab-cultivated cell tissues. In the EU, alternative proteins frequently fall under the novel food definition and represent the most homogeneous and recognisable subgroup within novel foods. Academic scholarship on alternative proteins views them as crucial for reducing reliance on traditional animal proteins and the associated greenhouse gas emissions.<sup>16</sup>

<sup>&</sup>lt;sup>12</sup> For an overview of the historical development of EU food law and of the adoption of pre-market approval schemes refer to: Sebastian Krapohl, 'Thalidomide, BSE and the Single Market: An Historical-Institutionalist Approach to Regulatory Regimes in the European Union' (2007) 46 European Journal of Political Research 25; Bernd MJ van der Meulen and others, 'Structural Precaution: The Application of Premarket Approval Schemes in EU Food Legislation' (2012) 67 Food and Drug Law Journal 453; Hanna Schebesta and Kai Purnhagen, *EU Food Law* (Oxford University Press, 2024), Chapter 1: 1:The Genesis and Evolution of EU Food Law.

<sup>&</sup>lt;sup>13</sup> European Commission, Communication on the European Green Deal (2019) COM/2019/640. Section 2: 2. Transforming the EU's economy for a sustainable future.

<sup>&</sup>lt;sup>14</sup> European Commission, 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 (2020) COM/2020/381, Section 3: Enabling the transition.

<sup>&</sup>lt;sup>15</sup> ibid. Sub-section 3.1.Research, innovation, technology and investments, "A key area of research will relate to (...) increasing the availability and source of alternative proteins such as plant, microbial, marine and insect-based proteins and meat substitutes."

<sup>&</sup>lt;sup>16</sup> Mario Herrero and others, 'Innovation Can Accelerate the Transition towards a Sustainable Food System' (2020) 1 Nature Food 266; Maria Grazia Calabrese and Pasquale Ferranti, 'Novel Foods: New Food Sources' in Pasquale Ferranti, Elliot Berry and Jock Anderson (eds), *Encyclopedia of Food Security and Sustainability* (Elsevier, 2019) pp. 271-275; Rachel 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. The definition of novel foods used in these articles does not always overall with the legal definition, but they all present relevant data on

For this reason, the European Commission specifically addresses the promotion of alternative proteins within the policy framework aimed at achieving the objectives of the European Green Deal and the Farm-to-Fork Strategy, known as the "Food 2030 Pathways for Action". In the analysis of the status and opportunities within the alternative protein sector, the Novel Food Regulation is recognised as a key factor in its development and as a potential obstacle to the sector growth:

"Authorisation procedures (e.g. for novel food) can take a long time and can be viewed as burdensome (administrative burden) especially for SMEs (small and medium enterprises); legal text can be quite complex or difficult to interpret and apply, it can be costly to comply with new regulatory requirements."<sup>17</sup>

As mentioned earlier, the promotion of innovation is not listed among the objectives of the Novel Food Regulation, which explicitly refers only to the functioning of the internal market and to protecting consumer health and safety.<sup>18</sup> However, Recital 29 of the Regulation states that:

"New technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured."

The following Recital 30 also claims that the efforts of innovators must be rewarded.<sup>19</sup> Although recitals are non-binding, they provide a more nuanced interpretation of legislative

the impact that new products and processes, especially alternative proteins, can have on mitigating climate change consequences.

<sup>&</sup>lt;sup>17</sup> European Commission. Directorate General for Research and Innovation, 'Food 2030 Pathways for Action: Research and Innovation Policy as a Driver for Sustainable, Healthy and Inclusive Food Systems' (Publications Office, 2020) https://data.europa.eu/doi/10.2777/104372 accessed 19 September 2024. Pathway 4 Alternative Proteins and Dietary Shift, Barriers and lock-ins, p 54.

<sup>&</sup>lt;sup>18</sup> NFR (n 7). Article 1(2).

<sup>&</sup>lt;sup>19</sup> ibid. Recital 30. "Under specific circumstances, in order to stimulate research and development within the agrifood industry, and thus innovation, it is appropriate to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation."

acts by clarifying their intent and scope.<sup>20</sup> Recitals 29 and 30 of the Novel Food Regulation highlight the connection between the regulatory framework for novel foods and innovation in the food sector.

Additionally, the connection between innovation and the Novel Food Regulation has been consistently emphasised in the political debate. During the European Parliament vote on the Novel Food Regulation on October 15, 2015, Members of Parliament's interventions focused on how the new regulation might influence innovation in the food sector.<sup>21</sup> Similarly, the promotion of innovation was listed among the objectives of the "Financial Statement of the Proposal for a Regulation on Novel Foods",<sup>22</sup> which served as the basis for drafting the Novel Food Regulation. Following the adoption of the regulation, guidance documents and official statements from the European Commission have highlighted the regulation's role in supporting and rewarding innovators. For instance, the "Q&A" document published after the legislation's adoption states that: *"The new Novel Food Regulation aims to help innovators and economic operators develop and put on the European Union market new food while maintaining a high level of consumer safety.*"<sup>23</sup>

Academic literature, before and after the adoption of the Novel Food Regulation, has examined the impact of the Novel Food Regulation on the food sector and underlined how regulatory barriers to the market entry of novel foods play a crucial role in shaping the future food system.<sup>24</sup> Supporting the innovation process can help achieve the legislation's objectives by promoting the adoption of healthier and sustainable food sources.<sup>25</sup>

<sup>&</sup>lt;sup>20</sup> Todas Klimas and Jurate Vaiciukaite, 'The Law of Recitals In European Community Legislation' (2008) 15 ILSA Journal of International & Comparative Law 61.

<sup>&</sup>lt;sup>21</sup> European Parliament, 'Debates - Novel Foods - Wednesday, 28 October 2015' <<u>https://www.europarl.europa.eu/doceo/document/CRE-8-2015-10-28-ITM-005\_EN.html</u>> accessed 19 September 2024. See in particular interventions from James Nicholson, rapporteur for the proposal of the Novel Food Regulation, and Commissioner Vytenis Povilas Andriukaitis.

<sup>&</sup>lt;sup>22</sup> European Commission, Proposal for a Regulation of the European Parliament and of the Council on Novel Foods /\* COM/2013/0894 final - 2013/0435 (COD) \*/ 2013. Legislative Financial Statement. Section 1.4.1(3).

<sup>&</sup>lt;sup>23</sup> European Commission, 'Q&A on the Novel Food Regulation' <a href="https://food.ec.europa.eu/system/files/2018-01/fs\_novel-food\_leg\_q-n-a-new-regulation-nf\_en.pdf">https://food.ec.europa.eu/system/files/2018-01/fs\_novel-food\_leg\_q-n-a-new-regulation-nf\_en.pdf</a>> accessed 19 September 2024. "Will the new Novel Food Regulation affect innovation in the food sector?".

<sup>&</sup>lt;sup>24</sup> Holle (n 8); Lietzow, Luckert and Schäfer (n 8).

<sup>&</sup>lt;sup>25</sup> Anu Lähteenmäki-Uutela and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336.

#### 1.3. The Novel Food Regulation and consumer perception of novel foods

The authorisation procedure aims to protect consumers from potential hazards posed by novel foods and to ensure that they are as safe as any other food. However, the regulatory requirements set out in the Novel Food Regulation are closely related to another fundamental challenge: gaining consumer acceptance and societal approval. Unfortunately, this challenge often proves difficult to overcome. Two examples illustrate this issue.

Since 2021, several insect products have been authorised for human consumption in the EU through the novel food authorisation procedure. This approval has sparked widespread opposition, primarily for two reasons.<sup>26</sup> Critics argue that consuming insects may pose potential safety risks, since they have not been traditionally consumed by Europeans. Additionally, they contend that incorporating insects into the European diet could undermine traditional diets. These objections persist even though insect-based novel foods have been authorised following rigorous risk assessments by the EFSA, and despite the fact that concerns about their impact on traditional diets fall outside the current scope of the Novel Food Regulation. These criticisms exemplify the challenges that even authorised novel foods may face in overcoming public opposition before and after their approval.

Similarly, on December 1<sup>st</sup>, 2023, the Italian government banned the production and sale of products of cellular agriculture, namely cultivated meat, and prohibited the use of meat-sounding denominations for plant-based products. The law is based on the precautionary principle aiming to safeguard consumer health and safety and preserve Italy's national gastronomic heritage.<sup>27</sup> The Italian ban has prompted similar legislative efforts in other EU member states such as France, Romania and Poland.<sup>28</sup> In January 2024, fourteen member states

<sup>&</sup>lt;sup>26</sup> Examples of public outcry for insects approvals in Italy and Germany can be found in Solvejg Hoffmann, 'Grillenmehl in Lebensmitteln: EU Erlaubt Beimischung von Insektenpulver' (*GEO*, 19 January 2023) <a href="https://www.geo.de/wissen/ernaehrung/insekten-in-lebensmitteln-jetzt-in-der-eu-zugelassen-33115156.html">https://www.geo.de/wissen/ernaehrung/insekten-in-lebensmitteln-jetzt-in-der-eu-zugelassen-33115156.html</a> accessed 19 September 2024 ; Marco Leardi, 'Gli insetti arrivano al supermercato. Un attacco alla dieta mediterranea' (*Il Giornale*, 24 January 2023) <a href="https://www.ilgiornale.it/news/europa/attacco-dieta-mediterranea-insetti-tavola-ora-sono-commercio-2108431.html">https://www.ilgiornale.it/news/europa/attacco-dieta-mediterranea-insetti-tavola-ora-sono-commercio-2108431.html</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>27</sup> LEGGE 1° dicembre 2023, n. 172. Disposizioni in materia di divieto di produzione e di immissione sul mercato di alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o di tessuti derivanti da animali vertebrati nonché di divieto della denominazione di carne per prodotti trasformati contenenti proteine vegetali. Article 1 outlines the objectives of the legislation; Article 2 directly refers to the precautionary principle.

<sup>&</sup>lt;sup>28</sup> Francesco Planchestainer, 'Meat Me in Italy: The Italian Ban on Sounding Names and Cell-Cultured Meat' (2024) 19 European Food and Feed Law Review 66.

expressed concerns within the Council of the European Union about the adequacy of the Novel Food Regulation in regulating cellular agriculture. The governments of these countries advocate for a more encompassing regulatory framework that would address the ethical, economic, and social issues raised by cultivated meat.<sup>29</sup> Farmers' associations and consumer groups have backed up all these initiatives.<sup>30</sup> While these actions may be motivated by legitimate concerns, they appeared premature, since no novel food applications for lab-grown meat or similar products had been submitted within the EU at the time.<sup>31</sup> This pre-emptive opposition underscores a persistent lack of trust in innovative products, even when they are still in the early stages of development.

These examples illustrate the common societal and consumer apprehension towards novel foods. Novel foods have the potential to revolutionise our food production systems, which can lead to significant changes in our diets and eating habits. Food is deeply intertwined with culture, evoking strong emotions and personal connections. As humans, we often approach new foods with a mix of fear and curiosity: instinctively aware of the risks they might pose, yet eager to try them.<sup>32</sup> Throughout history, human societies have often included new foods in their diets when their benefits were clear or when they appealed to their taste.<sup>33</sup>

The tendency to reject novel foods mirrors the opposition encountered by other technological innovations, such as Genetically Modified Organisms (GMOs). How society perceives the risks

<sup>&</sup>lt;sup>29</sup> General Secretariat of the Council 'Note to Council: The CAP's role on safeguarding high-quality and primary farm-based food production' (2024), 5469/1/24 REV 1.

<sup>&</sup>lt;sup>30</sup> See for example the position of the two main farmers associations in Italy and France: Confédération paysanne, 'Viande in Vitro: Pour La Confédération Paysanne c'est Non!' (*Press release*, 2023) <a href="https://www.confederationpaysanne.fr/actu.php?id=13176">https://www.confederationpaysanne.fr/actu.php?id=13176</a>> accessed 19 September 2024; Bluarancio S.p.A and Massimiliano Paoloni, 'Il Cibo Artificiale è Fuorilegge, Ha Vinto Coldiretti' (*Il punto Coldiretti*, 17 November 2023) <a href="https://www.ilpuntocoldiretti.it/attualita/economia/il-cibo-artificiale-e-fuorilegge-ha-vinto-coldiretti/">https://www.ilpuntocoldiretti.it/attualita/economia/il-cibo-artificiale-e-fuorilegge-ha-vinto-coldiretti/</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>31</sup> On July 26 2024, news of the first-ever application for a cultivated meat product in the EU was announced by the company Gourmey. As of September 2024, no official document concerning the application is available. For a brief overview of this development see: Tilman Reinhardt, Alessandro Monaco and Kai Purnhagen, 'Cultivated Foie Gras Flies into Europe – Prepare for Legal Disruption' (2024) European Law Blog <10.21428/9885764c.cff9f420> accessed 19 September 2024.

<sup>&</sup>lt;sup>32</sup> Harvey Levenstein, *Fear of Food: A History of Why We Worry about What We Eat* (University of Chicago, Press 2012). The book explores the historical and cultural reasons behind the anxiety and fear that people often have about the food they consume.

<sup>&</sup>lt;sup>33</sup> For a description of dietary changes due to the adoption of new foods see Jeffrey M Pilcher, *Food in World History* (Routledge, 2023), passim.

associated with novel foods can shape the contours of their regulation. The experience with GMOs foreshadows potential challenges that novel foods might face. Consumer scepticism has significantly influenced GMO regulation, resulting in a framework that scholars criticise for its detrimental impact on the EU biotech sector due to the regulatory hurdles it imposes.<sup>34</sup>

Legislators, influenced by public sentiment and debate, decide which aspects warrant oversight and craft regulatory frameworks accordingly. When public discourse frames new technologies negatively and consumer perception is wary, policymakers often lean toward more restrictive regulations. Overregulation can inflate costs and erect formidable barriers, hindering market entry and the broader acceptance of innovative products.<sup>35</sup> When risk factors initiating the legislation's application are not based on scientific and rational considerations, they lead to regulatory hurdles that stifle innovation and diminish potential benefits.<sup>36</sup> This dissertation explores how the triggers for regulatory action influence the innovation process and its outcomes.

#### 2. Objectives of the dissertation and research questions

This dissertation explores whether the EU regulatory framework for novel foods effectively balances its traditional focus on protecting human health and safety with the promotion of innovation in the food sector. It first examines the factors that trigger the application of the Novel Food Regulation and investigates their relationship with the psychological drivers influencing consumer perception of novel foods. Subsequently, the dissertation elaborates on proposals for amending the novel food framework to enhance its capacity to support and facilitate innovation within the EU food sector.

The originality of this research lies in its interdisciplinary approach to examining the psychological factors that influence the regulatory framework for novel foods in the EU. Additionally, this dissertation offers the first comparative analysis of the Novel Food

<sup>&</sup>lt;sup>34</sup> Andreas T Christiansen, Martin Marchman Andersen and Klemens Kappel, 'Are Current EU Policies on GMOs Justified?' (2019) 28 Transgenic Research 267.

<sup>&</sup>lt;sup>35</sup> Flora Southey, 'GMO "Overregulation" Hinders Tech Development, Market Diversity, and Food Security, Says Researcher' (*Food Navigator*, 8 April 2019) <a href="https://www.foodnavigator.com/Article/2019/04/08/GMO-overregulation-hinders-tech-development-market-diversity-and-food-security-says-researcher">https://www.foodnavigator.com/Article/2019/04/08/GMO-overregulation-hinders-tech-development-market-diversity-and-food-security-says-researcher</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>36</sup> Shmuel Becher, 'The Alternative Meat of the Matter' (2024) 98 Tulane Law Review 99.

Regulation with the regulatory frameworks of Australia-New Zealand and Singapore, focusing on how these jurisdictions foster innovation in the food sector. Finally, this dissertation provides the first in-depth analysis of the EU novel food framework using design thinking principles.

#### 2.1. Research questions

The overarching research question of the dissertation can be formulated as follows:

How does the EU regulatory framework for novel foods proportionally balance the promotion of innovation with its established objectives of ensuring the functioning of the internal market and protecting human health and safety, considering the risk triggers prompting the application of the legislation and the effects of subsequent regulatory provisions?

To operationalise it, four sub-questions have been formulated:

• Which risk triggers are currently employed for regulating novel foods in the EU?

The Novel Food Regulation applies to food products that fall under the definition of novel foods. Identifying which factors prompt the application of the Novel Food Regulation, essentially determining what distinguishes a food from a novel food, is instrumental for examining the foundation of the regulatory regime governing novel foods.

• How do these risk triggers relate to the psychological factors shaping consumer perception and acceptance of novel foods?

Once the risk triggers are identified, the dissertation explores their connection to the psychological factors affecting consumer acceptance of novel foods. The aim of this analysis is to assess the basis on which the legislators have identified these risk triggers and evaluate their suitability for regulating innovation.

• What impact do risk triggers have on the innovation process, and which are the resulting regulatory barriers for novel foods in the EU, compared to other jurisdictions?

Once the relationship between psychological factors influencing consumer perception of novel foods and the selection of specific risk triggers is established, the dissertation provides a

detailed analysis of the effects of the resulting regulatory requirements. This analysis aims to understand how these provisions influence the actions of innovators and other stakeholders, while also comparing the regulatory barriers in the EU with those in other jurisdictions.

• Which proposals can be advanced to amend the existing regulatory framework to facilitate the market entry and the adoption of novel foods, while still ensuring a high level of consumer protection?

Based on the analysis of the regulatory barriers impacting innovation within the Novel Food Framework, this dissertation will propose amendments to the existing framework to introduce a more innovation-friendly approach without compromising on the explicit objectives of the legislation, namely protecting consumer health and safety.

### 2.2. Alternative proteins as a case study for novel foods regulation

Throughout the dissertation, alternative proteins are used as a case study. For the purposes of this research, alternative proteins are defined as any new food source intended to replace traditional animal proteins. This includes plant-based products, fermentation-based products, cellular agriculture products, and insects.

The decision to use alternative proteins as a case study is based on several reasons. First, alternative proteins represent a distinct and recognisable sub-group within the broader category of novel foods, both in the European Union and other jurisdictions. Second, there is a substantial body of literature exploring consumer perception of alternative proteins. Lastly, alternative proteins are subject to significant public scrutiny and are central to regulatory initiatives concerning novel foods in the EU and other jurisdictions.

### 3. Theoretical framework

#### 3.1. Innovative regulations to regulate innovations: the concept of legal disruption

The relationship between regulation and innovation is complex, involving interactions among legal, political, and economic institutions. Depending on how it is designed and implemented, regulation can either hinder or promote the development and adoption of innovation. <sup>37</sup> While

<sup>&</sup>lt;sup>37</sup> Michael E Porter, 'America's Green Strategy' (1991) 264 Scientific American 168; Stephan Haggard, Andrew MacIntyre and Lydia Tiede, 'The Rule of Law and Economic Development' (2008) 11 Annual Review of Political Science 205; Margaret R Taylor, Edward S Rubin and David A Hounshell, 'Regulation as the Mother of 24

it is often advocated that more lenient regulatory frameworks benefit innovation, this is not always true.<sup>38</sup> Strict rules can prompt higher efforts to ensure compliance, and well-designed, context-specific regulatory frameworks, when applied consistently, can catalyse innovation by enabling radical breakthroughs.<sup>39</sup> Thus, regulation is sometimes viewed as a positive force in fostering innovation, particularly in the context of sustainability transformations.<sup>40</sup> In this regard, regulation goes beyond the enforcement of rules and positively steers the innovation process, providing the conditions that support and facilitate the work of innovators,<sup>41</sup> influencing not only the development of new technologies, but also their adoption and practical application.<sup>42</sup>

At the same time, innovation can also affect regulation when there is a mismatch between existing rules and the rapid pace of technological advancements. Regulators then either struggle to adapt the old regulatory frameworks to keep pace with evolving contexts or establish new

Innovation: The Case of SO2 Control\*' (2005) 27 Law & Policy 348; Rosina Watson and others, 'Policy for Sustainable Entrepreneurship: A Crowdsourced Framework' (2023) 383 Journal of Cleaner Production 135234. The seminal work of Porter refers to environmental regulation, which was earlier described as detrimental for business but that he saw as enhancing competitiveness, if well designed and tailored. His perspective is similar to Haggard et al.'s discussion on the complexity and contextual nature of context-specific regulations, that is necessary to support innovation. Taylor et al. explores the relationship between innovation and regulation, seeing the latter as a condition for stimulating the former. Watson et al. offer proposals of how sustainable entrepreneurship policy could facilitate and control the innovation process.

<sup>&</sup>lt;sup>38</sup> Anu Bradford, 'The False Choice Between Digital Regulation and Innovation' (2024) 118 Northwestern University Law Review. Accessed as preprint on SSRN Electronic Journal: https://dx.doi.org/10.2139/ssrn.4753107. Bradford debates and challenges the basic assumption that lenient regulation can lead to innovation, claiming that the relationship between regulation and innovation is more complex and multifaced.

<sup>&</sup>lt;sup>39</sup> Philippe Aghion, Antonin Bergeaud and John Van Reenen, 'The Impact of Regulation on Innovation' (*National Bureau of Economic Research*, 2021) < https://doi.org/10.3386/w28381> accessed 19 September 2024.

<sup>&</sup>lt;sup>40</sup> Taylor, Rubin and Hounshell (n 37); Porter (n 37); An alternative view on Porter's theory is given in Karen Palmer, Wallace E Oates and Paul R Portney, 'Tightening Environmental Standards: The Benefit-Cost or the No-Cost Paradigm?' (1995) 9 Journal of Economic Perspectives 119, where the lack of empirical evidence supporting the Porter's hypothesis is anecdotal.

<sup>&</sup>lt;sup>41</sup> Guichuan Zhou and others, 'Be Regulated before Be Innovative? How Environmental Regulation Makes Enterprises Technological Innovation Do Better for Public Health' (2021) 303 Journal of Cleaner Production 126965.

<sup>&</sup>lt;sup>42</sup> Becher (n 36); Shuai Shao and others, 'Environmental Regulation and Enterprise Innovation: A Review' (2020) 29 Business Strategy and the Environment 1465. Both Becher and Shao et al. refer to the role played by regulation in the adoption of innovations.

ones. Different innovations may require varying levels of regulatory adaptation.<sup>43</sup> The impact of new technologies on legal frameworks can range from minimal to highly disruptive. This phenomenon is known as "legal disruption".<sup>44</sup> If there is no legal disruption, the technology aligns with existing regulations. Minor disruption necessitates only slight adjustments. Significant legal disruption leads to the creation of entirely new frameworks.<sup>45</sup>





The Novel Food Regulation's existence and legislative history are an example of legal disruption. When the first novel food regulation was adopted in 1997,<sup>47</sup> the legislator recognised the need for a pre-market approval process for new foods and genetically modified organisms.

<sup>&</sup>lt;sup>43</sup> Christian Twigg-Flesner, 'Disruptive Technology - Disrupted Law? How the Digital Revolution Affects (Contract) Law' in Alberto De Franceschi (ed), *European Contract Law and the Digital Single Market* (Intersentia, 2016).

<sup>&</sup>lt;sup>44</sup> Roger Brownsword, 'Law Disrupted, Law Re-Imagined, Law Re-Invented' (2019) 2019 Technology and Regulation 10.

<sup>&</sup>lt;sup>45</sup> Twigg-Flesner (n 43).

<sup>&</sup>lt;sup>46</sup> ibid. The framework illustrated in Figure 2 is based on the theory of legal disruption as elaborated by Twigg Flesner; Figure 2 also derives from Figure 1 in Kai Purnhagen, 'You Want It Extra CRISPERY? Legal Disruption through New Plant Breeding Technologies in the EU' (2021) 40 Yearbook of European Law 374.

<sup>&</sup>lt;sup>47</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p.1 1997.

Over time, as the EU adopted a more comprehensive approach to food regulation, calls for reforming the 1997 regulation emerged,<sup>48</sup> leading to a new proposal from the Commission in 2008.<sup>49</sup> The revised Novel Food Regulation was eventually adopted in 2015. Today, the regulation faces similar adaptation challenges, with critics arguing for a regulatory framework better suited to emerging disruptive technologies, such as cultivated meat.

#### **3.2.** Factors influencing the adoption of a regulatory framework

The regulation of innovation is shaped by a complex interplay of economic, social, and cultural factors that affect its objectives and implementation.<sup>50</sup> In the EU food sector, the primary goal of regulating innovation is to ensure that new products and processes do not pose a threat to consumer health and safety. The Novel Food Regulation is designed to protect consumer interests and ensure the internal market's functioning. The authorisation procedures are specifically intended to assess and manage the potential risks of novel foods.

The perception of risk is rooted in human psychology. People often categorise novel products and processes based on similarities,<sup>51</sup> attempting to apply their pre-existing attitudes to these new categories.<sup>52</sup> For example, consumers might perceive cultivated meat grown in bioreactors as either a high-tech, unnatural product akin to GMOs or as a traditional fermentation process reminiscent of beer production. Emotions, personal attitudes, and cultural and social identities are crucial in shaping how novel foods are perceived and classified.<sup>53</sup> These psychological

<sup>&</sup>lt;sup>48</sup> Michael Hermann, 'The Impact of the European Novel Food Regulation on Trade and Food Innovation Based on Traditional Plant Foods from Developing Countries' (2009) 34 Food Policy 499.

<sup>&</sup>lt;sup>49</sup> European Commission. Proposal for a Regulation of the European Parliament and of the Council on novel foods /\* COM/2007/0872 final - COD 2008/0002.

<sup>&</sup>lt;sup>50</sup> George J Stigler, 'The Theory of Economic Regulation' (1971) 2 The Bell Journal of Economics and Management Science 3. Stigler's work highlights the inherent connection between economic regulation and political behavior, arguing that regulatory outcomes are often shaped by the interests and actions of organized groups within the political system.

<sup>&</sup>lt;sup>51</sup> Barbara Loken, Lawrence W Barsalou and Christopher Joiner, 'Categorization Theory and Research in Consumer Psychology: Category Representation and Category-Based Inference' in Curtis P Haugtvedt, Paul M Herr and Frank R Kardes (eds), *Handbook of consumer psychology* (Taylor & Francis Group/Lawrence Erlbaum Associates, 2008) pp. 133-163.

<sup>&</sup>lt;sup>52</sup> Barbara Loken and Deborah Roedder John, 'Diluting Brand Beliefs: When Do Brand Extensions Have a Negative Impact?' (1993) 57 Journal of Marketing 71.

<sup>&</sup>lt;sup>53</sup> Michael Siegrist and Christina Hartmann, 'Consumer Acceptance of Novel Food Technologies' (2020) 1 Nature Food 343; Elena Faccio and Lucrezia Guiotto Nai Fovino, 'Food Neophobia or Distrust of Novelties? Exploring Consumers' Attitudes toward GMOs, Insects and Cultured Meat' (2019) 9 Applied Sciences 4440.

factors produce biases and heuristics and significantly influence decision-making regarding novel foods, impacting their long-term adoption and acceptance.<sup>54</sup>

Regulation is not always driven by rational factors.<sup>55</sup> Especially when a topic is controversial and evokes strong emotional responses, regulatory decisions are often influenced by the psychological attitudes of society or by the actions of particularly vocal groups.<sup>56</sup> Policymakers are affected by social norms, cultural values, psychological factors and beliefs, which direct their focus toward issues perceived as significant by the public and lead to the formation of biases, which impact the formulation and implementation of regulatory measures.<sup>57</sup> This can sometimes result in costly and undesirable consequences, such as hindering the adoption of innovations that could benefit society.<sup>58</sup>

One example is the case of New Plant Breeding Techniques (NPBTs). NPBTs share similarities with traditional mutagenesis techniques used in plant breeding since the 1920s, but they allow for faster and more precise editing of the genome.<sup>59</sup> NPBTs are seen as a significant advancement over traditional breeding methods since they accelerate the development of new varieties with desirable traits.<sup>60</sup> However, opponents of NPBTs frame them as being more akin to transgenic GMOs than to traditional plant-breeding techniques. This perception has

<sup>&</sup>lt;sup>54</sup> Jennifer S Lerner and others, 'Emotion and Decision Making' (2015) 66 Annual Review of Psychology 799.

<sup>&</sup>lt;sup>55</sup> Roger G Noll and James E Krier, 'Some Implications of Cognitive Psychology for Risk Regulation' (1990) 19 The Journal of Legal Studies 747; Jeffrey Rachlinski and Cynthia Farina, 'Cognitive Psychology and Optimal Government Design' (2002) 87 Cornell Law review 549.

<sup>&</sup>lt;sup>56</sup> Cass R Sunstein, *Laws of Fear beyond the Precautionary Principle* (Cambridge University Press, 2005), pp. 13-34.

<sup>&</sup>lt;sup>57</sup> Russell B Korobkin, 'The Problems with Heuristics for Law' in Gerd Gigerenzer and Christoph Engel (eds), *Heuristics in the Law* (MIT Press, 2006) pp. 45-60.

<sup>&</sup>lt;sup>58</sup> Timur Kuran and Cass R Sunstein, 'Availability Cascades and Risk Regulation' (1999) 51 Stanford Law Review 683.

<sup>&</sup>lt;sup>59</sup> Frank Hartung and Joachim Schiemann, 'Precise Plant Breeding Using New Genome Editing Techniques: Opportunities, Safety and Regulation in the EU' (2014) 78 The Plant Journal 742.

<sup>&</sup>lt;sup>60</sup> Rim Lassoued and others, 'Expert Opinions on the Regulation of Plant Genome Editing' (2021) 19 Plant Biotechnology Journal 1104.

negatively impacted the reception of NPBTs within the EU, leading to regulatory stagnation and decelerating innovation in the sector.<sup>61</sup>

Regulation both shapes and adapts to technological innovation.<sup>62</sup> In an era of rapid changes to the food systems, regulation must create the proper context for developing innovations necessary to tackle challenges such as sustainability and food security. Legislators and policymakers must consider public opinion when designing such frameworks, but they should also balance citizens' biases by weighing the actual risks and benefits of new technologies.

#### 3.3. Design thinking principles for the regulation of innovation

Design thinking is a solution-focused method derived from design theory, the starting points of which are the users' implicit and explicit needs.<sup>63</sup> The application of principles from design thinking theory has been proposed to regulate disruptive innovations due to the significant emphasis placed on communication between product or service designers and end users.<sup>64</sup> For the scope of this dissertation, the authorisation procedures for novel foods are viewed as a legal service aimed at "users", primarily innovative companies seeking approvals for novel foods. In this context, the "designers" are the legislators who establish the principles for novel food authorisation procedures, along with the regulatory agencies that set the scientific requirements for risk assessment.<sup>65</sup>

Early-stage engagement between authorities and innovators, the core principle of design thinking, can help define the legislation's scope and identify critical points in the framework.<sup>66</sup>

65 ibid.

<sup>&</sup>lt;sup>61</sup> Purnhagen (n 46); Kai Purnhagen and Justus Wesseler, 'EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2020) 43 Applied Economic Perspective and Policy 1621.

<sup>&</sup>lt;sup>62</sup> Roger Brownsword, *Law, Technology and Society: Re-Imagining the Regulatory Environment* (Routledge 2019), Part Three: Re-imagining Legal Rules, passim.

<sup>&</sup>lt;sup>63</sup> Pietro Micheli and others, Doing Design Thinking: Conceptual Review, Synthesis, and Research Agenda (2019)36 Journal of Product Innovation Management 124.

<sup>&</sup>lt;sup>64</sup> Alice Armitage, Andrew Cordova and Rebecca Siegel, Design Thinking: The Answer to the Impasse Between Innovation and Regulation (2017) 2 Georgetown Law Technology Review 3.

<sup>&</sup>lt;sup>66</sup> Brahim Benichou Vranckaert Thomas Gils, Koen, 'Design Thinking in the Legislative Process: The Key to Useable Legislation?' (*CITIP blog*, 2021) <a href="https://www.law.kuleuven.be/citip/blog/design-thinking-in-the-legislative-process/">https://www.law.kuleuven.be/citip/blog/design-thinking-in-the-legislative-process/</a> accessed 19 September 2024.

This could cut down costs for businesses and public authorities and facilitate the development and adoption of novel foods.<sup>67</sup> Throughout this dissertation, the application of design thinking principles to the authorisation procedures for novel foods is proposed as a strategy to reduce the regulatory burden on the innovators without compromising on the protective objectives of the legislation.

### 4. Methodological approaches

This dissertation employs a variety of methodologies, detailed at the beginning of each chapter. The dissertation is essentially based on a doctrinal legal analysis of the provisions regulating novel foods in the EU. Doctrinal legal research is a method of legal analysis that focuses on the examination and interpretation of existing legal principles, rules, statutes, and case law, with the goal of providing a theoretical and analytical foundation for understanding and interpreting the law governing a particular subject.<sup>68</sup> The doctrinal legal analysis thus provides a theoretical and analytical foundation for understanding the EU.

The doctrinal legal analysis is frequently combined with studies of the practical applications of regulatory provisions. While doctrinal legal research focuses on the theoretical aspects of the law, the functional legal analysis seeks to understand how legal principles and regulatory provisions operate in practice and impact individuals, businesses, or society at large to achieve their purposes. To do so, the functional legal analysis often considers the social, economic, and political context in which regulatory provisions operate. In this dissertation, the functional legal analysis considers empirical data and case studies to elaborate proposals for reforming and improving the practical functioning of the novel food framework in the EU.

The dissertation relies on comparative legal analyses with novel food frameworks outside the European Union, specifically Singapore and Australia-New Zealand. Through the systematic comparison of regulatory provisions and their implementations across different jurisdictions, the comparative legal analysis allows for a deeper understanding of their strengths and

<sup>&</sup>lt;sup>67</sup> Allan Lind and Christiane Arndt, 'Perceived Fairness and Regulatory Policy: A Behavioural Science Perspective on Government-Citizen Interactions' *OECD Regulatory Policy Working Papers*, No. 6 (OECD Publishing, 2016) <http://dx.doi.org/10.1787/1629d397-en> accessed 19 September 2024.

<sup>&</sup>lt;sup>68</sup> Terry Hutchinson, 'The Doctrinal Method: Incorporating Interdisciplinary Methods in Reforming the Law' (2015) 3 Erasmus Law Review 130; Terry Hutchinson and Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17 Deakin Law Review 83.

weaknesses facilitating the identification of potential reforms.<sup>69</sup> For this dissertation, the aim of the comparative analyses is to uncover effective practices in other jurisdictions that could inform improvements to the novel food framework in the EU. The goal is to enhance the novel food framework's ability to foster innovation while ensuring consumer health and safety.

The legal analyses in this dissertation extend beyond the mere interpretation of regulatory provisions. They incorporate reflections on the lawmakers' intentions through a broad, interdisciplinary lens.<sup>70</sup> This called for insights from other fields and the production of empirical, original data. A systematic review of academic literature on how heuristics and biases influence consumer acceptance of novel foods offered the empirical foundation for interdisciplinary research at the intersection of law and psychology.<sup>71</sup> Semi-structured interviews with relevant stakeholders provided personal perspectives on how regulatory frameworks impact their decisions and actions.<sup>72</sup>

#### 5. Structure of the dissertation

The dissertation is divided into chapters based on articles published or currently under review in scientific journals, as outlined in Table 1. The articles have been adapted for the purpose of this dissertation to ensure internal coherence.<sup>73</sup> The dissertation also comprises a general introduction in Chapter 1 and a general conclusion in Chapter 8.

<sup>&</sup>lt;sup>69</sup> Julie De Coninck, 'The Functional Method of Comparative Law: "Quo Vadis"?' (2010) 74 Rabels Zeitschrift für ausländisches und internationales Privatrecht 318; Ralf Michaels, 'The Functional Method of Comparative Law' in Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law* (Oxford University Press, 2005) pp. 339-382.

<sup>&</sup>lt;sup>70</sup> Terry Hutchinson, 'Vale Bunny Watson? Law Librarians, Law Libraries, and Legal Research in the Post-Internet Era' (2014) 106 Law Library Journal 579; Lauren B Edelman and Robin Stryker, '23. A Sociological Approach to Law and the Economy' in Neil J Smelser and Richard Swedberg (eds), *The Handbook of Economic Sociology* (Princeton University Press 2010) pp. 527-551.

<sup>&</sup>lt;sup>71</sup> David Gough, Ruth Stewart and Jan Tripney, 'Using Research Findings' in Sandy Oliver and James Thomas (eds), *An Introduction to Systematic Reviews* (Sage, 2012) pp. 279-296.

<sup>&</sup>lt;sup>72</sup> Cormac McGrath, Per J Palmgren and Matilda Liljedahl, 'Twelve Tips for Conducting Qualitative Research Interviews' (2019) 41 Medical Teacher 1002.

<sup>&</sup>lt;sup>73</sup> This dissertation uses the Oxford Standard for Citation Of Legal Authorities (OSCOLA) referencing style. Some of the chapters were originally published in journals requiring the use of the American Psychological Association (APA) reference style. The reference style for these chapters was changed to OSCOLA to ensure internal coherence.

Throughout Chapters 2, 3 and 4, the dissertation delves into the concept of risk triggers, examining how they shape the novel food regulatory framework and reflect societal attitudes toward risk and food innovations. The second half of the thesis, in Chapters 5, 6 and 7, focuses on the resulting regulatory barriers in the EU novel food framework and its capacity to enable innovation.

Chapter 2 justifies the promotion of innovation as an implicit objective of the novel food framework in the EU and introduces the concept of risk triggers. Risk triggers are characteristics of innovative products and processes that distinguish them from traditional alternatives. Risk triggers are traits recognised by legislators as potentially dangerous, and thus prompt the application of specific regulatory provisions, such as authorisation procedures, labelling requirements and additional conditions of use. "Novelty" and "unnaturalness" are identified as the primary risk triggers driving the regulation of novel foods in the EU.

Chapter 3 presents the results of a systematic review of primary literature on consumer perception of novel foods in Western countries. The review analyses the impact of biases and heuristics on the perception of novel foods. The review clusters the emotions, personality traits, and socio-cultural factors responsible for consumer perception into three primary heuristics cues: the "affect", the "natural-is-better", and the "trust" heuristics. The chapter outlines how biases arising from these heuristics mirrors the use of "novelty" and "unnaturalness" as risk triggers for the regulation of novel foods in the EU.

Chapter 4 investigates the relationship between the biases and heuristics identified in the systematic review and the selection of "novelty" and "unnaturalness" as risk triggers for novel foods and GMOs in the EU. The choice "novelty" and "unnaturalness" are based on psychological mechanisms similar to the heuristics and biases shaping consumer perception of novel foods. The chapter first critically assesses whether these risk triggers, used to initiate regulatory actions, are suitable indicators of risk or if they merely mirror societal biases rather than objective safety concerns. It then examines how these biases influence the legislators' choices according to the Cognitive Psychology Theory.

Chapter 5 consists of a functional comparative legal analysis of the regulatory frameworks applicable to novel foods in the EU and Australia-New Zealand, using alternative proteins as a case study. The Australia-New Zealand jurisdiction was chosen for its similar, though not identical, definitions of novel foods and its authorisation procedures, which, like in the EU, are
also divided between a scientific risk assessment and political risk management. The chapter integrates classic comparative legal methods with empirical data, including the number of approvals and average lengths of procedures, as well as qualitative insights gathered from interviews with stakeholders. These interviews provide valuable perspectives on the regulatory barriers encountered in each framework, highlighting how these barriers affect innovation and market access for novel foods.

Chapter 6 discusses the potential advantages and drawbacks of the data protection clause, the main regulatory instrument for rewarding the efforts of innovators in the EU novel food sector. The chapter provides an overview of how the data protection clause operates and evaluates its effectiveness in promoting innovation. By analysing its application within the insect food sector, the chapter explores potential advantages and drawbacks of the data protection clause, considering scenarios that could arise from its widespread implementation. This analysis aims to assess whether the data protection clause adequately supports innovation while addressing any limitations or challenges it may present.

Chapter 7 compares the regulatory frameworks for novel foods in the EU and Singapore. While the EU is frequently criticised for imposing heavy regulatory obstacles on innovators, Singapore is often praised for its functioning and innovation-friendly framework, particularly for alternative protein companies. Utilising design thinking principles as a methodological lens, this chapter examines the authorisation procedures in both jurisdictions, identifying key strengths and weaknesses. While taking into account the inherent differences between the EU and Singapore, the chapter elaborates on proposals aimed at enhancing the Novel Food Regulation's ability to promote innovation in the EU. These proposals are designed to address critical points and improve the regulatory environment to better support innovation in the food sector.

Chapter 8 summarises the main findings of the dissertation and discusses its general implications and results. It further reflects on the dissertation's contributions to academic literature, its limitations and on potential future research in the field.

#### Table 1: Structure of the dissertation

	Title	Originally published in:
Chapter 1:	General introduction	
Chapter 2:	Risk Triggers as Innovation Triggers?	European Food and Feed Law Review
	Risk analysis and innovation's	(2022) Vol. 3, pp. 219-227
	promotion under the Novel Food	
	Regulation	Available at:
		https://effl.lexxion.eu/article/EFFL/2022/3/6
Chapter 3:	Consumer perception of novel foods and	Appetite (2024) Vol. 196, pp. 107 285
	the impact of heuristics and biases: a	Available at
	systematic review	Available al: https://doi.org/10.1016/j.oppot.2024.107285
Chanton 4	The role of housistics and hisses in the	<u>mtps://doi.org/10.1010/j.appet.2024.107285</u>
Chapter 4:	the role of neuristics and blases in the	European Journal of Risk Regulation (2025),
	and CMOs in the European Union	voi. 16 (1), pp. 217-227
	and GMOs in the European Union	Available at:
		https://doi.org/10.1017/err.2024.48
Chapter 5:	The Regulation of Novel Foods in the	British Food Journal (2025) Vol. 127 (13),
-	European Union and in Australia-New	рр. 171-189
	Zealand: Barriers and Incentives to	
	Innovation in the Alternative Proteins	Available at: <u>https://doi.org/10.1108/BFJ-</u>
	Sector	06-2024-0650
Chapter 6:	Data Protection under the Novel Food	European Food and Feed Law Review
	Regulation: valuable instrument or	(2023) Vol. 18, pp. 172-178
	barrier to Innovation? Insights from the	
	insect sector	Available at:
		https://effl.lexxion.eu/article/EFFL/2023/3/1
Chapter 7:	Design thinking principles in the	European Business Law Review (2025)
	regulation of novel foods in the	Vol. 36 (3), pp. 403-422
	European Union and Singapore: A	
	comparison	Available at:
		https://doi.org/10.54648/eulr2025026
Chapter 8:	Conclusions and General Discussion	

## **Chapter 2**

# **Risk Triggers as Innovation Triggers? Risk analysis and innovation's promotion under the Novel Food Regulation**

Based on: Alessandro Monaco, Kai Purnhagen. "Risk Triggers as Innovation Triggers? Risk analysis and innovation's promotion under the Novel Food Regulation." *European Food and Feed Law Review*, 3, 219-227 (2022). Available at: https://effl.lexxion.eu/article/EFFL/2022/3/6

#### **CRediT Authorship Contribution Statement**

**Alessandro Monaco**: Project Administration, Conceptualization, Methodology, Writing – original draft, Writing – review & editing. **Kai Purnhagen**: Supervision, Writing – review & editing, Funding acquisition.

## Abstract

Regulation (EU) No 2283/2015 on novel foods (NFR) defines the legal framework applicable to the majority of food innovations in the European Union. Following a risk analysis approach, the NFR requires pre-market authorisation for foods not available on the European market before 1997, to assess potential threats to human health and consumer interests. The NFR's regulatory scope requires the identification of certain factors that constitute a presumption of risk in innovative products and processes. We refer to such factors as "risk triggers". This chapter identifies "novelty" and "unnaturalness" as the main risk triggers associated with novel foods, even though the link between "novelty" and "unnaturalness" and a clear risk for consumer interests, human health or the environment is not evident *per se*. Novel foods, compared to non-novel food products, are thus subject to additional regulatory requirements investigating their safety. Benefits derived from their market entry and adoption are therefore delayed, or even lost. Consequently, the innovation process in the EU food sector, which we identify as an implicit objective of the NFR, is potentially hindered.

#### **1. Introduction**

Non-sustainable agricultural practices, intensive breeding and long supply chains have been identified by the European Commission as critical aspects contributing to environmental degradation and climate change.<sup>1</sup> The development of innovative products and processes in the form of alternative proteins, gene-edited crops, and digitalisation may remedy these shortfalls and contribute to the future of our society.<sup>2</sup> Designing a regulatory environment facilitating the innovation process in the food sector should arguably be a critical policy objective of the European Union (EU).

<sup>&</sup>lt;sup>1</sup> European Commission, 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 (2020) COM/2020/381.

<sup>&</sup>lt;sup>2</sup> Maria Carmela Annosi and others, 'Digitalization within Food Supply Chains to Prevent Food Waste. Drivers, Barriers and Collaboration Practices' (2021) 93 Industrial Marketing Management 208; Adenle, Ademola A., and others, 'Two Decades of GMOs: How Modern Agricultural Biotechnology Can Help Meet Sustainable Development Goals', in Ademola A. Adenle, and others (eds), *Science, Technology, and Innovation for Sustainable Development Goals: Insights from Agriculture, Health, Environment, and Energy* (Oxford Academic, 2020) pp. 401–422; A Parodi and others, 'The Potential of Future Foods for Sustainable and Healthy Diets' (2018) 1 Nature Sustainability 782.

Several scattered provisions govern the development and adoption of food innovations. These provisions range from the pre-market approval of certain categories of food innovations to labelling law and the Common Agricultural Policy.<sup>3</sup> In this chapter, we will concentrate on the role of Regulation (EU) No 2283/2015 on novel foods (NFR), which regulates the market entrance of those food innovations classified as novel food products and processes.<sup>4</sup>

The NFR pursues the objectives of its underlying competence norm Article 114 of the Treaty on the Functioning of the EU<sup>5</sup> (TFEU), namely the establishment and functioning of the internal market while taking as a base a high level of protection for human health and safety, the environment, and consumer interests. As a major regulatory tool to achieve these objectives, the NFR foresees an authorisation procedure based on risk analysis for products under its scope.

The NFR's focus on risk analysis has been well studied in regulatory literature,<sup>6</sup> as well as its impact on innovation.<sup>7</sup> What has not been considered so far is the role of the factors which initiate risk analysis and their ability to detect risky features of novel food products and processes.

The first goal of this chapter is therefore to identify and investigate such "risk triggers", which we define as follows: "*Features and characteristics of novel food products and/or processes identified by the legislator as risk factors that differentiate novel foods from comparable, non-novel alternatives, and that could potentially jeopardise the objectives of the legislation and therefore trigger its requirements*".

<sup>&</sup>lt;sup>3</sup> Kai Purnhagen, 'The Increasing Overlap of Agricultural, Free Movement and Competition Law in the EU' (2021) 46 European Law Review 20.

<sup>&</sup>lt;sup>4</sup> 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, p. 1–22. Hereinafter referred as "NFR".

<sup>&</sup>lt;sup>5</sup> Consolidated version of the Treaty on the Functioning of the European Union, OJ C 202, 7.6.2016, p. 1–388.

<sup>&</sup>lt;sup>6</sup> Alie de Boer and Aalt Bast, 'Demanding Safe Foods – Safety Testing under the Novel Food Regulation (2015/2283)' (2018) 72 Trends in Food Science & Technology 125.

<sup>&</sup>lt;sup>7</sup> Anu Lähteenmäki-Uutela and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336; Martin Holle, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing, 2018) pp. 291-330.

It is true that the NFR does not explicitly refer to the promotion of innovation as an objective. We will however illustrate that the NFR should be interpreted as inheriting the promotion of innovation as an implicit objective. Therefore, as a second objective, this chapter aims at discussing whether risk triggers chosen by the legislator are suitable to enable the innovation process in the EU.

#### 1.1. Methodology and structure of the chapter

To answer the research questions, we apply a doctrinal legal analysis to describe the collection and ordering of the available legal material (legislation, jurisprudence and legal literature), its syntax and norms.<sup>8</sup> The results of the doctrinal analysis are then combined with insights from a variety of other disciplines identified below. In section 2, we consider the principles and factors guiding analysis in the EU legal framework and the objectives of the NFR. In section 3 we investigate the legal place of innovation in the EU and present justifications to consider the promotion of innovation as a critical implicit goal of the NFR. In section 4, risk triggers of the NFR are identified and analysed. In section 5, based on the findings of the previous sections, risk triggers' efficacy to detect risky features of innovative products and their appropriateness to enable innovation in the EU food sector are assessed through findings from other disciplines, including natural science, technology, regulation, philosophy and economics.<sup>9</sup>

## 2. Regulation of food Innovations in the EU: objectives of the legislation

## 2.1. Risk regulation in the EU

In the EU, food law was largely developed as a response to several food safety crises, resulting in a consumer- and safety-oriented view of food regulation.<sup>10</sup>

<sup>&</sup>lt;sup>8</sup> Terry Hutchinson and Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17 Deakin Law Review 83.

<sup>&</sup>lt;sup>9</sup> Terry Hutchinson, 'The Doctrinal Method: Incorporating Interdisciplinary Methods in Reforming the Law' (2016) 3 Erasmus Law Review 130.

<sup>&</sup>lt;sup>10</sup> Sebastian Krapohl, 'Thalidomide, BSE and the Single Market: An Historical-Institutionalist Approach to Regulatory Regimes in the European Union' (2007) 46 European Journal of Political Research 25.

Regulation (EU) No 178/2002<sup>11</sup> (hereinafter General Food Law or GFL) defines risk as "*the function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard*".<sup>12</sup> The GFL requires to base on risk analysis any food-related measure adopted by the EU or member states, when necessary to protect human life and health.<sup>13</sup>

Risk analysis is a systematic approach to assess and evaluate risk, consisting of three interconnected components: risk assessment, risk management, and risk communication.<sup>14</sup> Risk assessment, the process of evaluating risk, shall be independent and based on scientific evidence.<sup>15</sup> Risk management, the balancing of policy alternatives, is in the hands of political authorities and considers, in addition to the risk assessment, other legitimate factors and the precautionary principle.<sup>16</sup> The precautionary principle stipulates that whenever a certain action might cause harm to the public or to the environment and there is no scientific consensus on the issue, the action in question should not be pursued.<sup>17</sup>

Risk analysis is initiated when specific risk triggers identified by the legislator characterise certain products and/or processes and create a presumption of risk, leading to a potential threat for the legislation's objectives.

<sup>&</sup>lt;sup>11</sup> 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. Hereinafter referred as "GFL".

<sup>&</sup>lt;sup>12</sup> ibid. Article 3(9).

<sup>&</sup>lt;sup>13</sup> ibid. Article 6(1).

<sup>&</sup>lt;sup>14</sup> ibid. Article 3(10).

<sup>&</sup>lt;sup>15</sup> ibid. Article 3(11).

<sup>&</sup>lt;sup>16</sup> ibid. Article 3(12). Recital 19 specifies offers an overview of factors that might be considered "(during risk analysis) other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls."

<sup>&</sup>lt;sup>17</sup> ibid. Article 7.

## 2.2. Objectives of the NFR

The NFR operates within the framework of the horizontally applicable GFL. Hence, the NFR is required to place products on the market which are not injurious to health or unfit for human consumption,<sup>18</sup> in order to pursue the objectives of Article 114 TFEU.

Article 1(2) of the NFR states that "the purpose of this Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests". Moreover, the NFR underlines the role of the free movement of goods in the internal market for the well-being of citizens and their social and economic interests, as well as the importance of protecting and improving the quality of the environment.<sup>19</sup>

The functioning of the internal market, the protection of human health, of the environment and of consumer interests are therefore the three explicit objectives of the regulation. No reference is made to the protection of the innovation process. This comes as no surprise, considering that innovation's promotion is usually not regarded as an explicitly voiced primary objective in EU law.

## **3.** Legal place of innovation in the EU

## **3.1. Innovation in the EU legal framework**

References to innovation are scarce in EU primary law. Article 3(3) TFEU states that the Union should promote scientific and technological advance. Article 173(1)(4) TFEU specifies that the Union's industrial policy should take advantage of innovation, research and technological development, and Article 17 TFEU calls for the formation of a European research area based on scientific and technological bases, to make the Union competitive while promoting research activities. Legislation applicable to innovation is made by general principles (e.g. consumer

 $<sup>^{18}</sup>$  ibid. Article 14(2)

<sup>&</sup>lt;sup>19</sup> NFR (n 4). Recital 1, 2.

protection, competition), specific rules (e.g. patent law), standards and sector specific legislation, such as the NFR.<sup>20</sup>

As part of the Europe2020 strategy, innovation is seen as "the creation of new or significantly improved products, processes, marketing, organisations that add values to markets, governments, and society".<sup>21</sup> The importance of the regulatory dimension to favour innovation is recognised by several initiatives, meant to drive legislation's drafting and implementation.<sup>22</sup> For example, TOOL #21. Research & Innovation, part of the 'Better Regulation Toolbox'<sup>23</sup>, presents a checklist according to which the impact of legislative proposals on innovation may be assessed. The purpose of this checklist is to help legislators in drafting innovation-friendly regulations. The 'Innovation Deals', instead, are fora created to discuss regulatory hurdles harming the introduction of innovations, meant to facilitate the communication between political authorities, innovators and involved stakeholders, to improve the legislation's implementation.<sup>24</sup>

The promotion of innovation centres around the debate on the so-called 'innovation principle'. The European Commission described the innovation principle as a "tool to help achieve EU policy objectives by ensuring that legislation is designed in a way that creates the best possible conditions for innovation to flourish".<sup>25</sup> It is meant to cover three phases: agenda setting,

<sup>&</sup>lt;sup>20</sup> Andrea Renda and Jacques Pelkmans, *Does EU Regulation Hinder or Stimulate Innovation?* (Centre for European Policy Studies, 2014) < https://www.ceps.eu/ceps-publications/does-eu-regulation-hinder-or-stimulate-innovation/> accessed 19 September 2024.

<sup>&</sup>lt;sup>21</sup> European Commission, Directorate General for Research and Innovation, 'Innovation Union: A Pocket Guide on a Europe 2020 Initiative' (Publications Office, 2013) Section 2, p 4. <a href="https://op.europa.eu/en/publication-detail/-/publication/6f270d5f-8086-4b70-82b2-c4353d253720">https://op.europa.eu/en/publication-detail/-/publication/6f270d5f-8086-4b70-82b2-c4353d253720</a>> accessed 19 September 2024

<sup>&</sup>lt;sup>22</sup> European Commission, Communication on Europe 2020, a Strategy for Smart, Sustainable and Inclusive Growth (2010) COM/2010/2020.

<sup>&</sup>lt;sup>23</sup> European Commission, 'Better Regulation Toolbox' (2021) < https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox\_en> accessed 19 September 2024.

<sup>&</sup>lt;sup>24</sup> European Commission, 'Identifying Barriers to Innovation' (2016) <https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers\_en> accessed 19 September 2024.

<sup>&</sup>lt;sup>25</sup> European Commission, 'Ensuring EU Legislation Supports Innovation' (2016) <https://research-and-innovation.ec.europa.eu/law-and-regulations/ensuring-eu-legislation-supports-innovation\_en> accessed 19 September 2024.

legislation drafting and implementation.<sup>26</sup> In particular, the innovation principle has been presented as a 'relevant factor' to be considered during risk management.<sup>27</sup> Despite some criticism,<sup>28</sup> some scholars are optimistic about the innovation principle, claiming that it could eventually offer a new perspective on what reasonable risk taking means.<sup>29</sup> Its application during legislation drafting would be helpful to assess the impact of new legislation on innovation correctly.<sup>30</sup>

Notwithstanding the increasing number of references to innovation in the initiatives of EU institutions and the debate around the innovation principle, the promotion of innovation is still far away from being openly and widely considered during the development of legislative acts like the NFR. In fact, despite constituting the core of the regulatory framework applicable to food innovations, the NFR does not refer to innovation in its articles, neither as an objective nor as a factor to consider for its application.

Scholars have consequently noted that the EU regulatory framework is not suitable to favour the adoption of food innovations.<sup>31</sup> However, if we take a closer look at the NFR, it might be argued that the promotion of innovation shall indeed be considered a goal of the regulation, even if it is not expressed explicitly.

<sup>&</sup>lt;sup>26</sup> European Commission, 'Research and Innovation - The Innovation Principle Factsheet' (2022) <a href="https://research-and-innovation.ec.europa.eu/document/download/294b40e0-ad5a-448e-9612-ea87b5b9e48e\_en?filename=ec\_rtd\_factsheet-innovation-principle.pdf">https://research-and-innovation.ec.europa.eu/document/download/294b40e0-ad5a-448e-9612-ea87b5b9e48e\_en?filename=ec\_rtd\_factsheet-innovation-principle.pdf</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>27</sup> European Risk Forum, 'The Innovation Principle, Stimulating Economic Recovery' *Open Letter to Barroso, Van Rompuy and Schultz* (24 October 2013)

<sup>&</sup>lt;https://corporateeurope.org/sites/default/files/corporation\_letter\_on\_innovation\_principle.pdf> accessed 19 September 2024.

<sup>&</sup>lt;sup>28</sup> The innovation principle was firstly developed in 2013 by the European Risk Forum, a think-tank formed by the CEOs of several companies operating in the EU. This has raised some concerns on the innovation principle, presented as an instrument designed to undermine the precautionary principle, see Paul Leonard, 'The Innovation Principle' *Encompass* (2016) <a href="https://encompass-europe.com/comment/the-innovation-principle">https://encompass-europe.com/comment/the-innovation-principle</a> accessed 19 September 2024; Rupert Read and Tim O'Riordan, 'The Precautionary Principle Under Fire' (2017) 59 Environment: Science and Policy for Sustainable Development 4.

<sup>&</sup>lt;sup>29</sup> Kathleen Garnett, Geert Van Calster and Leonie Reins, 'Towards an Innovation Principle: An Industry Trump or Shortening the Odds on Environmental Protection?' (2018) 10 Law, Innovation and Technology 1.

<sup>&</sup>lt;sup>30</sup> Andrea Renda and Felice Simonelli, *Study Supporting the Interim Evaluation of the Innovation Principle* (Centre for European Policy Studies, 2019) < https://doi.org/10.2777/620609> accessed 19 September 2024.

<sup>&</sup>lt;sup>31</sup> Lähteenmäki-Uutela and others (n 7).

#### 3.2. Innovation as an objective of the NFR

The promotion of innovation as an implicit objective of the NFR can be justified in four ways.

Looking at primary law, Article 173(1) fourth hyph. TFEU requires Union and Member States' actions to foster "better exploitation of the industrial potential of policies of innovation, research and technological development". Legislative acts based on Article 114 TFEU and their provisions, such as the authorisation procedures, may also qualify as "actions". Consequently, primary law requires fostering innovation in acts as stipulated in Article 173 TFEU. In addition, Article 114(3) TFEU requires the Commission to take as a base for its legislative proposals a high level of consumer protection concerning health, safety and the environment, keeping into account any new developments based on scientific facts. Food innovations have the potential for improving environmental sustainability, protecting consumers and providing better health compared to the status quo. Hence, without explicitly mentioning it, Article 114(3) TFEU requires to favour the adoption of innovations, if they can contribute to the objectives mentioned by this provision.

Second, the promotion of innovation is referred to in the recitals of the NFR. Recital 29 underlines the importance of a broader consideration of innovation as a meaningful implicit objective, particularly when innovations can contribute to the explicit goals of the NFR. While non-binding,<sup>32</sup> recitals can help to interpret the respective articles of the legislative act,<sup>33</sup> for example, clarifying their nature<sup>34</sup> or scope.<sup>35</sup> Recital 29 explicates the interconnection between innovations and the legislation's objectives representing a solid argument for considering the promotion of innovation as an implicit goal of the legislation: "*New technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured*". The following Recital 30 clarifies the chosen

<sup>&</sup>lt;sup>32</sup> Court of Justice of the European Union, Case *C-162/97, Criminal Proceedings against Nilsson, Hagelgren & Arrborn* [1998] ECLI:EU:C:1998:554, at paragraph 54.

<sup>&</sup>lt;sup>33</sup> Todas Klimas and Jurate Vaiciukaite, 'The Law of Recitals in European Community Legislation' (2008) 15 ILSA Journal of International & Comparative Law 61.

<sup>&</sup>lt;sup>34</sup> Court of Justice of the European Union, Case C-244/95 - P Moskof AE v Ethnikos Organismos Kapnou [1997] ECLI:EU:C:1997:551.

<sup>&</sup>lt;sup>35</sup> Court of Justice of the European Union, Case C-288/97 - Consorzio fra i Caseifici dell'Altopiano di Asiago v Regione Veneto [1999] ECLI:EU:C:1999:214.

instrument to "*stimulate research and development within the agri-food industry, and thus innovation*" under the NFR: the protection of data and information needed for receiving the authorisation, the so-called "data protection clause". In the eyes of the legislator, data protection is perceived as an effective way to promote innovation after the opening up of the regulations' scope, during the authorisation procedure and following the product's entrance into the market.<sup>36</sup> Under the NFR, authorisations are, in principle, horizontal, meaning not applicant-specific but product-specific. However, the protection of scientific data and information can be granted to applicants whenever studies used during the authorisation procedure were based on proprietary scientific data and if the authority could not have assessed the novel food (and therefore authorised) without those scientific data. The authorisation is then exclusively granted to the applicant for a period of five years. Other businesses willing to place the same products on the market will have to seek the permission from the holder of the authorisation or apply for another authorisation using their own scientific data. The decision to include the data protection clause in the NFR, despite making the authorisation in principle horizontal, reflects the desire of the legislator to protect the efforts of innovators.

Thirdly, the attention to innovation can be derived from the legislative history of the NFR. The promotion of innovation is mentioned among the objectives of the "Financial Statement of the Proposal for a Regulation on Novel Foods"<sup>37</sup>, one of the documents upon which the NFR was drafted. Additionally, when considering the interventions of the Members of the European Parliament before the voting on the NFR, the impact of the new legislation on innovation was treated as a critical feature of the new NFR. The transcript of the debate illustrates that the promotion of innovation was considered a clear objective of the legislation.<sup>38</sup>

Finally, the promotion of innovation is a goal commonly associated with the NFR in official documents and communications of the EU Commission, which highlight the important role the

<sup>&</sup>lt;sup>36</sup> NFR (n 4).

<sup>&</sup>lt;sup>37</sup> European Commission, Proposal for a Regulation of the European Parliament and of the Council on Novel Foods /\* COM/2013/0894 final - 2013/0435 (COD) \*/ 2013. Legislative Financial Statement. Section 1.4.1(3).

<sup>&</sup>lt;sup>38</sup> European Parliament, 'Debates - Novel Foods - Wednesday, 28 October 2015' <https://www.europarl.europa.eu/doceo/document/CRE-8-2015-10-28-ITM-005\_EN.html> accessed 19 September 2024. As an example of the importance of Novel Food Regulation for promoting innovation, consider the interventions from James Nicholson, rapporteur for the proposal of the Novel Food Regulation, and Commissioner Vytenis Povilas Andriukaitis.

NFR plays in creating a friendly regulatory environment for innovators in the food sector.<sup>39</sup> Such reference to the protection of the innovation process illustrates that the NFR is an instrument for ensuring that the objectives of the legislation are met while favouring innovation's potential.

If the promotion of innovation is considered a legitimate yet implicit objective of the NFR, risk triggers should be designed to achieve this goal as well, along with the other explicit objectives.

## 4. Risk triggers in the Novel Food Regulation

We define risk triggers as features and characteristics of products and/or processes identified by the legislator as risk factors that could potentially jeopardise the achievement of the objectives of the legislation.

To retrieve them, it is necessary to assess the scope and provisions of the NFR, isolating those aspects prompting the legislation's application. In other words, the specific traits and characteristics which differentiate novel foods from comparable, non-novel food products.

## 4.1. Novelty

The first risk trigger of the NFR can be identified in the novel food definition itself. Novel foods are defined as:

"Any food which was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the date of accession of Member States, and that fall under at least one of the categories of Article 3(2)(a) NFR."<sup>40</sup>

<sup>39</sup> 'O&A European Commission. on the Novel Food Regulation' (2018)<https://food.ec.europa.eu/system/files/2018-01/fs\_novel-food\_leg\_q-n-a-new-regulation-nf\_en.pdf> accessed 19 September 2024; European Commission, 'Approval of First Insect as Novel Food' (2021)<a href="https://ec.europa.eu/food/food/novel-food/authorisations/approval-first-insect-novel-food\_en">https://ec.europa.eu/food/food/novel-food/authorisations/approval-first-insect-novel-food\_en</a> accessed May 2021.

<sup>&</sup>lt;sup>40</sup> NFR (n 4). Article 3(2)(a).

Foods that are classified in a novel food category, i.e. they were not consumed to a significant degree within the Union before 15 May 1997, are legally presumed to be risky and a pre-market authorisation is required.

The first risk trigger for the NFR application is the legal "novelty" of food products and processes in the EU. The boundary is set on the date on which the first novel food regulation entered into force, on 15 May 1997.<sup>41</sup> The risk trigger is hence a legal benchmark, after which every novel food, without further distinction, needs to undergo the novel food's authorisation procedure.

One might argue that, by looking at the definition, the absence of human consumption should be the actual risk trigger. The safety of novel foods must be proven since no significant population of human beings has eaten them. However, this is not precisely the case, as demonstrated by the inclusion of insects under the NFR scope.

The status of insects as novel food was unclear under Regulation (EC) No 258/97,<sup>42</sup> which first introduced the concept of novel foods in the EU. Due to this legal gap, insects had been authorised for sale in some EU countries but not in others. Consequently, they have been consumed significantly in the EU for a documented period, but only after 1997. Since insects have now been explicitly included within the scope of the new NFR, and since they were not consumed in the EU before 1997, even though they are allowed to remain on the market under ad hoc transitional measures, they still need to undergo the authorisation procedures for novel foods.<sup>43</sup> Evidence of safety, proven by human consumption after 1997, is therefore not enough to overcome the "novelty" trigger set by the novel food definition.

<sup>&</sup>lt;sup>41</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p.1 1997.

<sup>&</sup>lt;sup>42</sup> Court of Justice of the European Union, Case *C-526/19 - Entoma SAS v Ministre de l'Économie et des Finances, Ministre de l'Agriculture et de l'Alimentation,* [2020] ECLI:EU:C:2020:769.

<sup>&</sup>lt;sup>43</sup> IPIFF, 'Contribution Paper: Application of the Novel Food Transitional Measure' (2020) <https://ipiff.org/wp-content/uploads/2020/12/10-12-2020-IPIFF-Contribution-paper-novel-food-transitional-measure.pdf> accessed 19 September 2024.

#### 4.2. Unnaturalness

Among novel foods, traditional foods from third countries<sup>44</sup> enjoy a different treatment. They are subject to a notification procedure, in which a risk assessment by EFSA is in principle not required, unless otherwise requested by a Member State or EFSA.<sup>45</sup> The notification procedure is meant to facilitate the placement on the market of those foods traditionally consumed outside of the EU. Looking at the definition of traditional foods, three conditions apply: (a) the history of safe food use in a third country must be demonstrated; (b) traditional foods must derive from primary production; (c) traditional foods shall be classified only under specific novel food categories.

Regarding the first condition, "history of safe food use" is defined as at least 25 years of continued use in the customary diet of a significant number of people in one or more third countries.<sup>46</sup> Evidence must be presented to demonstrate such continuous consumption.

The second condition shall be examined with the third one, the caveat specifying that only specific novel food categories allow classification as traditional foods. Primary production is defined in the GFL 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."*<sup>47</sup>

Finally, the novel food categories applicable to traditional foods are: (ii) food consisting of, isolated from or produced from microorganisms, fungi or algae; (iv) food consisting of, isolated from or produced from plants or their parts; (v) food consisting of, isolated from or produced from animals or their parts; (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae.

<sup>&</sup>lt;sup>44</sup> NFR (n 4). Article 3(2)(c).

<sup>&</sup>lt;sup>45</sup> ibid. Article 15

<sup>&</sup>lt;sup>46</sup> ibid. Article 3(2)(c).

<sup>&</sup>lt;sup>47</sup> GFL (n 12). Article 3(17).

Considering the definition of primary production and the applicable novel food categories, only novel foods obtained from microorganisms, fungi, algae, plants and animals can take advantage of the notification procedure. The traditional food definition hence leaves out novel foods in which human intervention and technological application go beyond the collection or basic processing of living organisms. In the original "Proposal for a Novel Food Regulation", the term "traditional" was even defined as free from the application of new production processes.<sup>48</sup> As a result, products obtained by high-pressure processing, for example, could not enjoy the status of 'traditional food'. Similarly, cultivated meat, despite being classified under category (vi), would face regulatory challenges to fit the definition of primary production.

In this case, the factor differentiating potential traditional foods from other novel foods can be recognised as the risk trigger. We argue that this difference is the perceived Unnaturalness of novel foods falling under the non-traditional novel food categories. All the excluded categories involve some sort of artificial intervention, which is hence presumed to carry a higher risk for human health and safety. The assumption of risks from artificial intervention, e.g. by modern technology, is reflected as well by the attention granted to nanofoods in the text, as a consequence of the hot debate they were subject to during the years of the new NFR's drafting.<sup>49</sup> Such aversion towards "unnatural" products and processes is constant in EU legislation, as it is particularly evident in the regulatory frameworks applicable to Genetically Modified Organisms (GMOs).<sup>50</sup>

## 5. Appropriateness of risk triggers

Considering the explicit goals of the NFR, one could expect that the chosen risk triggers are able to detect risky features of innovative products and processes to ensure that risk analysis will effectively assess any possible threats to consumer health, safety and for the environment. In addition, accepting the promotion of innovation as an implicit goal of the NFR, risk triggers should also serve this purpose, by focusing on any possible risk resulting from the innovation

<sup>&</sup>lt;sup>48</sup> European Commission (n 38). Recital 12.

<sup>&</sup>lt;sup>49</sup> Daniela Marrani, 'Nanotechnologies and Novel Foods in European Law' (2013) 7 NanoEthics 177.

<sup>&</sup>lt;sup>50</sup> Andreas T Christiansen, Martin Marchman Andersen and Klemens Kappel, 'Are Current EU Policies on GMOs Justified?' (2019) 28 Transgenic Research 267.

process and leaving out those developments that do not pose any menace to the legislation's objectives.

## 5.1. The use of "novelty" as risk trigger

Regulation can approach the degree of novelty of products and processes from two different perspectives. Regulation may be seen as contributing to innovation, incentivising businesses to innovate to overcome stricter standards and remain competitive at the same time.<sup>51</sup> Regulation that stipulates specific outcomes, for example limits on greenhouse gas emissions, might incentivise innovative solutions for ensuring compliance. However, sometimes innovations arguably involve higher risks than existing alternatives, and the legislator considers possible threats alongside potential benefits. The degree of novelty hence becomes a risk trigger, which justifies regulatory intervention, as we have seen in the EU with gene-editing techniques.<sup>52</sup>

Regarding novel foods, the second approach prevails in the EU. When drafting the legislation, the legislator considered the degree of novelty as potentially risky and decided to shape the regulatory requirements consequently. The focus of the legislation becomes the risk, while benefits are given less attention. Moreover, to define novelty, the legislation itself became the benchmark by setting the regulations' date of entry into force as the boundary between risky and non-risky.

The degree of novelty looked at in isolation, particularly if novelty is determined only from the legal perspective, does not however detect risky features of innovative products and processes comprehensively. Analysis of the composition of products, possible allergies and toxicological threats for human beings, and the impacts on the environment all feature in the authorisation procedure for novel foods, but only after the mechanism has been initiated. As an example, the potential of fungal mycelium to produce alternative proteins is currently being explored by several actors in the food sector. Unfortunately, even when focusing on the mycelium of commonly consumed species, such companies are likely to be subject to the novel food

<sup>&</sup>lt;sup>51</sup> Michael E Porter, 'America's Green Strategy' (1991) 264 Scientific American 168.

<sup>&</sup>lt;sup>52</sup> Kai Purnhagen and others, 'EU Court Casts New Plant Breeding Techniques into Regulatory Limbo' (2018) 36 Nature Biotechnology 799.

authorisation since the mycelium in itself has not been consumed before 1997, but only the fruiting bodies have.<sup>53</sup>

The assumption that "novelty" equates risk may hence be overinclusive and, as a consequence, the EU regulatory framework is likely to not enable the full potential of innovation in the EU food sector.

## 5.2. The use of "unnaturalness" as risk trigger

Assessing the role of "unnaturalness" as a risk trigger in relation to novel foods is difficult, as naturalness is perceived differently by people.<sup>54</sup> Unnaturalness is more a sense, which humans subjectively give to certain properties of products and processes following their artificial intervention.

Literature has identified two primary rationales of "unnaturalness", which is either historical or independence-based, or substantial or property-based.<sup>55</sup> Historical or independence-based arguments look into the degree of human intervention. An entity is more unnatural the deeper the level of human intervention is.<sup>56</sup> "Deep" can refer to time, effort, space, or the number of changes. The more time or effort a human intervention on an organism takes, the more direct it is or the more changes it induces, the more unnatural it appears. Throughout history, humans have acted on the surrounding environment to improve their food production processes. The development of agriculture, the domestication of species, and their selection can nevertheless be classified as innovations within their time context and, adopting the modern logic, would all have been classified as novel foods products and processes in their timeframe.

Substantial or property-based arguments refer instead to the presence of specific foreign properties in an organism that makes it more unnatural. The regulatory supervision under the

<sup>&</sup>lt;sup>53</sup> Alexandra Molitorisová, Alessandro Monaco and Kai Purnhagen, An Analysis of the Regulatory Framework Applicable to Products Obtained from Mushroom and Mycelium (2021) SSRN Electronic Journal: <https://dx.doi.org/10.2139/ssrn.3955899> accessed 19 September 2024

<sup>&</sup>lt;sup>54</sup> Helena Siipi, 'Dimensions of Naturalness' (2008) 13 Ethics and the Environment 71.

<sup>&</sup>lt;sup>55</sup> Christiansen, Andersen and Kappel (n 50).

<sup>&</sup>lt;sup>56</sup> Lee Keekok, *The Natural and the Artefactual: The Implications of Deep Science and Deep Technology for Environmental Philosophy* (Lexington Books, 1999) Chapter 4, passim.

NFR for food that "*contain or consist of engineered nanomaterials*" is a good example of this approach.

Both views on unnaturalness inherit an approach limiting the degree of innovation to certain unspecified boundaries in the name of connections between unnaturalness and (perceived) risk.<sup>57</sup> The legislator is in charge of defining these boundaries, but the current EU regulatory framework does not do that, as it focuses on the human intervention itself and not on the consequences it pertains to. It would be difficult to argue that cultured meat, for example, is, in principle, more dangerous than normal meat since they potentially cannot be distinguished.

"Unnaturalness", similar to "novelty", is a precondition and a consequence of the innovation process. Its use as a risk trigger for food innovations creates a regulatory environment in which all human interventions might be classified as risky, even when no connection with specific threats is made.

## 6. Conclusions

For the scope of this chapter, we defined risk triggers as peculiar features of products and/or processes that potentially jeopardise the objectives of the legislation and therefore trigger its requirements. In relation to novel foods, we identified two risk triggers: "novelty" and "unnaturalness".

Their use as risk triggers reflects the risk-based approach the EU has adopted regarding food law. "Novelty" and "unnaturalness" do not automatically reflect a well-defined threat to consumer interests, human health or the environment. As a result, even when there is scientific consensus on their safety, for example due to consumption in other parts of the world, novel foods are subject to costly and heavy regulatory requirements, which harm the innovation process, even if the promotion of innovation should be considered a legitimate legislative objective of the NFR.

To improve the current situation, two main paths might be followed. Firstly, the NFR could only be partially modified, maintaining the current risk triggers but amending key provisions, like the data protection clause, or speeding up the approval of specific products whose safety

<sup>&</sup>lt;sup>57</sup> James Paddock Collman, *Naturally Dangerous: Surprising Facts about Food, Health, and the Environment* (University Science Books 2001), passim.

has been largely documented. For example, in the recent EFSA's opinion on the "Safety of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia", the Panel on Nutrition, Novel Foods and Food Allergens exempted the applicant from providing toxicology studies in the approval procedure, since potential allergic reactions were not expected to be riskier than the normal consumption of pea, rice or the fruiting body of the shiitake mushrooms.<sup>58</sup> Secondly, the regulatory system could be extensively amended, following the legal disruption caused by innovation.<sup>59</sup> A new version of the NFR could be drafted, leading to a totally new regulatory approach, that could learn from past lessons and anticipate issues that might arise in the next years, like the regulation of cultured meat.<sup>60</sup>

<sup>&</sup>lt;sup>58</sup> EFSA Panel on Nutrition, Novel Foods and Food Allergens and others, 'Safety of Pea and Rice Protein Fermented by Shiitake (Lentinula Edodes) Mycelia as a Novel Food Pursuant to Regulation (EU) 2015/2283' (2022) 20 EFSA Journal e7205.

<sup>&</sup>lt;sup>59</sup> Kai Purnhagen, 'You Want It Extra CRISPERY? Legal Disruption through New Plant Breeding Technologies in the EU' (2021) 40 Yearbook of European Law 374.

<sup>&</sup>lt;sup>60</sup> Joseph Mohorčich and Jacy Reese, 'Cell-Cultured Meat: Lessons from GMO Adoption and Resistance' (2019) 143 Appetite 104408.

## Chapter 3

# Consumer Perception of Novel Foods and the Impact of Heuristics and Biases: a Systematic Review

Based on: Alessandro Monaco, Johannes Kotz, Mirna Al Masri, Anila Allmeta, Kai Purnhagen, Laura König. "Consumers' perception of novel foods and the impact of heuristics and biases: A systematic review." *Appetite*, 196, 107285 (2024). Available at: <u>https://doi.org/10.1016/j.appet.2024.107285</u>

#### **CRediT Authorship Contribution Statement**

**Alessandro Monaco**: Conceptualization, Data curation, Formal analysis, Project administration, Writing – original draft, Writing – review & editing. Johannes Kotz: Conceptualization, Data curation, Methodology. **Mirna Al Masri**: Data curation, Formal analysis. **Anila Allmeta**: Data curation, Formal analysis. **Kai Purnhagen**: Conceptualization, Supervision, Writing – review & editing, Funding acquisition. Laura König: Conceptualization, Formal analysis, Methodology, Supervision, Writing review & editing.

## Abstract

According to the definition adopted in the European Union, novel foods are foods that were not consumed to a significant degree within the Union before the 15<sup>th</sup> of May, 1997. This includes cultivated meat and insects. Novel foods are meant to play a critical role in the transition towards sustainable food systems. However, their success depends on whether and to what extent they will be incorporated into the diets at the population level. This chapter is based on a systematic review aiming to explore consumer perception of novel food products by narratively synthesising results on the influence of heuristics and biases triggered by emotions, personality traits, and socio-cultural factors. Empirical studies conducted in Western countries and published in English after 1997 were eligible, which led to 182 studies being included. Notably, most included studies focused on insects and cultivated meat. Disgust and fear are shown to be the main emotions driving rejection of novel foods, together with food neophobia and specific cultural norms common across countries included in the scope of the review. Familiarity with novel foods and curiosity both led to higher acceptance. Despite being investigated directly in a minority of studies, heuristics and related biases mostly fell under the "affect", the "natural-is-better", and the "trust" heuristics. The review also discusses the extent to which consumer perception reflects in the regulatory framework applicable to novel foods in the European Union, how it influences the regulation of insects and cultivated meat and which lessons can be drawn for the future of the regulatory framework.

## **1. Introduction**

With the European Green Deal, the European Union (EU) recognised the importance of transforming food systems towards sustainability in an era of increasing environmental concerns.<sup>1</sup> Alongside the traditional objectives of food safety and security, the Commission aimed to add sustainability and resilience. To accomplish these goals, novel foods are meant to play a critical role. Products categorised as novel foods such as insects or cultivated meat, have the potential to reduce greenhouse gas emissions, water use, and land use compared to traditional animal protein sources.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> European Commission, Communication on the European Green Deal (2019) COM/2019/640.

<sup>&</sup>lt;sup>2</sup> Mario Herrero and others, 'Innovation Can Accelerate the Transition towards a Sustainable Food System' (2020) 1 Nature Food 266; Rachel 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; Stefano Sforza, 'Food (In)Security: The Role of Novel Foods on Sustainability' in Lucia Scaffardi and Giulia Formici (eds), *Novel* 54

Novel foods are foods that were not consumed to a significant degree within the EU before May 15, 1997 and that fall under one of the novel food categories.<sup>3</sup> The novel food definition encompasses several products and processes, which range from insects to nanofoods, plant extracts, foods obtained through new processing technologies, and products derived from cell cultures such as cultivated meat. Before being placed on the market, novel foods are subject to an authorisation procedure to ensure their safety.<sup>4</sup>

Novel foods' widespread adoption and success will largely depend on consumer acceptance. Individual judgement and consequent decision-making, including but not limited to food choices, are shaped by two cognitive systems that work in parallel.<sup>5</sup> One is based on intuition, emotions, and past experiences (system 1); the other relies on reasoning and consideration of the available information and logic thinking (system 2). System 1 operates through heuristics, i.e. mental shortcuts that allow individuals to make fast decisions under uncertainty.<sup>6</sup> A wide range of heuristics governing human decision-making have been identified,<sup>7</sup> particularly when facing unknown risks.<sup>8</sup> Since consumers have limited information to evaluate aspects such as food safety or the sustainability impact of the food they consume, heuristic thinking is their primary decision-making mechanism when approaching food choices.<sup>9</sup>

*Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 59-79.

<sup>&</sup>lt;sup>3</sup> 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, p. 1–22. Hereinafter, referred as "NFR". Article 3(2).

<sup>&</sup>lt;sup>4</sup> Jessica Vapnek, Kai Purnhagen and Ben Hillel, 'Regulatory and Legislative Framework for Novel Foods', in Shivani Pathania and Brijesh Tiwari (eds), Food Formulation (John Wiley & Sons, Ltd 2021) pp. 285-308.

<sup>&</sup>lt;sup>5</sup> Daniel Kahneman, 'A Perspective on Judgment and Choice: Mapping Bounded Rationality' (2003) 58 American Psychologist 697.

<sup>&</sup>lt;sup>6</sup> Amos Tversky and Daniel Kahneman, 'Judgment under Uncertainty: Heuristics and Biases' (1974) 185 Science 1124.

<sup>&</sup>lt;sup>7</sup> Steve Dale, 'Heuristics and Biases: The Science of Decision-Making' (2015) 32 Business Information Review 93; Joyce Ehrlinger, Wilson O Readinger and Bora Kim, 'Decision-Making and Cognitive Biases', in Howard S Friedman (ed), *Encyclopedia of Mental Health* (Elsevier, 2016) pp. 5-12.

<sup>&</sup>lt;sup>8</sup> Paul Slovic and others, 'Affect, Risk, and Decision Making' (2005) 24 Health Psychology 35.

<sup>&</sup>lt;sup>9</sup> Benjamin Scheibehenne, Linda Miesler and Peter M Todd, 'Fast and Frugal Food Choices: Uncovering Individual Decision Heuristics' (2007) 49 Appetite 578.

Siegrist and Hartmann propose a framework that explains consumers' attitudes towards innovative technologies in the food sector through the influence of specific heuristics and biases.<sup>10</sup> According to their analysis, three heuristics are especially important: the "affect heuristic", i.e. the tendency to rely on emotions when making decisions; the "natural-is-better heuristic", i.e. the preference for products not produced through technological processes; and the "trust heuristic", i.e. when preference for products is determined by trust in the source of information about the products (e.g., organic labels for organic foods) and not their characteristics, which are often difficult to assess for consumers.

This systematic review aims to extend this framework by identifying relevant emotions, personality traits, and socio-cultural factors that are the basis for these heuristics. Emotions are psychological and physiological responses triggered by specific stimuli or situations,<sup>11</sup> often resulting in a behavioural response.<sup>12</sup> Emotions affect the evaluation of benefits and risks of an innovation,<sup>13</sup> and serve as a heuristic in themselves.<sup>14</sup> Importantly, emotions are subjective, state-like experiences. Personality traits, on the other hand, are stable patterns of thinking and feeling which characterise the behaviour of an individual across different situations and over time; yet they may be subject to a certain degree of change and development through new experiences.<sup>15</sup> Cultural factors and norms refer to the diverse and dynamic elements of a society's shared beliefs, values, customs, traditions, and practices that influence individuals'

<sup>&</sup>lt;sup>10</sup> Michael Siegrist and Christina Hartmann, 'Consumer Acceptance of Novel Food Technologies' (2020) 1 Nature Food 343.

<sup>&</sup>lt;sup>11</sup> Klaus R Scherer, 'What Are Emotions? And How Can They Be Measured?' (2005) 44 Social Science Information 695.

<sup>&</sup>lt;sup>12</sup> Jennifer S Lerner and others, 'Emotion and Decision Making' (2015) 66 Annual Review of Psychology 799.

<sup>&</sup>lt;sup>13</sup> Carmen Valor, Paolo Antonetti and Benedetta Crisafulli, 'Emotions and Consumers' Adoption of Innovations: An Integrative Review and Research Agenda' (2022) 179 Technological Forecasting and Social Change 121609.

<sup>&</sup>lt;sup>14</sup> Stephen Rice and others, 'What Factors Predict the Type of Person Who Is Willing to Fly in an Autonomous Commercial Airplane?' (2019) 75 Journal of Air Transport Management 131; Scott R Winter, Stephen Rice and Tracy L Lamb, 'A Prediction Model of Consumer's Willingness to Fly in Autonomous Air Taxis' (2020) 89 Journal of Air Transport Management 101926.

<sup>&</sup>lt;sup>15</sup> Avshalom Caspi, Brent W Roberts and Rebecca L Shiner, 'Personality Development: Stability and Change' (2005) 56 Annual Review of Psychology 453.

behaviours, preferences, and social interactions.<sup>16</sup> All these factors contribute to the action of heuristics shaping consumer perception of products categorised as novel foods in the EU.

### 1.1. Objectives of the systematic review

This review contributes to the growing body of literature which investigates acceptance of products categorised as novel foods. In particular, several recent reviews concern perception of product categories such as cultivated meat,<sup>17</sup> insects,<sup>18</sup> seaweed and milk alternatives.<sup>19</sup> Notably, these reviews focused on single categories of novel foods, which does not allow to compare consumers' perspectives towards different types of novel foods, or identify common motivations for consuming novel foods in general. Only one review adopted a legal definition of novel foods to define the scope of the research, but the authors only focused on factors shaping consumers' willingness to pay.<sup>20</sup>

In the present review, we use a broader conceptualisation of acceptance of novel foods. Specifically, we went beyond the classical understanding of willingness to pay by also including willingness to eat, consumer acceptance, perception, and attitudes towards novel foods as

<sup>&</sup>lt;sup>16</sup> Rain W Liu and others, 'Culture and Social Norms: Development and Application of a Model for Culturally Contextualized Communication Measurement (MC<sup>3</sup>M)' (2022) 6 Frontiers in Communication 770513

<sup>&</sup>lt;sup>17</sup> Rosires Deliza and others, 'Cultured Meat: A Review on Accepting Challenges and Upcoming Possibilities' (2023) 52 Current Opinion in Food Science 101050; Kevin Kantono and others, 'Consumer Acceptance and Production of In Vitro Meat: A Review' (2022) 14 Sustainability 4910; Ashkan Pakseresht, Sina Ahmadi Kaliji and Maurizio Canavari, 'Review of Factors Affecting Consumer Acceptance of Cultured Meat' (2022) 170 Appetite 105829; Shahida Anusha Siddiqui and others, 'Marketing Strategies for Cultured Meat: A Review' (2022) 12 Applied Sciences 8795.

<sup>&</sup>lt;sup>18</sup> Shahida Anusha Siddiqui and others, 'Consumer Acceptability of Plant-, Seaweed-, and Insect-Based Foods as Alternatives to Meat: A Critical Compilation of a Decade of Research' (2022) 0 Critical Reviews in Food Science and Nutrition 1; Sofia G Florença and others, 'The Motivations for Consumption of Edible Insects: A Systematic Review' (2022) 11 Foods 3643; Tieneke Kröger and others, 'Acceptance of Insect-Based Food Products in Western Societies: A Systematic Review' (2022) 8 Frontiers in Nutrition 759885;Giorgio Mina, Giovanni Peira and Alessandro Bonadonna, 'The Potential Future of Insects in the European Food System: A Systematic Review Based on the Consumer Point of View' (2023) 12 Foods 646.

<sup>&</sup>lt;sup>19</sup> Siddiqui and others (n 18); Meike Rombach, David L Dean and Vera Bitsch, "Got Milk Alternatives?" Understanding Key Factors Determining U.S. Consumers' Willingness to Pay for Plant-Based Milk Alternatives' (2023) 12 Foods 1277.

<sup>&</sup>lt;sup>20</sup> Maurizio Canavari, Alessandra Castellini and Vilma Xhakollari, 'Chapter 2 - A Short Review on Willingness to Pay for Novel Food' in Cristina Santini, Stefania Supino and Lucia Bailetti (eds), *Case Studies on the Business of Nutraceuticals, Functional and Super Foods* (Woodhead Publishing 2023) pp. 21-30.

potential outcomes. Furthermore, we use the legal perspective to define both the scope of the research and the interpretation of the results to derive implications for policymaking.

Since consumers' perception and narratives of disruptive innovations can influence the related social, regulatory, and political challenges,<sup>21</sup> understanding the psychological factors shaping consumer perception and decision-making offers valuable insights into the regulatory framework applicable to such products. Given the importance of heuristics in decision-making in daily life, we specifically focus on the identification of relevant heuristics.

Thus, this review aims to:

- identify which heuristics and cognitive biases have been described in primary research on novel foods' perception;
- determine how such heuristics and related cognitive biases, together with other psychological factors, affect consumers' perception of novel foods;
- investigate to what extent such perception is reflected in the regulatory framework and which conclusions can be drawn for the future regulation of novel foods.

## 2. Methodology

The protocol for the review was pre-registered on the Open Science Framework (OSF) in December 2021 (https://doi.org/10.17605/OSF.IO/TNG8P). Raw data are available on the OSF page: https://osf.io/d856v/?view\_only=ff8ae36000514811b2c640a0a26bd7f8.

## 2.1. Search strategy

In February 2022 the systematic literature search was conducted in four databases using the search terms listed in Table 1. The search terms reflected the most common novel foods and related psychological concepts and were refined after demonstrating face validity by retrieving key studies. The search was restricted to title, abstract and keywords, and to scientific articles published after 1997.

<sup>&</sup>lt;sup>21</sup> Neil Stephens and others, 'Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture' (2018) 78 Trends in Food Science and Technology 155.

Table 1: Databases and search query

Databases	Search query
Web of Science	("perception*" OR "attitude*" OR "acceptance"
	OR "consum* behavio#r" OR "consum*
Pro Quest	response" OR "willingness to consume" OR
PsycInfo	"willingness to buy" OR "consum* choice" OR
1 Sjenno	"food choice" OR "heuristic*" OR "bias*" OR
Pubmed	"neophobia" OR "neophilia" OR "yuck factor"
	OR "disgust" OR "trust" OR "naturalness" OR
	"unnaturalness" OR "aversion" OR "familiarit*"
	OR "preference" OR "food habit*" OR
	"rejection" OR "eating behavio#r*" OR "affect")
	AND ("novel food*" OR "algae" OR "edible
	fung*" OR "mycelium" OR "mycoprotein*" OR
	"innovative food*" OR "food innovation*" OR
	"cultured meat" OR "cultivated meat" OR "clean
	meat" OR "in vitro meat" OR "cell-based
	meat"OR "synthetic meat" OR "meat analogue*"
	OR "lab-grown" OR "plant-based protei*" OR
	"plant-based meat" OR "meat alternativ*" OR
	"innovative protei" OR "alternative protei"
	OR "entomophagy" OR "insects" OR "insect-
	based" OR "cheese alternatives" OR "milk
	alternatives" OR "plant-based milk" OR "food
	irradiation*" OR "Irradiated food*" OR "UV
	rays" OR "nanomaterial*")

In December 2022, forwards and backwards citation screening was conducted by one researcher (AM) through Google Scholar to identify relevant articles that were not identified through the initial search or that were published after the end of the search period.

#### 2.2. Eligibility criteria and data extraction

As per pre-defined eligibility criteria, articles were considered relevant if they were published in a peer-reviewed journal, in English, between 1997<sup>22</sup> and the date of conducting the search, and reported on empirical data collected in the EU or other Western countries<sup>23</sup> (Norway, United Kingdom, Switzerland, Iceland, United States, Canada, Australia, New Zealand) used to evaluate consumer perception (including consumer acceptance, reaction, willingness to eat, pay and consume) of novel food products as per legal definition in the EU. Accordingly, articles were excluded if they were published in any other language, before 1997, or not in peerreviewed journals. Reviews, meta-analyses and other overview articles were also excluded, as were studies conducted outside of the countries listed above. Studies were also excluded if they investigated foods that do not fall under the EU definition of novel foods, i.e. foods not consumed to a significant degree within the Union before May 15, 1997, or if they did not investigate consumer perception of these foods but only sensory analysis.

The screening of titles and abstracts and later full texts was conducted by two researchers independently. Data from all but n = 32 included studies were extracted by two independent researchers. Disagreements were resolved by discussion. The last thirty-two studies were extracted by one researcher, due to lack of resources and the absence of significant disagreement in the extraction of the previous articles. The extraction sheet is available on the OSF project page. Extracted information included: characteristics of the studies (quantitative, qualitative; between or within participants; observational or experimental; online or offline); details of the studies (study design), participants' details (age; gender; cultural background; economic conditions; food habits), results of the studies and any psychological explanation resulting that could possibly be related with consumers' perception of novel foods.

All studies were subject to a process of quality appraisal following respectively the CASP Checklist for qualitative studies,<sup>24</sup> or the Checklist for Analytical Cross-Sectional Studies of

<sup>&</sup>lt;sup>22</sup> The decision to include studies published after 1997 was based on the date of entry into force of the first novel food regulation in the European Union (15th May 1997), Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

<sup>&</sup>lt;sup>23</sup> While the definition of novel foods used in this review is applicable only in the European Union, food consumption patterns and drivers of food choices are highly similar among Western cultures. To be able to include as many studies as possible, we decided to include studies conducted in any country with Western lifestyles.

<sup>&</sup>lt;sup>24</sup> Critical Appraisal Skills Programme (CASP), 'Checklist for Qualitative Researches' <a href="https://casp-uk.net/casp-tools-checklists/">https://casp-uk.net/casp-tools-checklists/</a> accessed 19 September 2024.

the Johanna Briggs Institute,<sup>25</sup> depending on the study design. Studies were included in the review independent of the quality rating achieved.

## 3. Results

## 3.1. Overview of included studies

The PRISMA flow diagram of records is depicted in Figure 1. A total of N = 182 studies were included. Among them, n = 150 were the result of the first screening process, which led to the exclusion of n = 16123 studies after abstract screening, n = 15 studies for which full text was not available, and of n = 65 exclusions after the application of the eligibility criteria. The last n = 32 studies were retrieved through handsearching.

Hereinafter, to increase readability, studies included in the review are referred to using the name of the author(s) and the year of publication. For instance, "Russel and Knott, (2021)". The complete list of articles included in the systematic review is available in the Appendix at the end of the chapter. Hyperlinks to the articles are included in the text.

We adopted broad inclusion criteria to avoid missing relevant articles. For this reason, the final sample includes studies conducted in several Western countries and comparative studies, adopting diverse methodologies (qualitative vs. quantitative; observational vs. experimental) and which differ in terms of setups, number of participants, cultural background, and demographics. Most studies included in the review (n = 115) were conducted in countries within the European Union, particularly in Italy (n = 32), Germany (n = 18), Poland (n = 11), and the Netherlands (n = 10). Sixteen studies were comparative studies between countries within and outside of the EU, including the United Kingdom and Switzerland.

<sup>&</sup>lt;sup>25</sup> Johanna Briggs Institute, 'Checklist for Analytical Cross Sectional Studies' (2020) <https://jbi.global/critical-appraisal-tools> accessed 19 September 2024.

#### Figure 1: Screening process for included studies



The vast majority of the studies used a quantitative research design. Only a minority of studies (n = 20) consisted of a qualitative design or combined qualitative approaches with quantitative attributes (n = 13). The majority of the studies (n = 158) were conducted online, or in a mixed online/offline setting (n = 18). Forty-two studies included tasting of products, either during the initial data collection or as a follow-up (n = 4). Some studies (n = 7) claimed to involve the consumption of novel foods, but the participants only tasted non-novel alternatives (e.g. bovine burger patties for cultivated meat; whole wheat flour instead of insect flour). With one exception, studies involving tasting covered only insect products or regular meat presented as cultivated meat. Studies on the latter are all hypothetical, since cultivated meat products, as of now, are not widely available on the market in any Western country.<sup>26</sup>

Studies mainly focused on two types of novel foods: insects and cultivated meat. Insect products in various forms (whole insects, flour) were the object of n = 116 studies, while n = 42 focused on cultivated meat, i.e., cultivated cell tissues from animals through lab techniques. Other investigated novel foods are nanofoods (n = 8), algae (n = 2), jellyfish and hemp (n = 1 each). Nine studies covered both cultivated meat and insects, n = 1 study compared insects with camel milk, n = 1 study insects with jellyfish and n = 1 study insects, jellyfish and cultivated meat. There is a tendency to compare novel foods with non-novel foods (n = 51), mainly with plantbased meat, and/or with other technologies like GMO foods (n = 2). Without making a direct comparison, three studies used GMO acceptance as a predictor for cultivated meat and nanofoods acceptance.

The review showed that the research on food innovations categorised as novel foods in the EU is developing steadily. Our review considers studies published between 1997 and 2022, but 137 of the 182 articles were published in or after 2019. In particular, studies covering cultivated meat increased steadily after 2019, while other technologies like nanofoods have been studied comparatively more before 2019.

Among studies covering insects, the majority focused on the cricket species Acheta domesticus and *Gryllodes sigillatus* and/or *Tenebrio molitor*, the yellow mealworm (n = 48 studies). Two studies covered the *Alphitobius diaperinus*, the buffalo mealworm. The other studies covering

<sup>&</sup>lt;sup>26</sup> To our knowledge, at the moment of writing, in Western countries only one cultivated meat product had been authorised in the US, and applications had been submitted in Switzerland and Australia-New Zealand.

insects either did not specify which species were used in the research or focused on entomophagy in general.

#### 3.2. Emotions, personality traits and socio-cultural factors in novel foods perceptions

#### 3.2.1. The role of emotions in the perception of novel foods

Several emotions, i.e. physiological and psychological reactions to a stimulus or event, were related to novel foods. Disgust was by far the most common motivation for the rejection of novel foods, particularly when such foods are of animal origin, such as insects, but also for cultivated meat. Disgust is a basic human emotion, meant to protect us from potential danger hidden in unknown foodstuffs and thus included in our risk perception and evaluation mechanisms.<sup>27</sup> The majority of the studies (n = 98) included in the review focused on disgust as a predictor (Adamczyk et al., 2023; Ardoin and Prinyawiwatkul, 2020; Arena et al., 2020; Baker, Shin, and Kim, 2016; Balzan et al., 2016; Barsics et al., 2017; Bartkowicz, Morska, and Gdyni, 2017; Berger et al., 2018a; Berger et al., 2018b; Berger et al., 2019; Bogueva and Marinova, 2020; Bryant et al., 2019b; Burt et al., 2020; Caparros Megido et al., 2016; Castro and Chambers, 2019a, 2019b; Cavallo and Materia, 2018; Chan, 2019; Cicatiello et al., 2020; Circus and Robison, 2018; Clarkson et al., 2018; Dupont et al., 2022; Egolf et al., 2019; Fischer et al., 2018; Franceković et al., 2021; Fuentes et al., 2020; García-Segovia et al., 2020a; Gmuer et al., 2016; Gómez-Luciano et al., 2019; Gumussoy et al., 2021; Gurdian et al., 2021a; 2021b; Hamerman, 2016; Hartmann and Siegrist, 2016; Herbert and Beacom, 2021; Higa et al., 2021; Ho et al., 2022; Hocquette et al., 2022; Iseppi et al., 2021; Jensen and Lieberoth, 2019; Koch et al., 2021; Kornher et al., 2019; Kostecka et al., 2017; La Barbera et al., 2018, 2019; Laestadius and Caldwell, 2015; Lammers et al., 2019; Le Goff and Delarue, 2017; Lorini et al., 2021; Lupton and Turner, 2018a, 2018b; Malavalli et al., 2021; Mancini et al., 2019; Mazurek et al., 2023; Menozzi et al., 2017; Modlinska et al., 2020, 2021; Moruzzo et al., 2021; Music, 2021; Myers and Pettigrew, 2018; Naranjo-Guevara et al., 2021; Onwezen et al., 2019, 2022; Orsi et al., 2019; Palmieri et al., 2020; Piochi et al., 2022; Placentino et al., 2021; Poortvliet et al., 2019; Ritger et al., 2016; Ros-Baró et al., 2022; Rosenfeld and Tomiyama, 2022; Rovai et al., 2021, 2022; Ruby et al., 2015; Russell and Knott, 2021; Ruzgys and Pickering, 2020; Serpico et al., 2021; Siegrist

<sup>&</sup>lt;sup>27</sup> Valerie Curtis, 'Why Disgust Matters' (2011) 366 Philosophical Transactions of the Royal Society B: Biological Sciences 3478; Paul Rozin and April E Fallon, 'A Perspective on Disgust' (1987) 94 Psychological Review 23.

et al., 2018; Siegrist and Hartmann, 2020; Simion et al., 2020; Sogari et al., 2017; Sogari et al., 2019a; Szendrő et al., 2020; Tan et al., 2015; Torri et al., 2020; Tuccillo et al., 2020; Tucker, 2014; Ventanas et al., 2022; Verbeke et al., 2015; Videbæk and Grunert, 2020; White et al., 2023; Wilks et al., 2019, 2021; Zheng et al., 2019; Zielińska et al., 2020, 2021; Çınar et al., 2021).

The role of disgust in predicting rejection of novel foods was consistent across novel foods. The other predominant emotion covered by studies included in the review was fear. Fear referred either to the fear of contaminants or the fear of safety risks, particularly in studies focusing on insects (Ardoin and Prinyawiwatkul, 2020; Baker et al., 2016; Jensen and Lieberoth, 2019; Tan et al., 2015; Zielińska et al., 2020; Çınar et al., 2021), but also in studies covering cultivated meat (Laestadius and Caldwell, 2015; Malavalli et al., 2021); or both (Lupton and Turner, 2018a; Onwezen et al., 2022). When insects were the object of the study, disgust was mostly related to the fear of contamination (Balzan et al., 2016; Hamerman, 2016; Hartmann and Siegrist, 2016; Jensen and Lieberoth, 2019; Mancini et al., 2019; Myers and Pettigrew, 2018; Russell and Knott, 2021; Videbæk and Grunert, 2020). Framing of cultivated meat and insects as high-tech products also triggered fear and disgust (Bryant and Dillard, 2019; Zheng et al., 2019).

The focus across studies was almost always on negative emotions, although Onwezen et al., (2019) and (2022), Schouteten et al., (2016), Serpico et al., (2021), Tuccillo et al., (2020), and Ventanas et al., (2022) highlighted increased willingness to consume novel foods when positive emotions such as joy or feelings of adventure and freedom are associated with the experience.

#### 3.2.2. Personality traits: food neophobia, perceived unnaturalness and curiosity

Personality traits, i.e. relatively stable individual characteristics, were also frequently related to the (negative) perception of novel foods. In n = 94 studies, food neophobia, i.e. the tendency to reject foods that are unknown or unfamiliar, was referenced as a predictor for rejection of novel foods (Adamczyk et al., 2023; Ardoin and Prinyawiwatkul, 2020; Asioli, Bazzani, and Nayga, 2022; Baker et al., 2016; Balzan et al., 2016; Bartkowicz, 2020; Boereboom et al., 2022a; Boereboom et al., 2022b; Brunner and Nuttavuthisit, 2019; Bryant et al., 2019b; Califano et al., 2023; Caparros Megido et al., 2014; Caparros Megido et al., 2016; Castro and Chambers, 2019a; Cavallo and Materia, 2018; Cicatiello et al., 2016, 2020; Çınar et al., 2021; Clarkson et al., 2018; Conti et al., 2018; de Beukelaar et al.,

2019; De Koning et al., 2020; Dupont et al., 2022; Elorinne et al., 2019; Fischer et al., 2018; García-Segovia et al., 2020b; Gere et al., 2017; Gómez-Luciano et al., 2019, 2022; Grasso et al., 2019; Gurdian et al., 2021a, 2021b; Hamlin et al., 2022; Hartmann et al., 2015; Iannuzzi et al., 2019; Iseppi et al., 2021; Jensen and Lieberoth, 2019; Kornher et al., 2019; La Barbera et al., 2018, 2019; Lammers et al., 2019; Laureati et al., 2016; Le Goff and Delarue, 2017; Lombardi et al., 2019; Lundén et al., 2020; Lupton and Turner, 2018b; Mancini et al., 2019; Mazurek et al., 2023; Metcalf et al., 2021; Modlinska et al., 2020, 2021; Moruzzo et al., 2021; Music, 2021; Naranjo-Guevara et al., 2021; Onwezen et al., 2022; Orkusz et al., 2020; Orsi et al., 2019; Palmieri et al., 2023; Penedo et al., 2022; Piha et al., 2018; Piochi et al., 2022; Placentino et al., 2021; Ribeiro et al., 2022; Ritger et al., 2016; Rombach et al., 2022; Ros-Baró et al., 2022; Rovai et al., 2022; Ruby et al., 2015; Ruzgys and Pickering, 2020; Schäufele et al., 2019; Schlup and Brunner, 2018; Sidali et al., 2019; Siegrist and Hartmann, 2020; Simion et al., 2020; Sodano et al., 2016; Sogari et al., 2019a, 2019b; Stone et al., 2022; Szendrő et al., 2020; Tan et al., 2016a; Tan et al., 2016b; Torri et al., 2020; Tuccillo et al., 2020; Tucker, 2014; Vartiainen et al., 2020; Ventanas et al., 2022; Verbeke et al., 2015; Verneau et al., 2016; Videbæk and Grunert, 2020; White et al., 2023; Wilkinson et al., 2018; Wilks et al., 2019; Zielińska et al., 2021). Food neophobia was measured through variations of the Food Neophobia Scale (Cicatiello et al., 2020; Elorinne et al., 2019; Gómez-Luciano et al., 2019; Orkusz et al., 2020), sometimes re-designed to focus on specific aspects, as for the Insect Phobia Scale in Moruzzo et al. (2021).

Some studies (n = 10) focused also or exclusively on food technology neophobia, which refers to the feelings of distrust and aversion to consuming those foods that are the result of new technology applications (Boereboom et al., 2022a; De Koning et al., 2020; Dupont et al., 2022; Gómez-Luciano et al., 2019; Gorgitano et al., 2017; Kuang et al., 2020; Lammers et al., 2019; Modlinska et al., 2021; Rombach et al., 2022; Schlup and Brunner, 2018).

The theme of the rejection of products produced using new technologies such as cultivated meat or nanofoods was further studied across the review as "perceived unnaturalness" (n = 30 studies: Bryant and Dillard, 2019; Bryant et al., 2019a; Bryant and Barnett, 2019; Bryant and Sanctorum, 2021; Circus and Robison, 2018; Egolf et al., 2019; Franceković et al., 2021; Garcez de Oliveira Padilha et al., 2021; Gorgitano et al., 2017; Klöckner et al., 2022; Laestadius and Caldwell, 2015; Lensvelt and Steenbekkers, 2014; Lupton and Turner, 2018a, 2018b; Onwezen et al., 2019; Rosenfeld and Tomiyama, 2022; Ruby et al., 2015; Ruzgys and Pickering, 2020; Shaw and Mac Con Iomaire, 2019; Siegrist et al., 66 2018; Siegrist and Hartmann, 2020; Siegrist and Sütterlin, 2017; Slade, 2018; Sodano et al., 2016; Tucker, 2014; Verbeke et al., 2015; Weinrich et al., 2020; Wilks et al., 2019, 2021; Wilks and Phillips, 2017). The concept of perceived unnaturalness is broader than the simple food technology neophobia and refers to the preference for products perceived as free from modern technologies' application or excessive human intervention, felt as evil and against the myth of a benevolent nature. Perceived naturalness was normally a predictor for rejection of novel foods, particularly cultivated meat, but also nanofoods (Egolf et al., 2019; Gorgitano et al., 2017; Sodano et al., 2016), and insect products (Lensvelt and Steenbekkers, 2014; Lupton and Turner, 2018a,b; Ruby et al., 2015). Some studies related perceived unnaturalness to feelings of disgust (Bryant et al., 2019a; Circus and Robison, 2018; Franceković et al., 2021; Laestadius and Caldwell, 2015; Rosenfeld and Tomiyama, 2022; Siegrist et al., 2018; Verbeke et al., 2015).

Contrary to food neophobia and perceived unnaturalness, curiosity, i.e. the innate desire to explore, try new experiences and learn new information, was studied as a predictor for willingness to consume novel foods (Lupton and Turner, 2018a,b; Modlinska et al., 2020; Nyberg et al., 2020; Palmieri et al., 2020; Penedo et al., 2022; Placentino et al., 2021; Possidónio et al., 2021; Ribeiro et al., 2022; Ritger et al., 2016; Rombach et al., 2022; Ruby et al., 2015; Sogari, 2015; Sogari et al., 2017; Stone et al., 2022; Tan et al., 2015; Videbæk and Grunert, 2020; Zielińska et al., 2021). Curiosity was either examined directly as curiosity for new experiences or as neophilia towards new foods and acceptance for taking risks. It was related to a higher willingness to eat and try novel foods in most studies, with the exception of Palmieri et al. (2020).

#### 3.2.3. Familiarity, values and cultural influences

Familiarity refers to the previous exposure and acquaintance with a novel food.<sup>28</sup> It was associated with higher willingness to try and consume novel foods in n = 47 studies (Ali and Ali, 2022; Ardoin and Prinyawiwatkul, 2020; Asioli et al., 2022; Baker et al., 2016; Barsics et al., 2017; Barton, Richardson, and McSweeney, 2020; Baum, Bröring, and Lagerkvist, 2021; Bekker, Fischer, Tobi, and van Trijp, 2017; Bieberstein, et al., 2013; Bryant et al., 2019b; Bryant and Sanctorum, 2021; Caparros Megido et al., 2016; de Beukelaar et al.,

<sup>&</sup>lt;sup>28</sup> Joseph W Alba and J Wesley Hutchinson, 'Dimensions of Consumer Expertise' (1987) 13 Journal of Consumer Research 411.

2019; Franceković et al., 2021; Gallen et al., 2019; Garcez de Oliveira Padilha et al., 2021; Gurdian et al., 2021a; Hartmann et al., 2015; Herbert and Beacom, 2021; Higa et al., 2021; La Barbera et al., 2018; Lammers et al., 2019; Laureati et al., 2016; Lorini et al., 2021; Lupton and Turner, 2018a,b; Mancini and Antonioli, 2020a; Mancini et al., 2019; Modlinska et al., 2021; Naranjo-Guevara et al., 2021; Onwezen et al., 2019; Palmieri et al., 2019; Poortvliet et al., 2019; Possidónio et al., 2021; Schäufele et al., 2019; Schlup and Brunner, 2018; Simion et al., 2020; Steenis and Fischer, 2016; Szejda et al., 2021; Tan et al., 2015; Tan et al., 2017a; Tan et al., 2016b; Tan et al., 2017b; Verbeke et al., 2015; Weinrich et al., 2020; Wilkinson et al., 2018; Woolf et al., 2019, 2021). Some studies attempted to manipulate familiarity by providing information on the products. The provision of positive information regarding the products and its characteristics was shown to change the attitude of consumers towards novel foods (Bekker et al., 2017; Bieberstein et al., 2013; Iseppi et al., 2021; Laestadius and Caldwell, 2015; Mancini et al., 2019; Rabl and Basso, 2021; Sogari et al., 2019a; Verbeke, 2015). More specifically, informing about the environmental benefits and ethical aspects of the products reduced negative emotions like disgust or negative perception of unnaturalness (Barsics et al., 2017; Circus and Robison, 2018; Laestadius and Caldwell, 2015; Lorini et al., 2021; Naranjo-Guevara et al., 2021; Simion et al., 2020; Weinrich et al., 2020). Sometimes however, provision of technical information can be detrimental: Bryant and Dillard (2019), Franceković et al. (2021) noted how consumers were less disgusted by cultivated meat if less information about its production was provided.

Barsics et al., (2017), Hénault-Ethier et al., (2020), Jensen and Lieberoth, (2019), Myers and Pettigrew, (2018), Schäufele et al., (2019) and Stollar et al., (2022) noted that culture is a predictive factor for positive attitudes towards entomophagy, while Russell and Knott, (2021) found a lower willingness to consume insects in presence of moral concerns. Circus and Robison, (2018) found that moral and environmental concerns are strong motivators for consumers' willingness to consume cultivated meat, while conversely ethical considerations and feeling of unnaturalness can be predictors for rejection. Mancini and Antonioli, (2020a) did not find a direct relation between ethical appreciation of cultivated meat and willingness to consume. Bogueva and Marinova, (2020), Çınar et al., (2021), Sogari et al., 2019a, and Tucker (2014) identified masculinity as a predictor for rejection of cultivated meat and insects; both types of novel foods were seen as a threat to the set of beliefs, values, attitudes, and behaviours associated with being male. With the exception of Çınar et al., (2021) these studies were conducted in Australia and New Zealand where the production and consumption of meat is of
crucial economic importance. Finally, Wilks et al., (2019) relates rejection of cultivated meat to political conservativism.

#### 3.3. Heuristics and biases linked to novel foods

Among the 182 articles included in the review, only n = 14 studies (Bieberstein et al., 2013; Egolf et al., 2019; Gallen et al., 2019; Hamlin et al., 2022; Kusch and Fiebelkorn, 2019; La Barbera et al., 2018; Legendre et al., 2019; Rabl and Basso, 2021; Ruzgys and Pickering, 2020; Siegrist et al., 2007, 2008; Siegrist and Sütterlin, 2017; Wilks et al., 2019, 2021) make direct reference to heuristics and biases. According to Siegrist and Hartmann,<sup>29</sup> heuristic thinking can be linked to disgust sensitivity, food neophobia and cultural factors which shape consumers' individual perception of innovations. We thus adapted their framework for structuring our thematic analysis around the "affect", the "natural-is-better", and the "trust" heuristics. Importantly, many different heuristics have been listed in the literature, yet recent evidence indicates that they can often be subsumed under more general cognitive mechanisms, which is what we attempt to do in this section.<sup>30</sup>

#### 3.3.1. Affect heuristic

The "affect heuristic" occurs when the emotional state of people affects their evaluation of risks and benefits, which consequently influences their decision-making.<sup>31</sup> Egolf et al., (2019), La Barbera et al., (2018) highlighted the role of the dual-system for the perception of innovations and linked disgust with the impulsive System 1. Egolf et al., (2019) considered disgust as a direct trigger of the affect heuristic. Disgust drives people to unconsciously evaluate risks and benefits of novel technologies based on their (negative) perception, triggering the impulsive system rather than the reflective system. Siegrist et al., (2007) and (2008) also identified the perception of nanofoods to be shaped by the affect heuristic. Emotions and feelings evoked by nanofoods impact the perception of risks and benefits associated with them. Hamlin et al.,

<sup>&</sup>lt;sup>29</sup> Siegrist and Hartmann (n 10).

<sup>&</sup>lt;sup>30</sup> Aileen Oeberst and Roland Imhoff, 'Toward Parsimony in Bias Research: A Proposed Common Framework of Belief-Consistent Information Processing for a Set of Biases' (2023) 18 Perspectives on Psychological Science 1464.

<sup>&</sup>lt;sup>31</sup> Melissa L Finucane and others, 'The Affect Heuristic in Judgments of Risks and Benefits' (2000) 13 Journal of Behavioral Decision Making 411.

(2022) highlighted the importance of the affective dimensions for the perception of cultivated meat.

The substitution of factual data with emotional assessments was also investigated by Kusch and Fiebelkorn, (2019) and Gallen et al., (2019). Kusch and Fiebelkorn, (2019) focused on two biases: the "negative footprint illusion" and the quantity insensitivity. The "negative footprint illusion" is the tendency of people to think that their food choices are more sustainable than they truly are.<sup>32</sup> Similarly, quantity insensitivity refers to the inability of people to correctly estimate the environmental impact of a food (e.g., burger patties) based on both the property of the products (in this case, patties made from insects vs. meat vs. plant-based alternatives) and the consumed quantity.<sup>33</sup> Kusch and Fiebelkorn, (2019) showed how burdensome mental processes and complex calculations are substituted with feelings originating from subjective experiences. Gallen et al., (2019) explained the mechanisms at the base of consumer perception of insect foods mainly through the contagion and the representativeness heuristics. The contagion heuristic originates from the fear of contamination and disgust, while the representativeness heuristic increases consumers' acceptance when insect foods can be associated with known foods through visualisation.

#### 3.3.2. Natural-is-better heuristic

Not all of the studies focusing on perceived unnaturalness make direct reference to heuristic literature, although they often imply an influence on decision-making. Specifically, perceived unnaturalness becomes a heuristic when natural products are considered healthier and tastier, using naturalness as a qualitative attribute for evaluating the novel food.<sup>34</sup>

Siegrist and Sütterlin, (2017) specifically referred to a perceived unnaturalness heuristic shaping acceptance of cultivated meat. Consumers were found to be more willing to accept the risks associated with the consumption of traditional meat, because they perceived them as established and natural, while the risks derived from cultivated meat were perceived as new and

<sup>&</sup>lt;sup>32</sup> Karen Gorissen and Bert Weijters, 'The Negative Footprint Illusion: Perceptual Bias in Sustainable Food Consumption' (2016) 45 Journal of Environmental Psychology 50.

<sup>&</sup>lt;sup>33</sup> Byungdoo Kim and Jonathon P Schuldt, 'Judging the Environmental Impact of Green Consumption: Evidence of Quantity Insensitivity' (2018) 60 Journal of Environmental Psychology 122.

<sup>&</sup>lt;sup>34</sup> Sergio Román, Luis Manuel Sánchez-Siles and Michael Siegrist, 'The Importance of Food Naturalness for Consumers: Results of a Systematic Review' (2017) 67 Trends in Food Science and Technology 44.

unnatural. The role of the natural-is-better heuristic in the perception of cultivated meat was also highlighted by Wilks et al., (2019) and (2021). In Wilks et al., (2021) the authors further investigated perception of naturalness, and connected it to the dual-system model. They speculate that the naturalness bias originates in both systems, which means that it does not only relate to instincts. The naturalness bias was also seen as (deliberate) justification for feelings of wrongness or disgust, a finding confirmed by Siegrist et al., (2018). In both Wilks et al., (2019) and (2021) perception of unnaturalness did not always result in rejection on an individual level. Indeed, some people might be curious about trying foods produced through novel technologies.

#### 3.3.3. Trust heuristic

The "trust heuristic" describes the tendency of people to substitute the evaluation of specific attributes of a given product or production process with the general trust towards those new technologies, which can be influenced by trust in the source of information.<sup>35</sup> In their study, Rabl and Basso, (2021) explored the impact of the producer's corporate social responsibility on the perception of cultivated meat. The research specifically investigated how the company's commitment to economic, social, and environmental sustainability influences individuals' perception of cultivated meat. While the effect of positive corporate behaviour was negligible, negative corporate behaviour lead to a substantial negative effect on consumers' attitudes towards cultivated meat, decreasing its acceptance. Siegrist et al., (2007) also highlighted that the level of trust towards the food industry impacts the perception of risks and benefits associated with nanofoods. Among studies not directly referring to heuristics and biases, Bieberstein et al., (2013), Bryant and Dillard, (2019), Bryant and Sanctorum, (2021), Lin-Hi et al. (2022, 2023), Siegrist et al., (2007), Siegrist et al., (2008), Siegrist and Hartmann, (2020), Siegrist and Sütterlin, (2017), Sodano et al., (2016), Sogari et al., (2019a) and Zheng et al. (2019) also underlined the importance of consumers' trust towards companies and regulators for the acceptance of insects and cultivated meat. Some studies (Bogueva and Marinova, 2020; Sogari et al., 2019a; Wilks et al., 2019) have shown that rejection of insects and cultivated meat is sometimes due to the influence of a conspiracy theory that suggests novel foods are being promoted as part of a hidden agenda to replace traditional foods for economic purposes. In Wilks et al., (2019) and Siegrist et al., (2018), distrust toward

<sup>&</sup>lt;sup>35</sup> Nicole D Sintov and Kristin F Hurst, 'Experimental Support for a Trust Heuristic' (2023) 26 Journal of Risk Research 37.

science was similarly identified as a strong predictor for cultivated meat rejection. Gallen et al., (2019) ascribed higher acceptance of insect foods to the influence of trusted authorities and loved ones.

In Bieberstein et al., (2013), familiarity positively correlated with increased trust toward science and technology, and is shown to reduce negative risk perception and corresponding reactions. Legendre et al., (2019) noted that familiarity increased trust in media information and that heuristics help to filter relevant information to aid decision-making. Ruzgys and Pickering, (2020) alluded to the "mere exposure" effect when discussing the perception of cultivated meat among young consumers. The "mere exposure" effect refers to accepting and incorporating foods into the diet as a result of having had the opportunity to taste them multiple times. Accordingly, marketing and promotional efforts offering consumers the opportunity to sample and taste novel technologies could promote their acceptance.

### 4. Discussion

In the present review, we adopted a legal definition derived from the EU regulatory framework to define the scope of the research. The final sample includes studies on consumers' perception of novel foods conducted in several Western countries and comparative studies, adopting diverse methodologies (qualitative vs. quantitative; observational vs. experimental) and which differ in terms of setups, number of participants, cultural background, and demographics.

The review provides an extensive overview of psychological aspects shaping the perception of novel foods. The majority of studies included in the review focused on insects and cultivated meat, for which disgust and fear, food neophobia and specific cultural norms are most often associated with rejection. Familiarity with these products as well as curiosity were correlated with higher acceptance. Although less frequently investigated, similar patterns seem to play a role for the acceptance of other novel foods such as nanofoods. Furthermore, despite being investigated in a minority of studies, heuristics and related biases are shown to be related to the identified relevant emotions, personality traits and cultural factors. The heuristics and biases addressed in the literature could be grouped into three categories: the "affect heuristic", the "natural-is-better heuristic", and "the trust heuristic".

Building on the main findings of this review, we now discuss to what extent heuristics and related psychological factors affecting consumers' perception of novel foods are currently

reflected in the novel food framework, assuming that the debate leading to policy-making decisions is also rooted in basic psychological principles.

## 4.1. Consumer perception and the regulation of novel foods

The most consistent result across studies included in the review is the reluctance of consumers to consume novel foods. With no particular exception, studies showed that consumers are reluctant when asked to try, buy or consume novel food products such as insects, cultivated meat or nanofoods. Emotions like disgust and fear, personality traits such as food neophobia and perceived unnaturalness, trigger the heuristics ("affect", "natural-is-better", "trust") identified in our analysis, which highlight a consistent pattern of rejection's elements.

Regulation (EU) 2283/2015 defines the framework applicable to novel foods in the EU. When the legislation was drafted, regulators had to determine the scope of the framework by adopting a definition of novel foods. They decided to include all food products not consumed to a significant degree within the Union before 1997.<sup>36</sup> Novel foods would then be subject to a premarket authorisation procedure. The authorisation procedure has been criticized for being too complex, too long (taking up to three years), and too costly.<sup>37</sup> Facilitated procedures are in place for a particular category of novel foods, the traditional foods from third countries, which are novel foods derived from primary production that have a history of consumption in a third country.<sup>38</sup>

The decision to introduce a pre-market authorisation system was taken to protect human health and consumers' interests. The definition of novel foods however does not immediately reflect a safety risk, but it introduces the element of "novelty" to determine what is considered risky.<sup>39</sup> Thus, the decision to consider all products not consumed before 1997 in the EU as novel foods mirrors the food neophobia of consumers highlighted in this review.

<sup>&</sup>lt;sup>36</sup> NFR (n 3). Article 3(2)(a)

<sup>&</sup>lt;sup>37</sup> Anu Lähteenmäki-Uutela and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336.

<sup>&</sup>lt;sup>38</sup> NFR (n 3). Article 14.

<sup>&</sup>lt;sup>39</sup> Alessandro Monaco and Kai 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 219.

Similarly, the decision to offer a facilitated procedure for authorizing products for traditional foods from third countries is limited to those novel foods derived from primary production, defined in the EU as "*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*".<sup>40</sup> The decision to restrict the facilitated procedure only to such products reflects the importance of the "natural-is-better" heuristic.

Thus, the regulatory framework seems to mirror the heuristics shaping individual consumer's decision making. Scholars such as Slovic and Sunstein have shown how heuristics and biases shape legislators' attitudes toward risks.<sup>41</sup> Despite not being an exhaustive nor exclusive explanation for how Regulation (EU) 2283/2015 was drafted, analysing which heuristics and biases might have played a role in shaping the regulatory environment increases the comprehension of the legislators' decision-making processes.

# 4.2. Public debate on the regulation of insects and cultivated meat

In the EU, novel foods can enter the market if they are authorised through a risk analysis procedure, made by a risk assessment undertaken by the European Food Safety Authority (EFSA) and a final decision by political authorities, through a vote of EU Member States representatives in a dedicated committee.<sup>42</sup> Despite this rigorous and systematic framework, controversial novel foods like insects and cultivated meat have caused heated debates. This mirrors the results of this review, which showed that primary research on products categorised as novel foods has shifted almost exclusively to insects and cultivated meat: these two categories of novel foods have been the focus of the majority of the studies included in the review, while other novel foods received little to no attention.

For both insects and cultivated meat, the effects of the "affect heuristic" triggered by disgust and of the "trust heuristic" are crucial in the debate. In the case of insects, the feeling of disgust originates in them being seen as contaminants; this perception is culturally engrained in many

<sup>&</sup>lt;sup>40</sup> 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 2002. Article 3(17).

<sup>&</sup>lt;sup>41</sup> Paul Slovic, 'Perception of Risk' (1987) 236 Science 280; Timur Kuran and Cass R Sunstein, 'Availability Cascades and Risk Regulation' (1999) 51 Stanford Law Review 683.

<sup>&</sup>lt;sup>42</sup> NFR (n 3). Articles 10 to 13.

Western societies.<sup>43</sup> Thus, avoidance reactions to insects are typically learned at a young age, making the association difficult to delete or even flipped into a positive association.<sup>44</sup> Due to the social nature of disgust, a clear example of which is the acceptance of insects by some cultures and their rejection by others,<sup>45</sup> some scholars argued that information provision (e.g., about the authorisation procedure ensuring safety of insect-based foods) is insufficient in reducing disgust.<sup>46</sup>

The authorisation of the products should indicate to consumers that the authorised products are safe. However, following the EU authorisation of insect flour for uses in biscuits and pasta products, several conspiracy theories linked the promotion of insects' consumption with an attempt to destroy the national identity of Italy and Germany and called for their prohibition due to (unproven) safety risks.<sup>47</sup> Likewise, the recent ban on cultivated meat production adopted by the Italian government may have been influenced by negative perceptions of this technology.<sup>48</sup> Since no EU-wide authorisations have been granted yet to any of these products, the Italian government decided to act in advance by prohibiting the national production of cultivated meat, which seems more an attempt to gain approval from concerned voters rather than a decision based on scientific evidence. The concerns of the public are likely due to the

<sup>&</sup>lt;sup>43</sup> Paul Rozin and Jonathan Haidt, 'The Domains of Disgust and Their Origins: Contrasting Biological and Cultural Evolutionary Accounts' (2013) 17 Trends in Cognitive Sciences 367.

<sup>&</sup>lt;sup>44</sup> Niels Holm Jensen and Andreas Lieberoth, 'We Will Eat Disgusting Foods Together – Evidence of the Normative Basis of Western Entomophagy-Disgust from an Insect Tasting' (2019) 72 Food Quality and Preference 109.

<sup>&</sup>lt;sup>45</sup> Arnold van Huis, 'Potential of Insects as Food and Feed in Assuring Food Security' (2013) 58 Annual Review of Entomology 563.

<sup>&</sup>lt;sup>46</sup> Jan Andre Koch, Jan Willem Bolderdijk and Koert van Ittersum, 'No Way, That's Gross! How Public Exposure Therapy Can Overcome Disgust Preventing Consumer Adoption of Sustainable Food Alternatives' (2021) 10 Foods 1380.

<sup>&</sup>lt;sup>47</sup> Solvejg Hoffmann, 'Grillenmehl in Lebensmitteln: EU Erlaubt Beimischung von Insektenpulver' (*GEO*, 19 January 2023) <a href="https://www.geo.de/wissen/ernaehrung/insekten-in-lebensmitteln-jetzt-in-der-eu-zugelassen-33115156.html">https://www.geo.de/wissen/ernaehrung/insekten-in-lebensmitteln-jetzt-in-der-eu-zugelassen-33115156.html</a> accessed 19 September 2024 ; Marco Leardi, 'Gli insetti arrivano al supermercato. Un attacco alla dieta mediterranea' (*Il Giornale*, 24 January 2023) <a href="https://www.ilgiornale.it/news/europa/attacco-dieta-mediterranea-insetti-tavola-ora-sono-commercio-2108431.html">https://www.ilgiornale.it/news/europa/attacco-dieta-mediterranea-insetti-tavola-ora-sono-commercio-2108431.html</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>48</sup> Alessandro Bertero and others, 'We Need an Informed Discussion on Cultivated Meat' (2023) Nature Italy < 10.1038/d43978-023-00056-1 > accessed 19 September 2024; Daniela de Lorenzo, 'Italy Gets One Step Closer To Ban Cultivated Meat Production And Imports' (*Forbes*, 19 July 2023) < https://www.forbes.com/sites/danieladelorenzo/2023/07/19/italy-gets-one-step-closer-to-ban-cultivated-meat-production-and-imports/> accessed 19 September 2024.

complexity of the authorisation procedure system, which might trigger feelings of unease, fear, and even distrust towards authorities.<sup>49</sup>

According to the results of the review, familiarity seems to be the most reliable strategy to overcome disgust and trust issues. Public exposure to edible insects, and in the future cultivated meat, e.g. through public institutions, retailers and food producers, opinion leaders, and parents and caretakers, may establish new social norms regarding their consumption. While regulators may not directly influence these social norms through legislation, they can still have an indirect impact by establishing the necessary conditions that contribute to the formation of such norms.<sup>50</sup>

## 4.3. Limitations

Our review presents some limitations. First, the number of studies testing the influence of heuristics and biases, or at least explicitly discussing them as a potential explanation for findings, is very low. The majority of the studies investigated factors like disgust and food neophobia, emotions and personal traits that lead to or are caused by heuristics and biases.<sup>51</sup> Primary research included in the review thus lacks insights into underlying psychological mechanisms that explain the connection between the various psychological factors and perceptions and behaviour through heuristics and biases.

Second, the consumers' acceptance of novel foods is not only due to the influence of emotional factors, heuristics and biases. Aspects as religious beliefs, socio-economic status, level of education and age may also impact consumers' food choices.<sup>52</sup> Future reviews should also take these aspects into account.

Third, included articles mainly focus on negative emotions and avoidance reactions, which provide valuable insights into why novel foods are not yet consumed. However, to depict a more complete picture, future research should address positive emotions and other influencing

<sup>&</sup>lt;sup>49</sup> Rod A Herman and others, 'Transparency in Risk-Disproportionate Regulation of Modern Crop-Breeding Techniques' (2021) 12 GM Crops and Food 376.

<sup>&</sup>lt;sup>50</sup> Lucia A Reisch, 'Shaping healthy and sustainable food systems with behavioural food policy'(2021) 48 European Review of Agricultural Economics 665.

<sup>&</sup>lt;sup>51</sup> Lerner and others (n 12).

<sup>&</sup>lt;sup>52</sup> Pin-Jane Chen and Marta Antonelli, 'Conceptual Models of Food Choice: Influential Factors Related to Foods, Individual Differences, and Society' (2020) 9 Foods 1898; Eva C Monterrosa and others, 'Sociocultural Influences on Food Choices and Implications for Sustainable Healthy Diets' (2020) 41 Food and Nutrition Bulletin 59.

factors, like curiosity or familiarity, that improve the acceptance of consumers and their ability to overcome negative feelings. This could provide valuable starting points for interventions to promote the intake of novel foods.

Fourth, the research in the sector is dominated by two specific novel food categories: insects and cultivated meat. Only a small number of studies examined nanofoods, algae and jellyfish. Due to this imbalance, it is difficult to draw decisive conclusions as to whether the identified influences and mechanisms translate to other types of novel foods. Further, it must be noted that, in the EU, depending on the employed processes, cell-based products like cultivated meat or products of precision fermentation could potentially be classified as genetically modified organisms and not as novel foods.<sup>53</sup> Finally, we only considered studies published in English. Studies published in other languages like Italian, German, French or Spanish, that might have fallen into the scope of the review have not been included in the review.

## **5.** Conclusions

The review aimed to identify which heuristics and cognitive biases have been described in primary research on novel foods perception and determine how they, together with other psychological factors, affect consumer perception of novel foods. Heuristics and biases are the explicit focus only of a minority of studies, but they can be related to the emotions, personality traits and cultural factors investigated in a larger number of studies. The results of the review must be interpreted by considering the predominant number of studies focusing on insects and cultivated meat, which are potentially more controversial compared to other novel foods, for example, algae or plant-based protein extracts. Based on the studies included in this review, we conclude that disgust, fear and food neophobia are frequent reasons for the rejection of insects, cultivated meat, and nanofoods which trigger the action of different heuristics that we thematically cluster under the "affect", the "trust" and "the natural-is-better" heuristics. Yet, more studies are needed to test whether these findings also hold for other, less frequently studied novel foods. The regulatory framework applicable to novel foods in the EU reflects the consumer perception of novel foods since it focuses on novelty and unnaturalness as key factors to determine which products should be regulated. However, the negative perception of novel foods remains even when products are authorised and proven safe. Increasing familiarity with

<sup>&</sup>lt;sup>53</sup> Federica Ronchetti, Laura Springer and Kai Purnhagen, 'Pre-market Authorisation' in Federica Ronchetti, Laura Springer and Kai Purnhagen (eds), *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation*. (Springer Brief in Law, 2024) pp. 19-39.

novel foods like insects and cultivated meat seems to be the most effective way forward to increase consumer acceptance.

# Appendix: List of articles included in the review

	List of articles included in the systematic review
Adamczyk et	Adamczyk, D., Modlinska, K., Maison, D., Goncikowska, K., Ekström, S.
al., 2023	s., & Pisula, W. (2023). Creepy crawlies or beauty queens? The effect of
	type of insect on the evaluation of foods containing Insects. Journal of
	Insects as Food and Feed, 9(1), 25–42.
	https://doi.org/10.3920/JIFF2022.0007
Ali and Ali,	Ali, L., & Ali, F. (2022). Perceived risks related to unconventional
2022	restaurants: A perspective from edible Insects and live seafood
	restaurants. Food Control, 131, 108471.
	https://doi.org/10.1016/j.foodcont.2021.108471
Ardoin and	Ardoin, R., & Prinyawiwatkul, W. (2020). Product appropriateness,
Prinyawiwatkul	willingness to try and perceived risks of foods containing insect protein
, 2020	powder: A survey of U.S. consumers. International Journal of Food
	Science & Technology, 55(9), 3215–3226.
	https://doi.org/10.1111/ijfs.14612
Arena et al.,	Arena, E., Mazzaglia, A., Selvaggi, R., Pecorino, B., Fallico, B., Serranò,
2020	M., & Pappalardo, G. (2020). Exploring Consumer's Propensity to
	Consume Insect-Based Foods. Empirical Evidence from a Study in
	Southern Italy. Applied System Innovation, 3(3), Article 3.
	https://doi.org/10.3390/asi3030038
Asioli et al.,	Asioli, D., Bazzani, C., & Nayga Jr, R. M. (2022). Are consumers willing
2022	to pay for in-vitro meat? An investigation of naming effects. Journal of
	Agricultural Economics, 73(2), 356-375. https://doi.org/10.1111/1477-
	9552.12467

Baker, Shin,	Baker, M. A., Shin, J. T., & Kim, Y. W. (2016). An Exploration and
and Kim, 2016	Investigation of Edible Insect Consumption: The Impacts of Image and
	Description on Risk Perceptions and Purchase Intent. Psychology &
	Marketing, 33(2), 94–112. https://doi.org/10.1002/mar.20847
Balzan et al.,	Balzan, S., Fasolato, L., Maniero, S., & Novelli, E. (2016). Edible Insects
2016	and young adults in a north-east Italian city an exploratory study. British
	Food Journal, 118(2), 318-326. https://doi.org/10.1108/BFJ-04-2015-
	0156
Barsics et al.,	Barsics, F., Caparros Megido, R., Brostaux, Y., Barsics, C., Blecker, C.,
2017	Haubruge, E., & Francis, F. (2017). Could new information influence
	attitudes to foods supplemented with edible Insects? British Food Journal,
	119(9), 2027-2039. https://doi.org/10.1108/BFJ-11-2016-0541
Bartkowicz,	Bartkowicz, J. (2020). Attitude toward food in aspect of risks and benefits
2020	related to the consumption of edible Insects by Polish consumers.
	Roczniki Panstwowego Zakladu Higieny, 71(1), 67–79.
	https://doi.org/10.32394/rpzh.2020.0107
Bartkowicz,	Bartkowicz, J., Morska, A., & Gdyni. (2017). Tri-City Consumers
Morska, and	Attitudes towards Eating Edible Insect as an Alternative Source of Food.
Gdyni, 2017	1, 156–166.
Barton,	Barton, A., Richardson, C. D., & McSweeney, M. B. (2020). Consumer
Richardson, and	attitudes toward entomophagy before and after evaluating cricket (Acheta
McSweeney,	domesticus)-based protein powders. Journal of Food Science, 85(3), 781-
2020	788. https://doi.org/10.1111/1750-3841.15043

Baum, Bröring,	Baum, C. M., Bröring, S., & Lagerkvist, CJ. (2021). Information,
and Lagerkvist,	attitudes, and consumer evaluations of cultivated meat. Food Quality and
2021	Preference, 92, 104226. https://doi.org/10.1016/j.foodqual.2021.104226
Bekker,	Bekker, G. A., Fischer, A. R. H., Tobi, H., & van Trijp, H. C. M. (2017).
Fischer, Tobi,	Explicit and implicit attitude toward an emerging food technology: The
and van Trijp,	case of cultured meat. Appetite, 108, 245–254.
2017	https://doi.org/10.1016/j.appet.2016.10.002
Berger et al.,	Berger, S., Bärtsch, C., Schmidt, C., Christandl, F., & Wyss, A. M.
2018a	(2018). When Utilitarian Claims Backfire: Advertising Content and the
	Uptake of Insects as Food. Frontiers in Nutrition, 5, 88.
	https://doi.org/10.3389/fnut.2018.00088
Berger et al.,	Berger, S., Christandl, F., Schmidt, C., & Baertsch, C. (2018). Price-based
2018b	quality inferences for Insects as food. British Food Journal, 120(7), 1615-
	1627. https://doi.org/10.1108/BFJ-08-2017-0434
Berger et al.,	Berger, S., Christandl, F., Bitterlin, D., & Wyss, A. M. (2019). The social
2019	insectivore: Peer and expert influence affect consumer evaluations of
	Insects as food. Appetite, 141, 104338.
	https://doi.org/10.1016/j.appet.2019.104338
Bieberstein,	Bieberstein, A., Roosen, J., Marette, S., Blanchemanche, S., &
Roosen,	Vandermoere, F. (2013). Consumer choices for nano-food and nano-
Marette,	packaging in France and Germany. European Review of Agricultural
Blanchemanche	Economics, 40(1), 73-94. https://doi.org/10.1093/erae/jbr069
and	
Vandermoere,	
2013	

Boereboom et	Boereboom, A., Mongondry, P., de Aguiar, L. K., Urbano, B., Jiang, Z.
al., 2022a	(Virgil), de Koning, W., & Vriesekoop, F. (2022). Identifying Consumer
	Groups and Their Characteristics Based on Their Willingness to Engage
	with Cultured Meat: A Comparison of Four European Countries. Foods,
	11(2), Article 2. https://doi.org/10.3390/foods11020197
Boereboom et	Boereboom, A., Sheikh, M., Islam, T., Achirimbi, E., & Vriesekoop, F.
al., 2022b	(2022). Brits and British Muslims and their perceptions of cultured meat:
	How big is their willingness to purchase? Food Frontiers, 3.
	https://doi.org/10.1002/fft2.165
Bogueva and	Bogueva, D., & Marinova, D. (2020). Cultured Meat and Australia's
Marinova, 2020	Generation Z. Frontiers in Nutrition, 7.
	https://www.frontiersin.org/articles/10.3389/fnut.2020.00148
Brunner and	Brunner, T. A., & Nuttavuthisit, K. (2019). A consumer-oriented
Nuttavuthisit,	segmentation study on edible Insects in Switzerland and Thailand. British
2019	Food Journal, 122(2), 482-488. https://doi.org/10.1108/BFJ-08-2018-
	0526
Bryant and	Bryant, C. J., & Barnett, J. C. (2019). What's in a name? Consumer
Barnett, 2019	perceptions of in vitro meat under different names. Appetite, 137, 104-
	113. https://doi.org/10.1016/j.appet.2019.02.021
Bryant and	Bryant, C., & Dillard, C. (2019). The Impact of Framing on Acceptance
Dillard, 2019	of Cultured Meat. Frontiers in Nutrition, 6.
	https://www.frontiersin.org/articles/10.3389/fnut.2019.00103
Bryant et al.,	Bryant, C. J., Anderson, J. E., Asher, K. E., Green, C., & Gasteratos, K.
2019a	(2019). Strategies for overcoming aversion to unnaturalness: The case of

	clean meat. Meat Science, 154, 37–45.
	https://doi.org/10.1016/j.meatsci.2019.04.004
Bryant et al.,	Bryant, C., Szejda, K., Parekh, N., Deshpande, V., & Tse, B. (2019). A
2019b	Survey of Consumer Perceptions of Plant-Based and Clean Meat in the
	USA, India, and China. Frontiers in Sustainable Food Systems, 3.
	https://www.frontiersin.org/articles/10.3389/fsufs.2019.00011
Bryant and	Bryant, C., & Sanctorum, H. (2021). Alternative proteins, evolving
Sanctorum,	attitudes: Comparing consumer attitudes to plant-based and cultured meat
2021	in Belgium in two consecutive years. Appetite, 161, 105161.
	https://doi.org/10.1016/j.appet.2021.105161
Burt et al., 2020	Burt, K. G., Kotao, T., Lopez, I., Koeppel, J., Goldstein, A., Samuel, L.,
	& Stopler, M. (2020). Acceptance of Using Cricket Flour as a Low
	Carbohydrate, High Protein, Sustainable Substitute for All-Purpose Flour
	in Muffins. Journal of Culinary Science & Technology, 18(3), 201–213.
	https://doi.org/10.1080/15428052.2018.1563934
Califano et al.,	Califano, G., Furno, M., & Caracciolo, F. (2023). Beyond one-size-fits-
2023	all: Consumers react differently to packaging colors and names of
	cultured meat in Italy. Appetite, 182, 106434.
	https://doi.org/10.1016/j.appet.2022.106434
Caparros	Caparros Megido, R., Gierts, C., Blecker, C., Brostaux, Y., Haubruge, É.,
Megido et al.,	Alabi, T., & Francis, F. (2016). Consumer acceptance of insect-based
2016	alternative meat products in Western countries. Food Quality and
	Preference, 52, 237–243. https://doi.org/10.1016/j.foodqual.2016.05.004

Caparros	Caparros Megido, R., Sablon, L., Geuens, M., Brostaux, Y., Alabi, T.,
Megido et al.,	Blecker, C., Drugmand, D., Haubruge, É., & Francis, F. (2014). Edible
2014	Insects Acceptance by Belgian Consumers: Promising Attitude for
	Entomophagy Development. Journal of Sensory Studies, 29(1), 14-20.
	https://doi.org/10.1111/joss.12077
Castro and	Castro, M., & Chambers, E. (2019a). Consumer Avoidance of Insect
Chambers,	Containing Foods: Primary Emotions, Perceptions and Sensory
2019a	Characteristics Driving Consumers Considerations. Foods (Basel,
	Switzerland), 8(8), 351. https://doi.org/10.3390/foods8080351
Castro and	Castro, M., & Chambers, E. (2019b). Willingness to eat an insect based
Chambers,	product and impact on brand equity: A global perspective. Journal of
2019b	Sensory Studies, 34(2), e12486. https://doi.org/10.1111/joss.12486
Cavallo and	Cavallo, C., & Materia, V. C. (2018). Insects or not Insects? Dilemmas or
Materia, 2018	Attraction for Young Generations: A Case in Italy. International Journal
	on Food System Dynamics, 9(3), Article 3.
	https://doi.org/10.18461/ijfsd.v9i3.932
Chan, 2019	Chan, E. Y. (2019). Mindfulness and willingness to try Insects as food:
	The role of disgust. Food Quality and Preference, 71, 375–383.
	https://doi.org/10.1016/j.foodqual.2018.08.014
Cicatiello et al.	Cicatiello, C., De Rosa, B., Franco, S., & Lacetera, N. (2016). Consumer
2016	approach to Insects as food: Barriers and potential for consumption in
	Italy. British Food Journal, 118(9), 2271–2286.
	https://doi.org/10.1108/BFJ-01-2016-0015
Cicatiello et al.,	Cicatiello, C., Vitali, A., & Lacetera, N. (2020). How does it taste?
2020	Appreciation of insect-based snacks and its determinants. International

	Journal of Gastronomy and Food Science, 21, 100211.
	https://doi.org/10.1016/j.ijgfs.2020.100211
Çınar et al.,	Çınar, Ç., Karinen, A. K., & Tybur, J. M. (2021). The multidimensional
2021	nature of food neophobia. Appetite, 162, 105177.
	https://doi.org/10.1016/j.appet.2021.105177
Circus and	Circus, V. E., & Robison, R. (2018). Exploring perceptions of sustainable
Robison, 2018	proteins and meat attachment. British Food Journal, 121(2), 533–545.
	https://doi.org/10.1108/BFJ-01-2018-0025
Clarkson et al.,	Clarkson, C., Mirosa, M., & Birch, J. (2018). Consumer acceptance of
2018	Insects and ideal product attributes. British Food Journal, 120(12), 2898–
	2911. https://doi.org/10.1108/BFJ-11-2017-0645
Conti et al.,	Conti, C., Costa, A., Balzaretti, C. M., Russo, V., & Tedesco, D. E. A.
2018	(2018). Survey on Food Preferences of University Students: From
	Tradition to New Food Customs? Agriculture, 8(10), Article 10.
	https://doi.org/10.3390/agriculture8100155
de Beukelaar et	de Beukelaar, M. F. A., Zeinstra, G. G., Mes, J. J., & Fischer, A. R. H.
al., 2019	(2019). Duckweed as human food. The influence of meal context and
	information on duckweed acceptability of Dutch consumers. Food Quality
	and Preference, 71, 76-86. https://doi.org/10.1016/j.foodqual.2018.06.005
De Koning et	De Koning, W., Dean, D., Vriesekoop, F., Aguiar, L. K., Anderson, M.,
al., 2020	Mongondry, P., Oppong-Gyamfi, M., Urbano, B., Luciano, C. A. G.,
	Jiang, B., Hao, W., Eastwick, E., Jiang, Z. (Virgil), & Boereboom, A.
	(2020). Drivers and Inhibitors in the Acceptance of Meat Alternatives: de
	Beukelaar, The Case of Plant and Insect-Based Proteins. Foods. 9, 1292.
	https://doi.org/10.3390/foods9091292
	1

Dupont et al.,	Dupont, J., Harms, T., & Fiebelkorn, F. (2022). Acceptance of Cultured
2022	Meat in Germany-Application of an Extended Theory of Planned
	Behaviour. Foods (Basel, Switzerland), 11(3), 424.
	https://doi.org/10.3390/foods11030424
Egolf et al.,	Egolf, A., Hartmann, C., & Siegrist, M. (2019). When Evolution Works
2019	Against the Future: Disgust's Contributions to the Acceptance of New
	Food Technologies. Risk Analysis, 39(7), 1546–1559.
	https://doi.org/10.1111/risa.13279
Elorinne et al.,	Elorinne, AL., Niva, M., Vartiainen, O., & Väisänen, P. (2019). Insect
2019	Consumption Attitudes among Vegans, Non-Vegan Vegetarians, and
	Omnivores. Nutrients, 11(2), 292. https://doi.org/10.3390/nu11020292
Fischer et al.,	Fischer, A. R. H., & Steenbekkers, L. P. A. (Bea). (2018). All Insects are
2018	equal, but some Insects are more equal than others. British Food Journal
	(Croydon, England), 120(4), 852-863. https://doi.org/10.1108/BFJ-05-
	2017-0267
Franceković et	Franceković, P., García-Torralba, L., Sakoulogeorga, E., Vučković, T., &
al., 2021	Perez-Cueto, F. J. A. (2021). How Do Consumers Perceive Cultured Meat
	in Croatia, Greece, and Spain? Nutrients, 13(4), Article 4.
	https://doi.org/10.3390/nu13041284
Fuentes et al.,	Fuentes, S., Wong, Y. Y., & Gonzalez Viejo, C. (2020). Non-Invasive
2020	Biometrics and Machine Learning Modeling to Obtain Sensory and
	Emotional Responses from Panelists during Entomophagy. Foods, 9(7),
	Article 7. https://doi.org/10.3390/foods9070903
Gallen et al.,	Gallen, C., Pantin-Sohier, G., & Peyrat-Guillard, D. (2019). Cognitive
2019	acceptance mechanisms of discontinuous food innovations: The case of

	Insects in France. Recherche et Applications En Marketing (English
	Edition), 34(1), 48–73. https://doi.org/10.1177/2051570718791785
Garcez de	Garcez de Oliveira Padilha, L., Malek, L., & Umberger, W. J. (2021).
Oliveira Padilha	Food choice drivers of potential lab-grown meat consumers in Australia.
et al., 2021	British Food Journal, 123(9), 3014–3031. https://doi.org/10.1108/BFJ-03-
	2021-0214
García-Segovia	García-Segovia, P., Igual, M., & Martínez-Monzó, J. (2020).
et al., 2020a	Physicochemical Properties and Consumer Acceptance of Bread Enriched
	with Alternative Proteins. Foods, 9(7), Article 7.
	https://doi.org/10.3390/foods9070933
García-Segovia	García-Segovia P, García Alcaraz V, Tárrega A, Martínez-Monzó J.
et al., 2020b	Consumer perception and acceptability of microalgae based breadstick.
	Food Sci Technol Int. 2020 Sep;26(6):493-502. doi:
	10.1177/1082013220906235.
Gere et al.,	Gere, A., Székely, G., Kovács, S., Kókai, Z., & Sipos, L. (2017).
2017	Readiness to adopt Insects in Hungary: A case study. Food Quality and
	Preference, 59, 81-86. https://doi.org/10.1016/j.foodqual.2017.02.005
Gmuer et al.,	Gmuer, A., Nuessli Guth, J., Hartmann, C., & Siegrist, M. (2016). Effects
2016	of the degree of processing of insect ingredients in snacks on expected
	emotional experiences and willingness to eat. Food Quality and
	Preference, 54, 117-127. https://doi.org/10.1016/j.foodqual.2016.07.003
Gómez-Luciano	Gómez-Luciano, C. A., de Aguiar, L. K., Vriesekoop, F., & Urbano, B.
et al., 2019	(2019). Consumers' willingness to purchase three alternatives to meat
	proteins in the United Kingdom, Spain, Brazil and the Dominican

	Republic. Food Quality and Preference, 78, 103732.
	https://doi.org/10.1016/j.foodqual.2019.103732
Gómez-Luciano	Gómez-Luciano, C. A., Rondón Domínguez, F. R., Vriesekoop, F., &
et al., 2022	Urbano, B. (2022). Consumer Acceptance of Insects as Food: Revision of
	Food Neophobia Scales. Journal of International Food & Agribusiness
	Marketing, 34(3), 305–319.
	https://doi.org/10.1080/08974438.2021.1889733
Gorgitano et al.,	Gorgitano, M. T., Verneau, F., & Sodano, V. (2017). Sustainable food
2017	innovation finding the right balance between technological determinism
	and technophobia. Quality - Access to Success, 18, 231–236.
Grasso et al.,	Grasso, A. C., Hung, Y., Olthof, M. R., Verbeke, W., & Brouwer, I. A.
2019	(2019). Older Consumers' Readiness to Accept Alternative, More
	Sustainable Protein Sources in the European Union. Nutrients, 11(8),
	1904. https://doi.org/10.3390/nu11081904
Gumussoy et	Gumussoy, M., Macmillan, C., Bryant, S., Hunt, D. F., & Rogers, P. J.
al., 2021	(2021). Desire to eat and intake of 'insect' containing food is increased by
	a written passage: The potential role of familiarity in the amelioration of
	novel food disgust. Appetite, 161, 105088.
	https://doi.org/10.1016/j.appet.2020.105088
Gurdian et al.,	Gurdian, C. E., Torrico, D. D., Li, B., Tuuri, G., & Prinyawiwatkul, W.
2021a	(2021). Effect of Disclosed Information on Product Liking, Emotional
	Profile, and Purchase Intent: A Case of Chocolate Brownies Containing
	Edible-Cricket Protein. Foods, 10(8), Article 8.
	https://doi.org/10.3390/foods10081769

Gurdian et al.,	Gurdian, C. E., Torrico, D. D., Li, B., Tuuri, G., & Prinyawiwatkul, W.
2021b	(2021). Effect of Informed Conditions on Sensory Expectations and
	Actual Perceptions: A Case of Chocolate Brownies Containing Edible-
	Cricket Protein. Foods, 10(7), Article 7.
	https://doi.org/10.3390/foods10071480
Hamerman,	Hamerman, E. J. (2016). Cooking and disgust sensitivity influence
2016	preference for attending insect-based food events. Appetite, 96, 319-326.
	https://doi.org/10.1016/j.appet.2015.09.029
Hamlin et al.,	Hamlin, R. P., McNeill, L. S., & Sim, J. (2022). Food neophobia, food
2022	choice and the details of cultured meat acceptance. Meat Science, 194,
	108964. https://doi.org/10.1016/j.meatsci.2022.108964
Hartmann and	Hartmann, C., & Siegrist, M. (2016). Becoming an insectivore: Results of
Siegrist, 2016	an experiment. Food Quality and Preference, 51, 118–122.
	https://doi.org/10.1016/j.foodqual.2016.03.003
Hartmann et al.,	Hartmann, C., Shi, J., Giusto, A., & Siegrist, M. (2015). The psychology
2015	of eating Insects: A cross-cultural comparison between Germany and
	China. Food Quality and Preference, 44, 148–156.
	https://doi.org/10.1016/j.foodqual.2015.04.013
Hénault-Ethier	Hénault-Ethier, L., Marquis, D., Dussault, M., Deschamps, MH., &
et al., 2020	Vandenberg, G. (2020). Entomophagy knowledge, behaviours and
	motivations: The case of French Quebeckers. Journal of Insects as Food
	and Feed, 6(3), 245-259. https://doi.org/10.3920/JIFF2018.0039
Herbert and	Herbert, M., & Beacom, E. (2021). Exploring Consumer Acceptance of
Beacom, 2021	Insect-based Snack Products in Ireland. Journal of Food Products

	Marketing, 27(6), 267–290.
	https://doi.org/10.1080/10454446.2021.1994080
Higa et al.,	Higa, J. E., Ruby, M. B., & Rozin, P. (2021). Americans' acceptance of
2021	black soldier fly larvae as food for themselves, their dogs, and farmed
	animals. Food Quality and Preference, 90, 104119.
	https://doi.org/10.1016/j.foodqual.2020.104119
Ho et al., 2022	Ho, I., Gere, A., Chy, C., & Lammert, A. (2022). Use of Preference
	Analysis to Identify Early Adopter Mind-Sets of Insect-Based Food
	Products. Sustainability, 14(3), Article 3.
	https://doi.org/10.3390/su14031435
Hocquette et al.,	Hocquette, É., Liu, J., Ellies-Oury, MP., Chriki, S., & Hocquette, JF.
2022	(2022). Does the future of meat in France depend on cultured muscle
	cells? Answers from different consumer segments. Meat Science, 188,
	108776. https://doi.org/10.1016/j.meatsci.2022.108776
Iannuzzi et al.,	Iannuzzi, E., Sisto, R., & Nigro, C. (2019). The willingness to consume
2019	insect-based food: An empirical research on Italian consumers.
	Agricultural Economics (Zemědělská Ekonomika), 65(10), 454–462.
	https://doi.org/10.17221/87/2019-AGRICECON
Iseppi et al.,	Iseppi, L., Rizzo, M., Gori, E., Nassivera, F., Bassi, I., & Scuderi, A.
2021	(2021). Rasch Model for Assessing Propensity to Entomophagy.
	Sustainability, 13(8), Article 8. https://doi.org/10.3390/su13084346
Jensen and	Jensen NH and Lieberoth A, 'We Will Eat Disgusting Foods Together –
Lieberoth, 2019	Evidence of the Normative Basis of Western Entomophagy-Disgust from
	an Insect Tasting' (2019) 72 Food Quality and Preference 109
	l

Kantor and	Kantor BN and Kantor J, 'Public Attitudes and Willingness to Pay for
Kantor, 2021	Cultured Meat: A Cross-Sectional Experimental Study' (2021) 5 Frontiers
	in Sustainable Food Systems
	<a href="https://www.frontiersin.org/articles/10.3389/fsufs.2021.594650">https://www.frontiersin.org/articles/10.3389/fsufs.2021.594650</a>
Klöckner et al.,	Klöckner, C. A., Engel, L., Moritz, J., Burton, R. J., Young, J. F.,
2022	Kidmose, U., & Ryynänen, T. (2022). Milk, Meat, and Fish From the
	Petri Dish—Which Attributes Would Make Cultured Proteins
	(Un)attractive and for Whom? Results From a Nordic Survey. Frontiers in
	Sustainable Food Systems, 6.
	https://www.frontiersin.org/articles/10.3389/fsufs.2022.847931
Koch et al.,	Koch, J. A., Bolderdijk, J. W., & van Ittersum, K. (2021a). Disgusting?
2021	No, just deviating from internalized norms. Understanding consumer
	skepticism toward sustainable food alternatives. Journal of Environmental
	Psychology, 76, 101645. https://doi.org/10.1016/j.jenvp.2021.101645
Kornher et al.,	Kornher, L., Schellhorn, M., & Vetter, S. (2019). Disgusting or
2019	Innovative-Consumer Willingness to Pay for Insect Based Burger Patties
	in Germany. Sustainability, 11(7), Article 7.
	https://doi.org/10.3390/su11071878
Kostecka et al.,	Kostecka, J., Konieczna, K., & Cunha, L. M. (2017). Evaluation Of
2017	Insect-Based Food Acceptance By Representatives Of Polish Consumers
	In The Context Of Natural Resources Processing Retardation. Journal of
	Ecological Engineering, 18(2), 166–174.
	https://doi.org/10.12911/22998993/68301
Kuang et al.,	Kuang, L., Burgess, B., Cuite, C. L., Tepper, B. J., & Hallman, W. K.
2020	(2020). Sensory acceptability and willingness to buy foods presented as

	having benefits achieved through the use of nanotechnology. Food
	Quality and Preference, 83, 103922.
	https://doi.org/10.1016/j.foodqual.2020.103922
Kusch and	Kusch, S., & Fiebelkorn, F. (2019). Environmental impact judgments of
Fiebelkorn,	meat, vegetarian, and insect burgers: Unifying the negative footprint
2019	illusion and quantity insensitivity. Food Quality and Preference, 78,
	103731. https://doi.org/10.1016/j.foodqual.2019.103731
La Barbera et	La Barbera, F., Verneau, F., & Coppola, A. (2019). Entomophagy: A
al., 2019	contribution to the understanding of consumer intention. Calitatea-Acces
	La Succes, 20(2), 329–334.
La Barbera et	La Barbera, F., Verneau, F., Amato, M., & Grunert, K. (2018).
al., 2018	Understanding Westerners' disgust for the eating of Insects: The role of
	food neophobia and implicit associations. Food Quality and Preference,
	64, 120-125. https://doi.org/10.1016/j.foodqual.2017.10.002
Laestadius and	Laestadius, L. I., & Caldwell, M. A. (2015). Is the future of meat
Caldwell, 2015	palatable? Perceptions of in vitro meat as evidenced by online news
	comments. Public Health Nutrition, 18(13), 2457–2467.
	https://doi.org/10.1017/S1368980015000622
Lammers et al.,	Lammers, P., Ullmann, L. M., & Fiebelkorn, F. (2019). Acceptance of
2019	Insects as food in Germany: Is it about sensation seeking, sustainability
	consciousness, or food disgust? Food Quality and Preference, 77, 78-88.
	https://doi.org/10.1016/j.foodqual.2019.05.010
Laureati et al.,	Laureati, M., Proserpio, C., Jucker, C., & Savoldelli, S. (2016). New
2016	sustainable protein sources: Consumers' willingness to adopt Insects as

	feed and food. Italian Journal of Food Science, 28(4), 652–668.
	https://doi.org/10.14674/1120-1770/ijfs.v476
Le Goff and	Le Goff, G., & Delarue, J. (2017). Non-verbal evaluation of acceptance of
Delarue, 2017	insect-based products using a simple and holistic analysis of facial
	expressions. Food Quality and Preference, 56, 285–293.
	https://doi.org/10.1016/j.foodqual.2016.01.008
Legendre et al.,	Legendre, T. S., Jo, Y. H., Han, Y. S., Kim, Y. W., Ryu, J. P., Jang, S. J.,
2019	& Kim, J. (2019). The impact of consumer familiarity on edible insect
	food product purchase and expected liking: The role of media trust and
	purchase activism. Entomological Research, 49(4), 158–164.
	https://doi.org/10.1111/1748-5967.12342
Lensvelt and	Lensvelt, E. J. S., & Steenbekkers, L. P. A. (2014). Exploring Consumer
Steenbekkers,	Acceptance of Entomophagy: A Survey and Experiment in Australia and
2014	the Netherlands. Ecology of Food and Nutrition, 53(5), 543–561.
	https://doi.org/10.1080/03670244.2013.879865
Lin-Hi et al.,	Lin-Hi, N., Reimer, M., Schäfer, K., & Böttcher, J. (2023). Consumer
2023	acceptance of cultured meat: An empirical analysis of the role of
	organizational factors. Journal of Business Economics, 93(4), 707–746.
	https://doi.org/10.1007/s11573-022-01127-3
Lin-Hi et al.,	Lin-Hi, N., Schäfer, K., Blumberg, I., & Hollands, L. (2022). The
2022	omnivore's paradox and consumer acceptance of cultured meat: An
	experimental investigation into the role of perceived organizational
	competence and excitement. Journal of Cleaner Production, 338, 130593.
	https://doi.org/10.1016/j.jclepro.2022.130593

Lombardi et al.,	Lombardi, A., Vecchio, R., Borrello, M., Caracciolo, F., & Cembalo, L.
2019	(2019). Willingness to pay for insect-based food: The role of information
	and carrier. Food Quality and Preference, 72, 177–187.
	https://doi.org/10.1016/j.foodqual.2018.10.001
Lorini et al.,	Lorini, C., Ricotta, L., Vettori, V., Del Riccio, M., Biamonte, M., &
2021	Bonaccorsi, G. (2021). Insights into the Predictors of Attitude toward
	Entomophagy: The Potential Role of Health Literacy: A Cross-Sectional
	Study Conducted in a Sample of Students of the University of Florence.
	International Journal of Environmental Research and Public Health,
	18(10). https://doi.org/10.3390/ijerph18105306
Lundén et al.,	Lundén, S., Hopia, A., Forsman, L., & Sandell, M. (2020). Sensory and
2020	Conceptual Aspects of Ingredients of Sustainable Sources-Finnish
	Consumers' Opinion. Foods (Basel, Switzerland), 9(11), 1669.
	https://doi.org/10.3390/foods9111669
Lupton and	Lupton, D., & Turner, B. (2018a). Food of the Future? Consumer
Turner, 2018a	Responses to the Idea of 3D-Printed Meat and Insect-Based Foods. Food
	and Foodways, 26(4), 269–289.
	https://doi.org/10.1080/07409710.2018.1531213
Lupton and	Lupton, D., & Turner, B. (2018b). "I can't get past the fact that it is
Turner, 2018b	printed": Consumer attitudes to 3D printed food. Food, Culture &
	Society, 21(3), 402–418. https://doi.org/10.1080/15528014.2018.1451044
Malavalli et al.,	Malavalli, M. M., Hamid, N., Kantono, K., Liu, Y., & Seyfoddin, A.
2021	(2021). Consumers' Perception of In-Vitro Meat in New Zealand Using
	the Theory of Planned Behaviour Model. Sustainability, 13(13), Article
	13. https://doi.org/10.3390/su13137430
	I

Mancini and	Mancini, M. C., & Antonioli, F. (2020). To What Extent Are Consumers'
Antonioli,	Perception and Acceptance of Alternative Meat Production Systems
2020a	Affected by Information? The Case of Cultured Meat. Animals, 10(4),
	https://doi.org/10.3390/ani10040656
Mancini and	Mancini, M. C.; Antonioli, F. (2020) Exploring consumers' attitude
Antonioli,	towards cultured meat in Italy Meat Sci Apr;150():101-110
2020b	
Mancini et al.,	Mancini, S., Sogari, G., Menozzi, D., Nuvoloni, R., Torracca, B.,
2019	Moruzzo, R., & Paci, G. (2019). Factors Predicting the Intention of Eating
	an Insect-Based Product. Foods, 8(7), Article 7.
	https://doi.org/10.3390/foods8070270
Mazurek et al.,	Mazurek, A., Palka, A., Skotnicka, M., & Kowalski, S. (2023). Consumer
2023	Attitudes and Acceptability of Wheat Pancakes with the Addition of
	Edible Insects: Mealworm (Tenebrio molitor), Buffalo Worm
	(Alphitobius diaperinus), and Cricket (Acheta domesticus). Foods, 12(1),
	Article 1. https://doi.org/10.3390/foods12010001
Menozzi et al.,	Menozzi, D., Sogari, G., Veneziani, M., Simoni, E., & Mora, C. (2017).
2017	Eating novel foods: An application of the Theory of Planned Behaviour to
	predict the consumption of an insect-based product. Food Quality and
	Preference, 59, 27–34. https://doi.org/10.1016/j.foodqual.2017.02.001
Metcalf et al.,	Metcalf, D. A., Wiener, K. K. K., & Saliba, A. (2021). Comparing early
2021	hemp food consumers to non-hemp food consumers to determine
	attributes of early adopters of a novel food using the Food Choice
	Questionnaire (FCQ) and the Food Neophobia Scale (FNS). Future
	Foods, 3, 100031. https://doi.org/10.1016/j.fufo.2021.100031

Modlinska et	Modlinska, K., Adamczyk, D., Goncikowska, K., Maison, D., & Pisula,
al., 2020	W. (2020). The Effect of Labelling and Visual Properties on the
	Acceptance of Foods Containing Insects. Nutrients, 12(9), 2498.
	https://doi.org/10.3390/nu12092498
Modlinska et	Modlinska, K., Adamczyk, D., Maison, D., Goncikowska, K., & Pisula,
al., 2021	W. (2021). Relationship between Acceptance of Insects as an Alternative
	to Meat and Willingness to Consume Insect-Based Food-A Study on a
	Representative Sample of the Polish Population. Foods (Basel,
	Switzerland), 10(10), 2420. https://doi.org/10.3390/foods10102420
Moruzzo et al.,	Moruzzo, R., Mancini, S., Boncinelli, F., & Riccioli, F. (2021). Exploring
2021	the Acceptance of Entomophagy: A Survey of Italian Consumers. Insects,
	12(2), 123. https://doi.org/10.3390/Insects12020123
Music, 2021	Music, J. (2021). Finding alternatives: Canadian attitudes towards novel
	foods in support of sustainable agriculture. Future of Food: Journal on
	Food, Agriculture and Society, 9(3), Article 3.
	https://www.thefutureoffoodjournal.com/index.php/FOFJ/article/view/42
	3
Myers and	Myers, G., & Pettigrew, S. (2018). A qualitative exploration of the factors
Pettigrew, 2018	underlying seniors' receptiveness to entomophagy. Food Research
	International, 103, 163–169.
	https://doi.org/10.1016/j.foodres.2017.10.032
Naranjo-	Naranjo-Guevara, N., Fanter, M., Conconi, A. M., & Floto-Stammen, S.
Guevara et al.,	(2021). Consumer acceptance among Dutch and German students of
2021	Insects in feed and food. Food Science & Nutrition, 9(1), 414–428.
	https://doi.org/10.1002/fsn3.2006

Nyberg et al.,	Nyberg, M., Olsson, V., & Wendin, K. (2020). Reasons for eating
2020	Insects? Responses and reflections among Swedish consumers.
	International Journal of Gastronomy and Food Science, 22, 100268.
	https://doi.org/10.1016/j.ijgfs.2020.100268
Onwezen et al.,	Onwezen, M. C., van den Puttelaar, J., Verain, M. C. D., & Veldkamp, T.
2019	(2019). Consumer acceptance of Insects as food and feed: The relevance
	of affective factors. Food Quality and Preference, 77, 51–63.
	https://doi.org/10.1016/j.foodqual.2019.04.011
Onwezen et al.,	Onwezen, M. C., Verain, M. C. D., & Dagevos, H. (2022). Positive
2022	emotions explain increased intention to consume five types of alternative
	proteins. Food Quality and Preference, 96, 104446.
	https://doi.org/10.1016/j.foodqual.2021.104446
Orkusz et al.,	Orkusz, A., Wolańska, W., Harasym, J., Piwowar, A., & Kapelko, M.
2020	(2020). Consumers' Attitudes Facing Entomophagy: Polish Case
	Perspectives. International Journal of Environmental Research and Public
	Health, 17(7), Article 7. https://doi.org/10.3390/ijerph17072427
Orsi et al., 2019	Orsi, L., Voege, L. L., & Stranieri, S. (2019). Eating edible Insects as
	sustainable food? Exploring the determinants of consumer acceptance in
	Germany. Food Research International, 125, 108573.
	https://doi.org/10.1016/j.foodres.2019.108573
Palmieri et al.,	Palmieri, N., Nervo, C., & Torri, L. (2023). Consumers' attitudes towards
2023	sustainable alternative protein sources: Comparing seaweed, Insects and
	jellyfish in Italy. Food Quality and Preference, 104, 104735.
	https://doi.org/10.1016/j.foodqual.2022.104735

Palmieri et al.,	Palmieri, N., Perito, M. A., & Lupi, C. (2020). Consumer acceptance of
2020	cultured meat: Some hints from Italy. British Food Journal, 123(1), 109-
	123. https://doi.org/10.1108/BFJ-02-2020-0092
Palmieri et al.,	Palmieri, N., Perito, M. A., Macrì, M. C., & Lupi, C. (2019). Exploring
2019	consumers' willingness to eat Insects in Italy. British Food Journal,
	121(11), 2937–2950. https://doi.org/10.1108/BFJ-03-2019-0170
Penedo et al.,	Penedo, A. O., Bucher Della Torre, S., Götze, F., Brunner, T. A., &
2022	Brück, W. M. (2022). The Consumption of Insects in Switzerland:
	University-Based Perspectives of Entomophagy. Foods, 11(18), Article
	18. https://doi.org/10.3390/foods11182771
Piha et al., 2018	Piha, S., Pohjanheimo, T., Lähteenmäki-Uutela, A., Křečková, Z., &
	Otterbring, T. (2018). The effects of consumer knowledge on the
	willingness to buy insect food: An exploratory cross-regional study in
	Northern and Central Europe. Food Quality and Preference, 70, 1–10.
	https://doi.org/10.1016/j.foodqual.2016.12.006
Piochi et al.,	Piochi, M., Micheloni, M., & Torri, L. (2022). Effect of informative
2022	claims on the attitude of Italian consumers towards cultured meat and
	relationship among variables used in an explicit approach. Food Research
	International, 151, 110881. https://doi.org/10.1016/j.foodres.2021.110881
Placentino et	Placentino, U., Sogari, G., Viscecchia, R., De Devitiis, B., & Monacis, L.
al., 2021	(2021). The New Challenge of Sports Nutrition: Accepting Insect Food as
	Dietary Supplements in Professional Athletes. Foods, 10(5), Article 5.
	https://doi.org/10.3390/foods10051117
Poortvliet et al.,	Poortvliet, P. M., Van der Pas, L., Mulder, B. C., & Fogliano, V. (2019).
2019	Healthy, but Disgusting: An Investigation Into Consumers' Willingness to

	Try Insect Meat. Journal of Economic Entomology, 112(3), 1005–1010.
	https://doi.org/10.1093/jee/toz043
Possidónio et	Possidónio, C., Prada, M., Graça, J., & Piazza, J. (2021). Consumer
al., 2021	perceptions of conventional and alternative protein sources: A mixed-
	methods approach with meal and product framing. Appetite, 156, 104860.
	https://doi.org/10.1016/j.appet.2020.104860
Rabl and Basso,	Rabl, V. A., & Basso, F. (2021). When Bad Becomes Worse: Unethical
2021	Corporate Behavior May Hamper Consumer Acceptance of Cultured
	Meat. Sustainability, 13(12), Article 12.
	https://doi.org/10.3390/su13126770
Ribeiro et al.,	Ribeiro, J. C., Gonçalves, A. T. S., Moura, A. P., Varela, P., & Cunha, L.
2022	M. (2022). Insects as food and feed in Portugal and Norway – Cross-
	cultural comparison of determinants of acceptance. Food Quality and
	Preference, 102, 104650. https://doi.org/10.1016/j.foodqual.2022.104650
Ritger et al.,	Ritger, S., Mirosa, M., Mangan-Walker, E., & Clarkson, C. (2016).
2016	ENTOMOPHAGY Understanding New Zealand Consumers' Attitudes
	Toward Eating Insects.
	https://ourarchive.otago.ac.nz/handle/10523/10817
Rombach et al.,	Rombach, M., Dean, D., Vriesekoop, F., de Koning, W., Aguiar, L. K.,
2022	Anderson, M., Mongondry, P., Oppong-Gyamfi, M., Urbano, B., Gómez
	Luciano, C. A., Hao, W., Eastwick, E., Jiang, Z. (Virgil), & Boereboom,
	A. (2022). Is cultured meat a promising consumer alternative? Exploring
	key factors determining consumer's willingness to try, buy and pay a
	premium for cultured meat. Appetite, 179, 106307.
	https://doi.org/10.1016/j.appet.2022.106307

Ros-Baró et al.,	Ros-Baró, M., Sánchez-Socarrás, V., Santos-Pagès, M., Bach-Faig, A., &
2022	Aguilar-Martínez, A. (2022). Consumers' Acceptability and Perception of
	Edible Insects as an Emerging Protein Source. International Journal of
	Environmental Research and Public Health, 19(23), Article 23.
	https://doi.org/10.3390/ijerph192315756
Rosenfeld and	Rosenfeld, D. L., & Tomiyama, A. J. (2022). Would you eat a burger
Tomiyama,	made in a petri dish? Why people feel disgusted by cultured meat. Journal
2022	of Environmental Psychology, 80, 101758.
	https://doi.org/10.1016/j.jenvp.2022.101758
Rovai et al.,	Rovai, D., Amin, S., Lesniauskas, R., Wilke, K., Garza, J., & Lammert,
2022	A. (2022). Are early adopters willing to accept frozen, ready-to-cook
	mealworms as a food source? Journal of Sensory Studies, 37(5), e12774.
	https://doi.org/10.1111/joss.12774
Rovai et al.,	Rovai, D., Michniuk, E., Roseman, E., Amin, S., Lesniauskas, R., Wilke,
2021	K., Garza, J., & Lammert, A. (2021). Insects as a sustainable food
	ingredient: Identifying and classifying early adopters of edible Insects
	based on eating behavior, familiarity, and hesitation. Journal of Sensory
	Studies, 36(5), e12681. https://doi.org/10.1111/joss.12681
Ruby et al.,	Ruby, M. b., Rozin, P., & Chan, C. (2015). Determinants of willingness
2015	to eat Insects in the USA and India. Journal of Insects as Food and Feed,
	1(3), 215–225. https://doi.org/10.3920/JIFF2015.0029
Russell and	Russell, P. S., & Knott, G. (2021). Encouraging sustainable insect-based
Knott, 2021	diets: The role of disgust, social influence, and moral concern in insect
	consumption. Food Quality and Preference, 92, 104187.
	https://doi.org/10.1016/j.foodqual.2021.104187

Ruzgys and	Ruzgys, S., & Pickering, G. J. (2020). Perceptions of Cultured Meat
Pickering, 2020	Among Youth and Messaging Strategies. Frontiers in Sustainable Food
	Systems, 4. https://www.frontiersin.org/articles/10.3389/fsufs.2020.00122
Schäufele et al.,	Schäufele, I., Barrera Albores, E., & Hamm, U. (2019). The role of
2019	species for the acceptance of edible Insects: Evidence from a consumer
	survey. British Food Journal, 121(9), 2190–2204.
	https://doi.org/10.1108/BFJ-01-2019-0017
Schlup and	Schlup, Y., & Brunner, T. (2018). Prospects for Insects as food in
Brunner, 2018	Switzerland: A tobit regression. Food Quality and Preference, 64, 37–46.
	https://doi.org/10.1016/j.foodqual.2017.10.010
Schouteten et	Schouteten, J. J., De Steur, H., De Pelsmaeker, S., Lagast, S., Juvinal, J.
al., 2016	G., De Bourdeaudhuij, I., Verbeke, W., & Gellynck, X. (2016). Emotional
	and sensory profiling of insect-, plant- and meat-based burgers under
	blind, expected and informed conditions. Food Quality and Preference,
	52, 27-31. https://doi.org/10.1016/j.foodqual.2016.03.011
Serpico et al.,	Serpico, M., Rovai, D., Wilke, K., Lesniauskas, R., Garza, J., & Lammert,
2021	A. (2021). Studying the Emotional Response to Insects Food Products.
	Foods, 10(10), 2404. https://doi.org/10.3390/foods10102404
Shaw and Mac	Shaw, E., & Mac Con Iomaire, M. (2019). A comparative analysis of the
Con Iomaire,	attitudes of rural and urban consumers towards cultured meat. British
2019	Food Journal, 121(8), 1782–1800. https://doi.org/10.1108/BFJ-07-2018-
	0433
Sidali et al.,	Sidali, K. L., Pizzo, S., Garrido-Pérez, E. I., & Schamel, G. (2019).
2019	Between food delicacies and food taboos: A structural equation model to
	assess Western students' acceptance of Amazonian insect food. Food

	Research International, 115, 83–89.
	https://doi.org/10.1016/j.foodres.2018.07.027
Siegrist and	Siegrist, M., & Hartmann, C. (2020). Perceived naturalness, disgust, trust
Hartmann, 2020	and food neophobia as predictors of cultured meat acceptance in ten
	countries. Appetite, 155, 104814.
	https://doi.org/10.1016/j.appet.2020.104814
Siegrist and	Siegrist, M., & Sütterlin, B. (2017). Importance of perceived naturalness
Sütterlin, 2017	for acceptance of food additives and cultured meat. Appetite, 113, 320-
	326. https://doi.org/10.1016/j.appet.2017.03.019
Siegrist et al.,	Siegrist, M., Cousin, ME., Kastenholz, H., & Wiek, A. (2007). Public
2007	acceptance of nanotechnology foods and food packaging: The influence
	of affect and trust. Appetite, 49(2), 459–466.
	https://doi.org/10.1016/j.appet.2007.03.002
Siegrist et al.,	Siegrist, M., Stampfli, N., Kastenholz, H., & Keller, C. (2008). Perceived
2008	risks and perceived benefits of different nanotechnology foods and
	nanotechnology food packaging. Appetite, 51(2), 283–290.
	https://doi.org/10.1016/j.appet.2008.02.020
Siegrist et al.,	Siegrist, M., Sütterlin, B., & Hartmann, C. (2018). Perceived naturalness
2018	and evoked disgust influence acceptance of cultured meat. Meat Science,
	139, 213–219. https://doi.org/10.1016/j.meatsci.2018.02.007
Simion et al.,	Simion, VE., Martins, O., Tudor, L., Mitranescu, E., & Zamfirache, I.
2020	(2020). Consumption of Edible Insects – Factors Influencing Individuals
	to Try New Foods. Rev Rom Med Vet, 30(3), 44–50.

Slade, 2018	Slade, P. (2018). If you build it, will they eat it? Consumer preferences
	for plant-based and cultured meat burgers. Appetite, 125, 428–437.
	https://doi.org/10.1016/j.appet.2018.02.030
Sodano, 2016	Sodano, V., Gorgitano, M. T., Verneau, F., & Vitale, C. D. (2016).
	Consumer acceptance of food nanotechnology in Italy. British Food
	Journal, 118(3), 714-733. https://doi.org/10.1108/BFJ-06-2015-0226
Sogari, 2015	Sogari, G. (2015). Entomophagy and Italian consumers: An exploratory
	analysis. Progress in Nutrition, 7, 311–316.
Sogari et al.,	Sogari, G., Menozzi, D., & Mora, C. (2017). Exploring young foodies'
2017	knowledge and attitude regarding entomophagy: A qualitative study in
	Italy. International Journal of Gastronomy and Food Science, 7, 16–19.
	https://doi.org/10.1016/j.ijgfs.2016.12.002
Sogari et al.,	Sogari, G., Bogueva, D., & Marinova, D. (2019). Australian Consumers'
2019a	Response to Insects as Food. Agriculture, 9(5), Article 5.
	https://doi.org/10.3390/agriculture9050108
Sogari et al.,	Sogari, G., Menozzi, D., & Mora, C. (2019). The food neophobia scale
2019b	and young adults' intention to eat insect products. International Journal of
	Consumer Studies, 43(1), 68–76. https://doi.org/10.1111/ijcs.12485
Steenis and	Steenis, N. D., & Fischer, A. R. (2016). Consumer attitudes towards
Fischer, 2016	nanotechnology in food products: An attribute-based analysis. British
	Food Journal, 118(5). https://doi.org/10.1108/BFJ-09-2015-0330
Stollar et al.,	Stollar, M., Rumble, J., Buck, E., Specht, A., Hu, W., & Knipe, C. L.
2022	(2022). Consumers' Purchasing Intent Regarding Conventional, Plant-
	Based, and Cultured Meats. Journal of Applied Communications, 106(1).
	https://doi.org/10.4148/1051-0834.2407

Stone et al.,	Stone, H., Fitz Gibbon, L., Millan, E., & Murayama, K. (2022). Curious			
2022	to eat Insects? Curiosity as a Key Predictor of Willingness to try novel			
	food. Appetite, 168, 105790. https://doi.org/10.1016/j.appet.2021.105790			
Szejda et al.,	Szejda, K., Bryant, C. J., & Urbanovich, T. (2021). US and UK Consumer			
2021	Adoption of Cultivated Meat: A Segmentation Study. Foods, 10(5),			
	Article 5. https://doi.org/10.3390/foods10051050			
Szendrő et al.,	Szendrő, K., Tóth, K., & Nagy, M. Z. (2020). Opinions on Insect			
2020	Consumption in Hungary. Foods, 9(12), 1829.			
	https://doi.org/10.3390/foods9121829			
Tan et al., 2015	Tan, H. S. G., Fischer, A. R. H., Tinchan, P., Stieger, M., Steenbekkers,			
	L. P. A., & van Trijp, H. C. M. (2015). Insects as food: Exploring cultural			
	exposure and individual experience as determinants of acceptance. Food			
	Quality and Preference, 42, 78–89.			
	https://doi.org/10.1016/j.foodqual.2015.01.013			
Tan et al.,	Tan, H. S. G., Fischer, A. R. H., van Trijp, H. C. M., & Stieger, M.			
2016a	(2016). Tasty but nasty? Exploring the role of sensory-liking and food			
	appropriateness in the willingness to eat unusual novel foods like Insects.			
	Food Quality and Preference, 48, 293–302.			
	https://doi.org/10.1016/j.foodqual.2015.11.001			
Tan et al.,	Tan, H. S. G., van den Berg, E., & Stieger, M. (2016). The influence of			
2016b	product preparation, familiarity and individual traits on the consumer			
	acceptance of Insects as food. Food Quality and Preference, 52, 222-231.			
	https://doi.org/10.1016/j.foodqual.2016.05.003			
Tan et al.,	Tan, H. S. G., Tibboel, C. J., & Stieger, M. (2017). Why do unusual novel			
2017a	foods like Insects lack sensory appeal? Investigating the underlying			
	sensory perceptions. Food Quality and Preference, 60, 48–58.			
------------------	--	--	--	--
	https://doi.org/10.1016/j.foodqual.2017.03.012			
Tan et al.,	Tan, H. S. G., Verbaan, Y. T., & Stieger, M. (2017). How will better			
2017b	products improve the sensory-liking and willingness to buy insect-based			
	foods? Food Research International, 92, 95–105.			
	https://doi.org/10.1016/j.foodres.2016.12.021			
Torri et al.,	Torri, L., Tuccillo, F., Bonelli, S., Piraino, S., & Leone, A. (2020). The			
2020	attitudes of Italian consumers towards jellyfish as novel food. Food			
	Quality and Preference, 79, 103782.			
	https://doi.org/10.1016/j.foodqual.2019.103782			
Tuccillo et al.,	Tuccillo, F., Marino, M. G., & Torri, L. (2020). Italian consumers'			
2020	attitudes towards entomophagy: Influence of human factors and properties			
	of Insects and insect-based food. Food Research International, 137,			
	109619. https://doi.org/10.1016/j.foodres.2020.109619			
Tucker, 2014	Tucker, C. A. (2014). The significance of sensory appeal for reduced			
	meat consumption. Appetite, 81, 168–179.			
	https://doi.org/10.1016/j.appet.2014.06.022			
Vartiainen et	Vartiainen, O., Elorinne, AL., Niva, M., & Väisänen, P. (2020). Finnish			
al., 2020	consumers' intentions to consume insect-based foods. Journal of Insects			
	as Food and Feed, 6(3), 261–272. https://doi.org/10.3920/JIFF2019.0042			
Ventanas et al.,	Ventanas, S., González-Mohino, A., Olegario, L. S., & Estévez, M.			
2022	(2022). Newbie consumers try pizzas in which bacon is replaced by			
	Tenebrio molitor L. larvae: Not as healthy as expected and not as terrible			
	as they thought. International Journal of Gastronomy and Food Science,			
	29, 100553. https://doi.org/10.1016/j.ijgfs.2022.100553			

Verbeke, 2015	Verbeke, W. (2015). Profiling consumers who are ready to adopt Insects		
	as a meat substitute in a Western society. Food Quality and Preference,		
	39, 147–155. https://doi.org/10.1016/j.foodqual.2014.07.008		
Verbeke et al.,	Verbeke, W., Marcu, A., Rutsaert, P., Gaspar, R., Seibt, B., Fletcher, D.,		
2015	& Barnett, J. (2015). 'Would you eat cultured meat?': Consumers'		
	reactions and attitude formation in Belgium, Portugal and the United		
	Kingdom. Meat Science, 102, 49–58.		
	https://doi.org/10.1016/j.meatsci.2014.11.013		
Verneau et al.,	Verneau, F., La Barbera, F., Kolle, S., Amato, M., Del Giudice, T., &		
2016	Grunert, K. (2016). The effect of communication and implicit associations		
	on consuming Insects: An experiment in Denmark and Italy. Appetite,		
	106, 30–36. https://doi.org/10.1016/j.appet.2016.02.006		
Verneau et al.,	Verneau F, La Barbera F, Amato M, Riverso R, Grunert KG. Assessing		
2020	the Role of Food Related Lifestyle in Predicting Intention towards Edible		
	Insects. Insects. 2020 Sep 25;11(10):660. doi: 10.3390/insects11100660.		
Videbæk and	Videbæk, P. N., & Grunert, K. G. (2020). Disgusting or delicious?		
Grunert, 2020	Examining attitudinal ambivalence towards entomophagy among Danish		
	consumers. Food Quality and Preference, 83, 103913.		
	https://doi.org/10.1016/j.foodqual.2020.103913		
Weinrich et al.,	Weinrich, R., Strack, M., & Neugebauer, F. (2020). Consumer acceptance		
2020	of cultured meat in Germany. Meat Science, 162, 107924.		
	https://doi.org/10.1016/j.meatsci.2019.107924		
White et al.,	White, K., Al-Shawaf, L., Lewis, D., & Wehbe, Y. (2023). Food		
2023	neophobia and disgust, but not hunger, predict willingness to eat insect		

	protein. Personality and Individual Differences, 202, 111944.			
	https://doi.org/10.1016/j.paid.2022.111944			
Wilkinson et	Wilkinson, K., Muhlhausler, B., Motley, C., Crump, A., Bray, H., &			
al., 2018	Ankeny, R. (2018). Australian Consumers' Awareness and Acceptance of			
	Insects as Food. Insects, 9(2), Article 2.			
	https://doi.org/10.3390/Insects9020044			
Wilks and	Wilks, M., & Phillips, C. J. C. (2017). Attitudes to in vitro meat: A survey			
Philips, 2017 of potential consumers in the United States. PloS One, 12(2), e				
	https://doi.org/10.1371/journal.pone.0171904			
Wilks et al.,	Wilks, M., Phillips, C. J. C., Fielding, K., & Hornsey, M. J. (2019).			
2019	Testing potential psychological predictors of attitudes towards cultured			
	meat. Appetite, 136, 137-145. https://doi.org/10.1016/j.appet.2019.01.027			
Wilks et al.,	Wilks, M., Hornsey, M., & Bloom, P. (2021). What does it mean to say			
that cultured meat is unnatural? Appetite, 156, 104960.				
	https://doi.org/10.1016/j.appet.2020.104960			
Woolf et al.,	Woolf, E., Maya, C., Yoon, J., Shertukde, S., Toia, T., Zhao, J., Zhu, Y.,			
2021	Peter, P. C., & Liu, C. (2021). Information and taste interventions for			
	improving consumer acceptance of edible Insects: A pilot study. Journal			
	of Insects as Food and Feed, 7(2), 129–139.			
	https://doi.org/10.3920/JIFF2020.0057			
Woolf et al.,	Woolf, E., Zhu, Y., Emory, K., Zhao, J., & Liu, C. (2019). Willingness to			
2019	consume insect-containing foods: A survey in the United States. LWT,			
	102, 100–105. https://doi.org/10.1016/j.lwt.2018.12.010			

Zheng et al.,	Zheng, Y., Bolton, L. E., & Alba, J. W. (2019). Technology Resistance:		
2019	The Case of Food Production Processes. Journal of Public Policy &		
	Marketing, 38(2), 246–262. https://doi.org/10.1177/0743915618812453		
Zielińska et al.,	Zielińska, E., Zieliński, D., Karaś, M., & Jakubczyk, A. (2020).		
2020	Exploration of consumer acceptance of Insects as food in Poland. Journal		
	of Insects as Food and Feed, 6(4), 383–392.		
	https://doi.org/10.3920/JIFF2019.0055		
Zielińska et al.,	Zielińska, E., Pankiewicz, U., & Sujka, M. (2021). Nutritional,		
2021	Physiochemical, and Biological Value of Muffins Enriched with Edible		
	Insects Flour. Antioxidants (Basel, Switzerland), 10(7), 1122.		
	https://doi.org/10.3390/antiox10071122		

## **Chapter 4**

## 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 lengthy 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 chapter 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.

#### **1. Introduction**

Despite their potential to mitigate the negative effects of population growth, climate change, biodiversity loss, and environmental degradation,<sup>1</sup> 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,<sup>2</sup> namely premarket approval, mandatory labelling and traceability requirements. Scholars have criticised

<sup>&</sup>lt;sup>1</sup>Adenle, Ademola A., and others, 'Two Decades of GMOs: How Modern Agricultural Biotechnology Can Help Meet Sustainable Development Goals', in Ademola A. Adenle, and others (eds), *Science, Technology, and Innovation for Sustainable Development Goals: Insights from Agriculture, Health, Environment, and Energy* (Oxford Academic, 2020) pp. 401–422; A Parodi and others, 'The Potential of Future Foods for Sustainable and Healthy Diets' (2018) 1 Nature Sustainability 782.

<sup>&</sup>lt;sup>2</sup> Anu Lähteenmäki-Uutela and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336; Jessica Vapnek, Kai Purnhagen and Ben Hillel, 'Regulatory and Legislative Framework for Novel Foods', in Shivani Pathania and Brijesh Tiwari (eds), *Food Formulation* (John Wiley & Sons, Ltd 2021) pp. 285-308.

these regulatory measures for slowing down the innovation process in the EU food sector<sup>3</sup> and for delaying the realisation of the benefits these innovations can bring.<sup>4</sup>

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.<sup>5</sup> Third, legislators and policymakers consider the perception of these products by the general public.<sup>6</sup> Consumer 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

<sup>&</sup>lt;sup>3</sup> Justus Wesseler and Nicholas Kalaitzandonakes, 'Present and Future EU GMO Policy' in Liesbeth Dries and others (eds), *EU Bioeconomy Economics and Policies: Volume II* (Springer International Publishing, 2019) pp. 245-256; Martin Holle, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing, 2018) pp. 291-330; Giovanni Tagliabue and Klaus Ammann, 'Some Basis for a Renewed Regulation of Agri-Food Biotechnology in the EU' (2018) 31 Journal of Agricultural and Environmental Ethics 1.

<sup>&</sup>lt;sup>4</sup> Parodi and others (n 1); Stefano Sforza, 'Food (In)Security: The Role of Novel Foods on Sustainability' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 59-79.

<sup>&</sup>lt;sup>5</sup> Flora Southey, "Vegan Cheese" Banned but "Veggie Burger" Still on the Table, Votes European Parliament' (*Food Navigator*, 23 October 2020) <a href="https://www.foodnavigator.com/Article/2020/10/23/Vegan-cheese-banned-but-veggie-burger-still-on-the-table-votes-European-Parliament">https://www.foodnavigator.com/Article/2020/10/23/Vegan-cheese-banned-but-veggie-burger-still-on-the-table-votes-European-Parliament> accessed 19 September 2024.

<sup>&</sup>lt;sup>6</sup> Elena Faccio and Lucrezia Guiotto Nai Fovino, 'Food Neophobia or Distrust of Novelties? Exploring Consumers' Attitudes toward GMOs, Insects and Cultured Meat' (2019) 9 Applied Sciences 4440.

related biases.<sup>7</sup> Heuristics and biases subsequently affect consumers' willingness to adopt novel foods and GMOs.<sup>8</sup>

This chapter 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.

#### 1.1. Structure of the chapter

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

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.

#### 2. Heuristics and biases in consumer perception of novel foods and GMOs

#### 2.1. Heuristics and biases

Heuristics are mental shortcuts used to solve problems and guide our minds to make decisions under uncertainty.<sup>9</sup> 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,

<sup>&</sup>lt;sup>7</sup> Jennifer S Lerner and others, 'Emotion and Decision Making' (2015) 66 Annual Review of Psychology 799.

<sup>&</sup>lt;sup>8</sup> Michael Siegrist and Christina Hartmann, 'Consumer Acceptance of Novel Food Technologies' (2020) 1 Nature Food 343.

<sup>&</sup>lt;sup>9</sup> Amos Tversky and Daniel Kahneman, 'Judgment under Uncertainty: Heuristics and Biases' (1974) 185 Science 1124.

"System 2" is the process of evaluating all data and information to make informed choices through effortful mental activities.<sup>10</sup>

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.<sup>11</sup> For this reason, mental shortcuts are essential for responding to information overload.<sup>12</sup> Unfortunately, heuristics can sometimes promote long-term biases, systematic errors in thinking that interfere with our decision-making and influence our perception of risk.<sup>13</sup> Take as an example a flight booking: a photo or a report of an aeroplane crash might influence the perceived risk of flying more than any statistics showing that aeroplanes are safer than cars. This would ultimately prompt us to decide to use a car, a result of the availability heuristic.<sup>14</sup> Heuristics and subsequent biases are generated by emotions, personal attitudes, membership in social groups, and cultural and social identity, and are context-dependent.<sup>15</sup>

#### 2.2. Consumer perception of GMOs and novel foods

Despite some fluctuations over the years,<sup>16</sup> consumer perception of GMOs in the EU has never been positive.<sup>17</sup> 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

<sup>&</sup>lt;sup>10</sup> Daniel Kahneman, *Thinking, Fast and Slow* (Farrar, Straus and Giroux, 2013).

<sup>&</sup>lt;sup>11</sup> Gordon B Moskowitz, Social Cognition: Understanding Self and Others (Guilford Press, 2005).

<sup>&</sup>lt;sup>12</sup> Steve Dale, 'Heuristics and Biases: The Science of Decision-Making' (2015) 32 Business Information Review 93.

<sup>&</sup>lt;sup>13</sup> Paul Slovic and Ellen Peters, 'Risk Perception and Affect' (2006) 15 Current Directions in Psychological Science 322.

<sup>&</sup>lt;sup>14</sup> Valerie S Folkes, 'The Availability Heuristic and Perceived Risk' (1988) 15 Journal of Consumer Research 13.

<sup>&</sup>lt;sup>15</sup> Lerner and others (n 7).

<sup>&</sup>lt;sup>16</sup> Mihael Cristin 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.

<sup>&</sup>lt;sup>17</sup> Lynn J Frewer and others, 'Public Perceptions of Agri-Food Applications of Genetic Modification – A Systematic Review and Meta-Analysis' (2013) 30 Trends in Food Science & Technology 142.

based on ethics and risk aversion towards potential long-term effects.<sup>18</sup> In particular, the general public has difficulties in perceiving the benefits of GMOs for food uses.<sup>19</sup> 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.<sup>20</sup> The aversion is further fuelled by anti-biotech advocates and their negative (visual) portrayals of GMOs.<sup>21</sup>

On the contrary, assessing public perception of novel foods as a whole is difficult, because of how diverse novel foods 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.<sup>22</sup> For example, cultivated meat, products of precision fermentation, and insects, which are occasionally considered alternative proteins.<sup>23</sup> Studies on alternative proteins represent the majority of the literature evaluating consumer perception of novel foods, focusing mainly on insects and cultivated meat.<sup>24</sup> Factors that

<sup>&</sup>lt;sup>18</sup> Joseph Mohorčich and Jacy Reese, 'Cell-Cultured Meat: Lessons from GMO Adoption and Resistance' (2019) 143 Appetite 104408.

<sup>&</sup>lt;sup>19</sup> George 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.

<sup>&</sup>lt;sup>20</sup> Stefaan Blancke and others, 'Fatal Attraction: The Intuitive Appeal of GMO Opposition' (2015) 20 Trends in Plant Science 414.

<sup>&</sup>lt;sup>21</sup> Kelly A Clancy and Benjamin Clancy, 'Growing Monstrous Organisms: The Construction of Anti-GMO Visual Rhetoric through Digital Media' (2016) 33 Critical Studies in Media Communication 279.

<sup>&</sup>lt;sup>22</sup> Good Food Institute, 'Defining Alternative Protein' <a href="https://gfi.org/defining-alternative-protein/">https://gfi.org/defining-alternative-protein/</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>23</sup> Andrea M Liceaga and others, 'Insects as an Alternative Protein Source' (2022) 13 Annual Review of Food Science and Technology 19. 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.

<sup>&</sup>lt;sup>24</sup> Alessandro Monaco and others, 'Consumers' Perception of Novel Foods and the Impact of Heuristics and Biases: A Systematic Review' (2024) 196 Appetite 107285; Christina Hartmann and Michael Siegrist, 'Consumer Perception and Behaviour Regarding Sustainable Protein Consumption: A Systematic Review' (2017) 61 Trends in Food Science & Technology 11.

negatively affect the perception of novel foods are disgust, food neophobia, and perception of unnaturalness.<sup>25</sup> On the contrary, familiarity is related to higher consumer acceptance.<sup>26</sup>

Siegrist and Hartmann<sup>27</sup> 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.<sup>28</sup>

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.<sup>29</sup> Biological hazards like bacterial 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

<sup>&</sup>lt;sup>25</sup> Hely Tuorila and Christina Hartmann, 'Consumer Responses to Novel and Unfamiliar Foods' (2020) 33 Current Opinion in Food Science 1.

<sup>&</sup>lt;sup>26</sup> Monaco and others (n 24).

<sup>&</sup>lt;sup>27</sup> Siegrist and Hartmann (n 8).

<sup>&</sup>lt;sup>28</sup> Scott Eidelman and Christian S Crandall, 'Bias in Favor of the Status Quo' (2012) 6 Social and Personality Psychology Compass 270.

<sup>&</sup>lt;sup>29</sup> Giovanni Tagliabue, 'Nature as a Totem, "GMOs" as a Contemporary Taboo' (2016) 18 North American Journal of Psychology 283; Brian P Meier, Amanda J Dillard and Courtney M Lappas, 'Naturally Better? A Review of the Natural-Is-Better Bias' (2019) 13 Social and Personality Psychology Compass e12494.

conditioned by the "framing effect", according to which decisions are taken based on how information is presented,<sup>30</sup> and to a "confirmation bias", which builds up a certain position by considering only information and data in line with their a priori considerations.<sup>31</sup>

# **3.** Risk triggers in the legal framework applicable to GMOs and novel foods in the EU

#### 3.1. Legal Framework applicable to GMOs and novel foods in the EU

Regulation (EU) 2015/2283<sup>32</sup> on novel foods (NFR) defines novel foods as foods that were not used for human consumption to a significant degree within the EU before the 15<sup>th</sup> of May, 1997 and that fall under at least one of the novel food categories.<sup>33</sup> 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".<sup>34</sup>

In the EU, the NFR and Regulation (EC) 1829/2003<sup>35</sup> on the placing on the market of genetically modified food and feed (the "GMOR") are the two pieces of legislation that regulate

<sup>&</sup>lt;sup>30</sup> Juan-José Igartua and Lifen Cheng, 'Moderating Effect of Group Cue While Processing News on Immigration: Is the Framing Effect a Heuristic Process?' (2009) 59 Journal of Communication 726.

<sup>&</sup>lt;sup>31</sup> Raymond S Nickerson, 'Confirmation Bias: A Ubiquitous Phenomenon in Many Guises' (1998) 2 Review of General Psychology 175.

<sup>&</sup>lt;sup>32</sup> 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, p. 1–22. Hereinafter referred to as "NFR".

<sup>&</sup>lt;sup>33</sup> ibid. Article 3(2).

<sup>&</sup>lt;sup>34</sup> 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. OJ L 106, 17.4.2001, p. 1–39. Article 2(2).

<sup>&</sup>lt;sup>35</sup> 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, p. 1–23.

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.<sup>36</sup> Accordingly, they both aim at protecting human health, the environment, and consumer interests, along with ensuring the functioning of the internal market.

The NFR and the GMOR follow the principle of risk analysis, as stipulated in Article (6)(1) of Regulation (EC) No 178/2002<sup>37</sup> 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.<sup>38</sup> The latter are supposed to make decisions based on EFSA's opinion, relevant legal provisions, the precautionary principle and other legitimate factors.<sup>39</sup> 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.

#### 3.2. 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

<sup>&</sup>lt;sup>36</sup> Consolidated version of the Treaty on the Functioning of the European Union, OJ C 202, 7.6.2016, p. 1–388.

<sup>&</sup>lt;sup>37</sup> 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. Hereinafter referred to as "GFL".

<sup>&</sup>lt;sup>38</sup> ibid. Article 6.

<sup>&</sup>lt;sup>39</sup> ibid. Recital 19 specifies offers an overview of factors that might be considered "(during risk analysis) other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls."

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.<sup>40</sup>

Novel foods are foods not consumed to a significant degree within the Union before the 15<sup>th</sup> of 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 in itself a risk factor. 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,<sup>41</sup> 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.<sup>42</sup>

Alongside "novelty", "unnaturalness" is also used as a trigger in the novel food framework. The "traditional foods from third countries", despite falling within the novel food definition, enjoy a facilitated "notification procedure" instead of the normal authorisation procedure.<sup>43</sup> The "notification procedure", in the absence of duly justified safety objections from the EFSA or the Member States, requires significantly less time to place products on the market. Such preferential treatment is granted only to foods with a history of safe use in a third country,

<sup>&</sup>lt;sup>40</sup> Andreas T Christiansen, Martin Marchman Andersen and Klemens Kappel, 'Are Current EU Policies on GMOs Justified?' (2019) 28 Transgenic Research 267; Hans-Georg 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; Alessandro Monaco and Kai 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 219.

<sup>&</sup>lt;sup>41</sup> Singapore Food Agency, 'Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients' (2023) <a href="https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-food-and-novel-food-ingredients.pdf">https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-foods-and-novel-food-ingredients.pdf</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>42</sup> FSANZ, 'Australia New Zealand Food Standards Code –Standard 1.1.2 – Definitions used throughout the Code' [F2024C00725].

<sup>&</sup>lt;sup>43</sup> Lucia Scaffardi, 'A Peculiar Category of Novel Foods: Traditional Foods Coming from Third Countries and the Regulatory Issues Involving Sustainability, Food Security, Food Safety, and the Free Circulation of Goods' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 37-58.

derived from primary production and that can be classified into one of the novel food categories (ii), (iv), (v), (vi).<sup>44</sup> 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*".<sup>45</sup> 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,<sup>46</sup> 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.<sup>47</sup> For this reason, manipulation of the genome through hybridisation is acceptable, while lab

<sup>45</sup> GFL (n 37). Article 3(17)

<sup>46</sup> Holle (n 3).

<sup>&</sup>lt;sup>44</sup> NFR (n 32). Article 3(2)(c). The novel foods 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.

<sup>&</sup>lt;sup>47</sup> James Paddock Collman, *Naturally Dangerous: Surprising Facts about Food, Health, and the Environment* (University Science Books 2001), passim.

modification of the genome is not, a false belief based on a misunderstood and unscientific conception of what "genetically modified organisms" means.<sup>48</sup>

In addition to "unnaturalness", "novelty" is used as a risk trigger 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 genome. NPBTs are subject to the GMO framework, despite firm opposition from the scientific community,<sup>49</sup> since NPBTs show similarities with traditional mutagenesis techniques, which are exempted from the application of the GMO framework.<sup>50</sup> Their regulatory treatment was upheld by the Court of Justice of the EU in *Confédération paysanne and Others*,<sup>51</sup> 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.<sup>52</sup> 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<sup>53</sup> and is likely to have a negative impact on innovation and growth in the EU.<sup>54</sup>

<sup>52</sup> ibid. Paragraph 51.

<sup>&</sup>lt;sup>48</sup> Klaus 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.

<sup>&</sup>lt;sup>49</sup> Kai Purnhagen and Justus Wesseler, 'EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2020) 43 Applied Economic Perspective and Policy 1621.

<sup>&</sup>lt;sup>50</sup> Giovanni Tagliabue, 'Product, Not Process! Explaining a Basic Concept in Agricultural Biotechnologies and Food Safety' (2017) 13 Life Sciences, Society and Policy 3.

<sup>&</sup>lt;sup>51</sup> Court of Justice of the European Union, Case *C-528/16 - Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt* [2018] ECLI:EU:C:2018:583.

<sup>&</sup>lt;sup>53</sup> Dennis Eriksson and Tomasz Zimny, 'Critical Observations on the French Conseil d'État Ruling on Plant Mutagenesis' (2020) 6 Nature Plants 1392.

<sup>&</sup>lt;sup>54</sup> Justus Wesseler and others, '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 839.

#### 4. The use of "novelty" and "unnaturalness" as risk triggers

#### 4.1. 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,<sup>55</sup> while the Political Culture Theory emphasises that shared beliefs and cultural values shape political behaviour.<sup>56</sup>

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,<sup>57</sup> 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.<sup>58</sup> Authors such as Slovic<sup>59</sup> or Kuran and Sunstein<sup>60</sup> 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.<sup>61</sup> They might lead legislators to underestimate certain costs and benefits,

<sup>&</sup>lt;sup>55</sup> Guy Peters, *Institutional Theory in Political Science, Fourth Edition: The New Institutionalism* (Edward Elgar Publishing, 2019), passim.

<sup>&</sup>lt;sup>56</sup> Stephen Welch, *The Theory of Political Culture* (OUP Oxford, 2013), passim.

<sup>&</sup>lt;sup>57</sup> Eyal Zamir and Raanan Sulitzeanu-Kenan, 'Explaining Self-Interested Behavior of Public-Spirited Policy Makers' (2018) 78 Public Administration Review 579.

<sup>&</sup>lt;sup>58</sup> Roger G Noll and James E Krier, 'Some Implications of Cognitive Psychology for Risk Regulation' (1990) 19 The Journal of Legal Studies 747; Jeffrey Rachlinski and Cynthia Farina, 'Cognitive Psychology and Optimal Government Design' (2002) 87 Cornell Law review 549.

<sup>&</sup>lt;sup>59</sup> Paul Slovic, 'Perception of Risk' (1987) 236 Science 280.

<sup>&</sup>lt;sup>60</sup> Timur Kuran and Cass R Sunstein, 'Availability Cascades and Risk Regulation' (1999) 51 Stanford Law Review 683.

<sup>&</sup>lt;sup>61</sup> Moshe Hirsch, 'Regulators' Mindsets, Ingroup Favoritism, and the National Treatment Obligation in World Trade Organization Law' (2022) 23 German Law Journal 298.

or vice versa,<sup>62</sup> and to adopt different risk management strategies in different contexts. One example is the World Trade Organisation 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.<sup>63</sup>

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.<sup>64</sup> As a result, policymakers are keener to redirect limited resources to issues that are considered critical by public perception or relevant interest groups.<sup>65</sup> 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.

#### 4.2. 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.<sup>66</sup> Moreover, even when

<sup>&</sup>lt;sup>62</sup> Jim AC Everett, Nadira S Faber and Molly Crockett, 'Preferences and Beliefs in Ingroup Favoritism' (2015) 9 Frontiers in Behavioral Neuroscience 15.

<sup>&</sup>lt;sup>63</sup> Arno Scherzberg, 'EU–US Trade Disputes about Risk Regulation: The Case of Genetically Modified Organisms' (2006) 19 Cambridge Review of International Affairs 121; Giovanni Tagliabue, 'The Precautionary Principle: Its Misunderstandings and Misuses in Relation to "GMOs" (2016) 33 New Biotechnology 437.

<sup>&</sup>lt;sup>64</sup> Russell B Korobkin, 'The Problems with Heuristics for Law' in Gerd Gigerenzer and Christoph Engel (eds), *Heuristics in the Law* (MIT Press, 2006) pp. 45-60.

<sup>&</sup>lt;sup>65</sup> Robert G Cooper and Elko J Kleinschmidt, 'Winning Businesses in Product Development: The Critical Success Factors' (1996) 39 Research-Technology Management 18.

<sup>&</sup>lt;sup>66</sup> Holle (n 3); Wesseler and Kalaitzandonakes (n 3); Agustina I Whelan, Patricia Gutti and Martin A Lema, 'Gene Editing Regulation and Innovation Economics' (2020) 8 Frontiers in Bioengineering and Biotechnology 303.

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.<sup>67</sup> Davison and Ammann<sup>68</sup> 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.<sup>69</sup>

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 considered an implicit objective within the NFR,<sup>70</sup> it is evident that EU legislators did not regard innovation promotion as a secondary goal in the GMO framework.<sup>71</sup> 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.<sup>72</sup>

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.<sup>73</sup> Others have called for "better politics", involving more communication between

<sup>&</sup>lt;sup>67</sup> Michele Mastroeni, James Mittra and Joyce Tait, 'Political Influences on Biotechnology-Based Innovation for European Agriculture: Risk-Assessment and Risk Management' (2019) 33 Technology Analysis & Strategic Management 271.

<sup>&</sup>lt;sup>68</sup> John Davison and Klaus Ammann, 'New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology' (2017) 8 GM Crops & Food 13.

<sup>&</sup>lt;sup>69</sup> Francesco Planchestainer, 'Meat Me in Italy: The Italian Ban on Sounding Names and Cell-Cultured Meat' (2024) 19 European Food and Feed Law Review 66.

<sup>&</sup>lt;sup>70</sup> Monaco and Purnhagen (n 40).

<sup>&</sup>lt;sup>71</sup> Dennis Eriksson and Sevasti Chatzopoulou, 'Responsible Decision-Making for Plant Research and Breeding Innovations in the European Union' (2018) 9 GM Crops & Food 39; Christiansen, Andersen and Kappel (n 40).

<sup>&</sup>lt;sup>72</sup> Kai Purnhagen, 'You Want It Extra CRISPERY? Legal Disruption through New Plant Breeding Technologies in the EU' (2021) 40 Yearbook of European Law 374.

<sup>&</sup>lt;sup>73</sup> Stuart J Smyth and others, 'Removing Politics from Innovations That Improve Food Security' (2021) 30 Transgenic Research 601.

the public and scientific authorities.<sup>74</sup> 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.<sup>75</sup> 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.<sup>76</sup> 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.

#### **5.** 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 triggers 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 novel foods and GMOs is key for designing regulatory systems

<sup>&</sup>lt;sup>74</sup> Alan Raybould, 'Improving the Politics of Biotechnological Innovations in Food Security and Other Sustainable Development Goals' (2021) 30 Transgenic Research 613; Lonneke M Poort and others, 'Restore Politics in Societal Debates on New Genomic Techniques' (2022) 39 Agriculture and Human Values 1207.

<sup>&</sup>lt;sup>75</sup> Tagliabue (n 50).

<sup>&</sup>lt;sup>76</sup> Kai Purnhagen and others, 'Options for Regulating New Genomic Techniques for Plants in the European Union' (2023) 9 Nature Plants 1958.

capable of favouring the innovation process, alongside ensuring the protection of human health, the environment and consumer interests.<sup>77</sup>

<sup>&</sup>lt;sup>77</sup> Lucia A Reisch, 'Shaping healthy and sustainable food systems with behavioural food policy'(2021)48 European Review of Agricultural Economics 665.

## Chapter 5

# Regulatory Barriers and Incentives for Alternative Proteins in the European Union and Australia-New Zealand

Based on: Alessandro Monaco. "The Regulation of Novel Foods in the European Union and in Australia-New Zealand: Barriers and Incentives to Innovation in the Alternative Proteins Sector." *British Food Journal*, 127(13), 171-189 (2025). Available at: <u>https://doi.org/10.1108/BFJ-06-2024-0650</u>

#### Abstract

This chapter aims to discuss the innovation challenge in the alternative protein sectors of the European Union (EU) and Australia-New Zealand (AUSNZ) by comparing their respective novel food frameworks. The research investigates which regulatory provisions stakeholders perceive as barriers to innovation and proposes measures to address these obstacles. Alternative proteins are often legally treated as "novel foods" in both the EU and AUSNZ. A functional comparative legal analysis of the novel food frameworks of these jurisdictions was conducted, complemented by qualitative interviews with stakeholders active in the EU or AUSNZ alternative protein sectors. The interviews aimed to gather stakeholders' perspectives on the framework within which they operate and discuss ways to foster innovation in their jurisdictions. While the AUSNZ framework is generally perceived as more innovation-friendly, particularly regarding breakthrough innovations such as cultivated meat, the EU is viewed as a challenging regulatory environment because of its lengthy authorisation procedures and lack of support from regulatory authorities. The differing levels of communication and opportunities for dialogue between stakeholders and regulators, along with the political stances of the EU member states, have emerged as the main elements to explain such differences. In both jurisdictions, a lack of support for small-scale companies was identified as a key factor hindering the innovation process.

#### 1. Introduction

"Alternative proteins" comprise a diverse range of protein sources that serve as substitutes or alternatives to traditional animal-based proteins such as meat, dairy, and eggs.<sup>1</sup> Examples include plant-based protein extracts, products of biomass and precision fermentation, animal cell tissues grown in bioreactors such as cultivated meat, and, under some classifications, insects.<sup>2</sup> Alternative proteins have entered the public debate because they provide an alternative to conventional production methods of animal proteins, which rank among the most polluting

<sup>&</sup>lt;sup>1</sup> Good Food Institute, 'Defining Alternative Protein' <a href="https://gfi.org/defining-alternative-protein/">https://gfi.org/defining-alternative-protein/</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>2</sup> Andrea M Liceaga and others, 'Insects as an Alternative Protein Source' (2022) 13 Annual Review of Food Science and Technology 19.

human activities.<sup>3</sup> Alternative proteins are expected to play a critical role in the transition toward more sustainable and environmentally friendly food systems.<sup>4</sup>

In the European Union (EU) and Australia-New Zealand (AUSNZ), alternative proteins are often classified as novel foods, a specific legal category of food products that require prior approval before being placed on the market. The novel food frameworks in these two jurisdictions share similarities and present some differences. In the EU novel foods are regulated by Regulation (EU) No  $2283/2015^5$  on novel foods (hereafter the "Novel Food Regulation" or NFR). Novel foods are defined as foods that were not consumed to a significant degree within the EU before May 15, 1997. In AUSNZ novel foods and novel food ingredients are regulated under Standard 1.5.1 – Novel Foods<sup>6</sup> of the Food Standards Code. They are defined as non-traditional foods that require assessment for public health and safety considerations.

Both frameworks are based on a risk analysis approach that aims to ensure the protection of human health, safety, and consumer interest. Both procedures involve a scientific assessment conducted by scientific authorities and a final political decision over authorisation. The EU and AUSNZ differ in their approach to early engagement mechanisms between applicants and public authorities in the inclusion of public consultations during the authorisation procedure and in the political handling of risk management.

Integrating controversial and revolutionary innovations such as cultivated meat into the food system requires regulatory adaptation. Depending on its design and implementation, regulation can either impede or encourage the development and adoption of innovative solutions.<sup>7</sup> In the

<sup>&</sup>lt;sup>3</sup> Xiaoming Xu and others, 'Global Greenhouse Gas Emissions from Animal-Based Foods Are Twice Those of Plant-Based Foods' (2021) 2 Nature Food 724.

<sup>&</sup>lt;sup>4</sup> Steven J Davis and others, 'Food without Agriculture' (2024) 7 Nature Sustainability 90; Mario Herrero and others, 'Innovation Can Accelerate the Transition towards a Sustainable Food System' (2020) 1 Nature Food 266; Rachel 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.

<sup>&</sup>lt;sup>5</sup> 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, p. 1–22. Hereinafter referred as the "NFR".

<sup>&</sup>lt;sup>6</sup> Food Standards Australia New Zealand (Hereinafter: FSANZ), 'Australia New Zealand Food Standards Code – Standard 1.5.1 – Novel foods' [F2017C00324].

 <sup>&</sup>lt;sup>7</sup> Stephan Haggard, Andrew MacIntyre and Lydia Tiede, 'The Rule of Law and Economic Development' (2008)
11 Annual Review of Political Science 205; Michael E Porter, 'America's Green Strategy' (1991) 264 Scientific

food sector, regulation has traditionally focused on consumer protection,<sup>8</sup> and recent scholarship has emphasised the need for regulatory frameworks to enable the innovation process to avoid losing the potential benefits that food innovations are expected to bring.<sup>9</sup>

This chapter aims to discuss the innovation challenge in the alternative protein sectors of the EU and AUSNZ by comparing their respective novel food frameworks. The study investigates which regulatory provisions stakeholders perceive as barriers to innovation and proposes measures to address these obstacles.

#### 2. Methodology

#### 2.1. Doctrinal legal analysis

This chapter relies on a functional comparative legal analysis of the EU and AUSNZ novel food frameworks.<sup>10</sup> The comparative legal analysis was based on two sequential components. Initially, I conducted a doctrinal legal analysis of the novel food frameworks in the EU and AUSNZ to capture their overarching approach to the regulation of novel foods and, specifically, alternative proteins. The doctrinal legal analysis involved gathering and organising available legal materials, such as legislation, case law, and legal literature, along with their syntax and norms.<sup>11</sup>

American 168; Margaret R Taylor, Edward S Rubin and David A Hounshell, 'Regulation as the Mother of Innovation: The Case of SO2 Control\*' (2005) 27 Law & Policy 348.

<sup>&</sup>lt;sup>8</sup> Alie de Boer and Aalt Bast, 'Demanding Safe Foods – Safety Testing under the Novel Food Regulation (2015/2283)' (2018) 72 Trends in Food Science & Technology 125; Bernd MJ van der Meulen and others, 'Structural Precaution: The Application of Premarket Approval Schemes in EU Food Legislation' (2012) 67 Food and Drug Law Journal 453.

<sup>&</sup>lt;sup>9</sup> Anu Lähteenmäki-Uutela and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336; Mark J Post and others, 'Scientific, Sustainability and Regulatory Challenges of Cultured Meat' (2020) 1 Nature Food 403; Kai Purnhagen and Justus Wesseler, 'EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2020) 43 Applied Economic Perspective and Policy 1621; Liesbeth Dries, 'Future Developments in the EU Food Sector' in Liesbeth Dries and others (eds), *EU Bioeconomy Economics and Policies: Volume II* (Springer International Publishing, 2019) pp. 83-90.

<sup>&</sup>lt;sup>10</sup> Terry Hutchinson, 'The Doctrinal Method: Incorporating Interdisciplinary Methods in Reforming the Law' (2015) 3 Erasmus Law Review 130; Julie De Coninck, 'The Functional Method of Comparative Law: "Quo Vadis"?' (2010) 74 Rabels Zeitschrift für ausländisches und internationales Privatrecht 318; Ralf Michaels, 'The Functional Method of Comparative Law' in Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law* (Oxford University Press, 2005) pp. 339-382.

<sup>&</sup>lt;sup>11</sup> Terry Hutchinson and Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17 Deakin Law Review 83.

To expand the doctrinal legal analysis, I considered data such as the number of novel food applications concerning alternative proteins received by the authorities in the EU and AUSNZ, the number of approvals, the average duration of the procedure, and the number of terminations of procedures.

I used the EUR-LEX database to access EU legislation and the website of the Food Standards Australia, New Zealand Authority (FSANZ) to access the Food Standards Code. To collect novel foods approval data, I relied on the official databases provided by the European Commission and FSANZ. For the EU, these included the "Summary of applications and notifications",<sup>12</sup> the "List of Procedures Terminations"<sup>13</sup> and the "Union List of Approved Novel Foods".<sup>14</sup> For AUSNZ, I relied on "Schedule 25 - Approved Novel Foods"<sup>15</sup> of the Food Standards Code and on the database "Applications for the Food Standards Code".

#### 2.2. Qualitative interviews

The legal analysis was combined with 14 qualitative semi-structured interviews with EU and AUSNZ stakeholders.<sup>16</sup> The interviews complemented the legal analysis by offering insights into stakeholders' perception of the two frameworks.<sup>17</sup> Interviewees helped identify potential regulatory barriers in the novel food frameworks and suggested solutions that could be implemented to enable innovation in the alternative protein sectors of the EU and AUSNZ.

The interviews were conducted between December 2023 and April 2024. The research was preregistered in the OSF (link: <u>https://doi.org/10.17605/OSF.IO/XUWZS</u>) and approved by the Ethical Committee of the University of Bayreuth (Antrags-Nr. 23-040). Potential interviewees

<sup>&</sup>lt;sup>12</sup> European Commission, 'Summary of Applications and Notifications' <a href="https://food.ec.europa.eu/safety/novel-food/authorisations/summary-applications-and-notifications\_en">https://food.ec.europa.eu/safety/novel-food/authorisations/summary-applications-and-notifications\_en</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>13</sup> European Commission, 'Decisions Terminating the Procedure' <a href="https://food.ec.europa.eu/safety/novel-food/decisions-terminating-procedure\_en">https://food.ec.europa.eu/safety/novel-food/decisions-terminating-procedure\_en</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>14</sup> Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, C/2017/8878, OJ L 351, 30.12.2017, p. 72–201. Annex I.

<sup>&</sup>lt;sup>15</sup> FSANZ, 'Australia New Zealand Food Standards Code – Schedule 25 – Permitted novel foods' [F2023C00770].

<sup>&</sup>lt;sup>16</sup> Hutchinson (n 10); Mark Van Hoecke, 'Methodology of Comparative Legal Research' (2015) Law and Method <a href="http://www.bjutijdschriften.nl/doi/10.5553/REM/.000010">http://www.bjutijdschriften.nl/doi/10.5553/REM/.000010</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>17</sup> Cormac McGrath, Per J Palmgren and Matilda Liljedahl, 'Twelve Tips for Conducting Qualitative Research Interviews' (2019) 41 Medical Teacher 1002.

were identified by considering the relevant databases and sector associations. The final sample of interviewed stakeholders comprised a diverse range of individuals, including innovators from alternative protein start-ups and companies, organisations active in the alternative protein sector, representatives of public authorities, and consultants specialising in novel foods (see Table 1).

Prior to the interview, participants were provided with an introduction to the research objectives and informed that their responses would be audio-recorded, transcribed, and anonymised for the purpose of this research. When participants demanded it, a preliminary list of questions was shared with them. Twelve interviews were conducted online using Microsoft Teams, and two interviews were conducted in person. All interviews lasted for approximately forty-five minutes. Interviews were transcribed using the software "f4x speech recognition".

The transcribed interviews were analysed through iterative thematic analysis.<sup>18</sup> After familiarisation with the data and a preliminary coding process conducted using a set of predetermined codes drawn from the literature, further codes and sub-codes were developed based on the empirical data.<sup>19</sup> The web version of ATLAS.ti software was used for coding.

Through continued data analysis, four overarching themes have been identified: barriers to the authorisation procedure, interactions between applicants and regulators, influence of political authorities in the authorization procedures, and suggestions to improve regulatory frameworks. Combining the results of the functional comparative analysis and the perceptions of innovators collected through semi-structured interviews, this study offers a comprehensive understanding of the novel food frameworks in the EU and AUSNZ and their influence on the respective alternative protein sectors.

<sup>&</sup>lt;sup>18</sup> Joanne Neale, 'Iterative Categorization (IC): A Systematic Technique for Analysing Qualitative Data' (2016) 111 Addiction 1096.

<sup>&</sup>lt;sup>19</sup> Virginia Braun and others, 'Thematic Analysis' in Pranee Liamputtong (ed), *Handbook of Research Methods in Health Social Sciences* (Springer, 2019) pp. 843-860.

Table 1: List of interviewees

Participant codes	Role	Expertise
EU 1	Consultant	Novel foods
EU 2	Company/start-up	Insects
EU 3	Public authority	Novel foods
EU 4	Consultant, company/start-up	Novel foods
EU 5	Company/start-up	Biomass fermentation
EU 6	Sector organisation/think-tank	Novel foods, alternative proteins
EU 7	Consultant	Novel foods
AUSNZ 1	Company/start-up	Plant-based proteins
AUSNZ 2	Company/start-up	Cellular agriculture
AUSNZ 3	Sector organisation/think-tank	Novel foods, alternative protein
AUSNZ 4	Company/start-up	Cellular agriculture
AUSNZ 5	Company/start-up Cellular agriculture	
AUSNZ 6	Sector organisation/think-tank Cellular agriculture	
AUSNZ 7	Company/start-up Cellular agriculture	

#### 3. The novel food frameworks in the EU and AUSNZ

#### **3.1. The EU Novel Food Regulation**

In the EU, novel foods are defined as foods that were not consumed to a significant degree within the EU before the 15<sup>th</sup> of May 1997 that can be classified into one of the ten novel food categories.<sup>20</sup> The Novel Food Regulation aims to protect public health, safety, and consumer interests and ensure the internal market's functioning.<sup>21</sup> Therefore, novel foods require premarket approval before being placed on the market. The authorisation procedure is based on risk analysis, a systematic approach in which the European Food Safety Authority (EFSA) is responsible for conducting the risk assessment, while the European Commission and the member states are in charge of risk management (see Figure 1).<sup>22</sup>

The EFSA's assessment shall determine that the novel food does not pose a safety risk to human health due to its composition and conditions of use, is as safe as comparable foods, and, when the novel food is intended to substitute another food, does not differ from it in a way that would be nutritionally disadvantageous for the consumers.<sup>23</sup> The EFSA should adopt its Opinion within nine months.<sup>24</sup> When additional information is required from the EFSA to the applicant, the nine-month period can be extended.<sup>25</sup>

Within seven months of the date of publication of the EFSA Opinion, the Commission prepares a draft implementing act authorising the novel food, which is then submitted to the "Standing Committee on Plants, Animals, Food and Feed" (PAFF Committee), formed by representatives

<sup>25</sup> ibid. Article 11(4).

<sup>&</sup>lt;sup>20</sup> NFR (n 5). Article 3(2)(a).

<sup>&</sup>lt;sup>21</sup> ibid. Article 1(2).

<sup>&</sup>lt;sup>22</sup> Jessica Vapnek, Kai Purnhagen and Ben Hillel, 'Regulatory and Legislative Framework for Novel Foods', in Shivani Pathania and Brijesh Tiwari (eds), *Food Formulation* (John Wiley & Sons, Ltd 2021) pp. 285-308.

<sup>&</sup>lt;sup>23</sup> NFR (n 5). Article 7.

<sup>&</sup>lt;sup>24</sup> ibid. Article 11(1).

of the EU member states, for a final vote.<sup>26</sup> To date, there has been no record of a novel food application rejected by the PAFF Committee.

The authorisation is, in principle, generic, meaning that every food business operator can place the novel food on the market when the authorisation's conditions are respected.<sup>27</sup> The applicant can apply for a five-year exclusivity period for placing the product on the market when proprietary scientific studies are deemed necessary for the good outcome of the application.<sup>28</sup> Other applicants are still free to apply for independent authorisation for a similar or even equal product but only if they submit their own proprietary scientific data.<sup>29</sup>

#### Figure 1: Authorisation procedure for novel foods in the EU



Novel alternative proteins authorised as novel foods in the EU

To assess the function of the novel food framework in the EU alternative protein sector, I adopted a working definition of "novel alternative proteins". For the scope of this analysis,

<sup>&</sup>lt;sup>26</sup> ibid. Article 12.

<sup>&</sup>lt;sup>27</sup> Hanna Schebesta and Kai Purnhagen, EU Food Law (Oxford University Press, 2024). Chapter 7, p 171.

<sup>&</sup>lt;sup>28</sup> NFR (n 5). Article 26.

<sup>&</sup>lt;sup>29</sup> Alessandro Monaco, 'Data Protection Under the Novel Food Regulation: Valuable Instrument or Barrier to Innovation? Insights from the Insect Sector' (2023) 18 European Food and Feed Law Review 172.

"novel alternative proteins" refer to those whole foods and food ingredients that are included in the Union List of Novel Foods<sup>30</sup> and intend to substitute traditional animal proteins in the food categories "meat", "milk", and "dairy analogues". Isolates used exclusively in food supplements were not considered part of this definition.

In the EU context, insect-food products fall under the working definition. Despite being animals, insects in the EU are perceived as non-traditional animal proteins that can provide a more sustainable alternative.<sup>31</sup> As they have not been traditionally consumed in the EU, insect products require authorisation as novel foods.

Since 2018, 42 applications concerning novel alternative proteins have been submitted for approval under NFR.<sup>32</sup> Most of them concerned insects. As of October 2024, 10 novel alternative proteins have been included in the Union List for Novel Foods for use in meat and dairy analogues: six concerned insects, three plant-based ingredients, and one mycelium-fermented substrate. The average duration of the procedure, calculated from the day of submission of the application and the date of authorisation, was 1121 days, approximately 37 months, or more than 3 years (see Table 2). The steps of the timeline stated in the NFR are rarely respected.

<sup>&</sup>lt;sup>30</sup> Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, C/2017/8878, OJ L 351, 30.12.2017, p. 72–201

<sup>&</sup>lt;sup>31</sup> Liceaga and others (n 2); Åsa Berggren, Anna Jansson and Matthew Low, 'Approaching Ecological Sustainability in the Emerging Insects-as-Food Industry' (2019) 34 Trends in Ecology & Evolution 132.

<sup>&</sup>lt;sup>32</sup> Thirty-six applications concerning alternative proteins are available in the "Summary of applications and notifications" on the website of the EU Commission. Some of these applications concerned extension of existing authorisations. By examining the list of terminated procedures, nine concerned novel alternative proteins. For six of them, it was not possible to find the related application in the "Summary of Applications and Notifications". Considering the additional six, the total number of applications is deemed to be at least forty-two.

Table 2: Timeline for approval of novel alternative proteins in the EU

Novel food	Submission	EFSA	Publication	Inclusion in the Union
	date:	Opinion	of EFSA	List of Novel Foods:
		requested:	<b>Opinion:</b>	
Acheta	24/07/2019	08/07/2020	23/03/2022	03/01/2023
domesticus (house				
cricket) partially				
defatted powder				
Frozen, paste,	07/01/2018	17/07/2018	26/04/2022	05/01/2023
dried and powder				
forms				
of Alphitobius				
diaperinus larvae				
(lesser				
mealworm)				
Pea and rice	12/12/2019	22/04/2020	28/02/2022	3/01/2023
protein fermented				
by Lentinula				
edodes (Shiitake				
mushroom)				
mycelia				
Frozen, dried and	20/12/2018	04/09/2019	07/07/2021	10/02/2022
powder forms				
of Acheta				
domesticus (house				
cricket)				
Frozen, dried and	28/12/2018	09/07/2019	25/05/2021	12/11/2021
powder forms of				
Locusta				
migratoria				
(migratory locust)				
Partially defatted	31/12/2018	19/06/2019	30/06/2020	02/02/2021
rapeseed powder				
from Brassica				
rapa L. and				
Brassica napus L.				

Mung bean	10/03/2020	05/08/2020	14/09/2021	22/04/2022
(Vigna				
radiata) protein				
<u></u>	10/00/0010	00/05/0010	24/14/2020	0.1 /0.4 /0.0.1
Dried Tenebrio	13/02/2018	03/07/2018	24/11/2020	01/06/2021
<i>molitor</i> Larva				
(yellow				
mealworm)				
Partially	20/11/2020	10/06/2021	24/05/2023	20/12/2023
hydrolysed				
protein from spent				
barley (Hordeum				
vulgare) and rice				
(Oryza sativa)				

No application concerning cultivated meat products, defined as animal tissues grown under laboratory conditions, or dairy proteins produced via precision fermentation has been submitted.<sup>33</sup> To date, five products of cell culture from plant cells have been authorised as novel foods, all of which are used in food supplements, while eight novel food ingredients produced via precision fermentation have been approved and included in the Union List of Authorised Novel Foods (see Table 3).

<sup>&</sup>lt;sup>33</sup> In July 2024, the French company Gourmey announced its submission for a cultivated foie gras. At the moment of writing, in September 2024 no official summary or details concerning the application are available yet.

Precision fermentation	Products of cell cultures
L-Alanyl-L-Glutamine	Ajuga reptans extract from cell cultures
Ice Structuring Protein type III HPLC 12	Dried extract of Lippia citriodora
3'-Sialyllactose (3'-SL) sodium salt	Echinacea angustifolia extract
(microbial source)	
Lacto-N-tetraose ('LNT') (microbial source)	Echinacea purpurea extract
Lacto-N-tetraose ('LNT') (produced by	Apple fruit cell culture biomass
derivative strains of E. coli BL21(DE3))	
2'-Fucosyllactose/Difucosyllactose mixture	
('2'-FL/DFL') (microbial source)	
3-Fucosyllactose ('3-FL') (produced by a	
derivative strain of E. coli BL21(DE3))	

Table 3: Products of cell cultures and precision fermentation authorised as novel foods in the EU

#### **3.2.** The AUSNZ novel food framework

Australia and New Zealand share the "Australia New Zealand Food Standards Code", a joint, supranational set of standards developed by the Food Standards Australia New Zealand Authority (FSANZ) to regulate the food supply chain.<sup>34</sup> Novel foods are regulated according to Standard 1.1.1. and 1.5.1. Novel foods must be approved and included in the Food Standards Code's "Schedule 25 Permitted novel foods" before being placed on the market.

The determination of the novel food status is a two-step process. The food must first be considered "non-traditional". Non-traditional foods are foods, substances derived from food, or any other substance with no history of human consumption in AUSNZ. When non-traditional foods require an assessment of public health and safety considerations, they are classified as novel foods. Such safety considerations concern the potential for adverse effects on humans, the composition or structure of the food, the process by which the food has been prepared, the source from which it is derived, patterns and levels of food consumption, and any other relevant matters.<sup>35</sup> To determine whether a food is novel or not, applicants can also consult the Advisory

<sup>&</sup>lt;sup>34</sup> Elizabeth A Szabo and others, 'Outcome Based Regulations and Innovative Food Processes: An Australian Perspective' (2008) 9 Innovative Food Science & Emerging Technologies 249.

<sup>&</sup>lt;sup>35</sup> FSANZ, 'Australia New Zealand Food Standards Code –Standard 1.1.2 – Definitions used throughout the Code' [F2024C00725].

Committee on Novel Foods (ACNF),<sup>36</sup> which will produce a non-legally binding opinion on whether a food is (1) non-traditional and (2) novel. Such opinions are publicly available.<sup>37</sup>

Applicants wishing to market new food ingredients or substances, including novel foods, must submit an application to FSANZ for approval. The authorisation procedure is divided between a risk assessment and a risk management phase. FSANZ can process the application as a general application or as a major application.<sup>38</sup> FSANZ initiates major procedures when the application is deemed to lead to a new food regulatory measure and requires extensive technical evaluation (Figure 2).<sup>39</sup>

The procedure is expected to last from nine to twelve months, depending on how the FSANZ will categorise the application, with the final official approval calling for another two months.<sup>40</sup> The timeline can be stopped if more information is required from the applicant. Applicants incur a fee if FSANZ grants an exclusive commercial benefit, if priority is sought for the application, or if pre-submission consultation with FSANZ is required.<sup>41</sup> Pre-submission consultations are strongly recommended by FSANZ.<sup>42</sup>

If the application is treated as a major application, two rounds of public consultations are conducted, whereas for general applications, only one is required. For major applications, FSANZ publishes the results of the risk assessment, and the general public and stakeholders can comment on the report to provide input and raise any concerns regarding the novel food.

<sup>39</sup> ibid. Section 2.2.7.

<sup>41</sup> ibid.

<sup>&</sup>lt;sup>36</sup> FSANZ, 'Advisory Committee Novel Foods'

<sup>&</sup>lt;a href="https://www.foodstandards.gov.au/industry/novel/novelcommittee/Pages/default.aspx">https://www.foodstandards.gov.au/industry/novel/novelcommittee/Pages/default.aspx</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>37</sup> FSANZ, 'Record of Views Formed in Response to Inquiries' <https://www.foodstandards.gov.au/business/novel/novelrecs > accessed 19 September 2024.

<sup>&</sup>lt;sup>38</sup> FSANZ, 'Application Handbook' (2019)

<sup>&</sup>lt;https://www.foodstandards.gov.au/code/changes/Documents/Application%20Handbook%20at%201%20July%202019.pdf> accessed 19 September 2024. Section 2.2.

<sup>&</sup>lt;sup>40</sup> Simon Brooke-Taylor and Kirsten Grinter, 'Novel Food and Ingredients: Laws and Regulations Australia and New Zealand' in Pasquale Ferranti (ed), *Sustainable Food Science - A Comprehensive Approach* (Elsevier, 2023) pp. 75–85.

<sup>&</sup>lt;sup>42</sup> FSANZ, 'Pre-Application Assistance'<https://www.foodstandards.gov.au/food-standards-code/changing-the-code/pre-application-assistance> accessed 19 September 2024.
The FSANZ prepares draft regulatory measures considering the received inputs. These measures cover aspects such as the conditions of use, labelling, and allergen declaration. After a second round of public comments, the final recommendation of FSANZ must be formally approved by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum). The Australian Government chairs the Forum, which comprises ten Ministers from relevant portfolios, including health and agriculture from Australian states and Territories, and the New Zealand Government. The Forum can approve the FSANZ proposal or ask for a revision of the recommendation. To date, there is no record of a novel food application being rejected at this step. Applicants can be granted exclusivity to place the product on the market for a period of fifteen months following approval. Other applicants can obtain the same authorisation by submitting their own applications.<sup>43</sup>





Novel alternative proteins authorised as novel foods in AUSNZ

The number of novel foods approved in AUSNZ is low: just 14 novel foods are included in "Schedule 25 – Permitted novel foods" of the Food Standards code. Only one is a novel

<sup>&</sup>lt;sup>43</sup> FSANZ, 'Exclusivity of Use for Novel Foods and Nutritive Substances' <a href="https://www.foodstandards.gov.au/industry/novel/Pages/Exclusivity-of-use-for-novel-foods-and-nutritive-substances.aspx">https://www.foodstandards.gov.au/industry/novel/Pages/Exclusivity-of-use-for-novel-foods-and-nutritive-substances.aspx</a>> accessed 19 September 2024.

alternative protein according to the working definition: the "A1175 - Rapeseed protein isolate"<sup>44</sup> to be used in meat analogues.

One application currently under review concerns a novel alternative protein: "A1269 - Cultured Quail as a Novel Food",<sup>45</sup> the first-ever application for a cultivated meat product in AUSNZ. Among the applications that were abandoned, withdrawn or rejected (11 in total) the only one concerning a novel alternative protein was "A1263 - *Rhodomonas salina* biomass and extract as a novel food".<sup>46</sup> When considering these numbers, which are comparatively lower than those of the EU, some factors must be considered.

In AUSNZ, foods might be "non-traditional" but also not "novel" if they do not trigger safety concerns. As of August 2024, the ACNF has assessed 16 inquiries concerning novel alternative proteins per working definition. Of these, only rapeseed protein isolates have been subject to submitted and approved applications. Several insect species are considered non-traditional; however, because they did not raise safety concerns, they were categorised as non-novel by the ACNF.<sup>47</sup> This is the case for *Tenebrio molitor* and *Achaeta domesticus* which have been the subjects of several novel food applications in the EU.

Novel foods, together with food additives or foods produced using gene technology, are products that require pre-market approval. While the EU has different frameworks regulating novel foods, genetically modified organisms and food additives, in Australia and New Zealand, the authorisation procedure is the same, with the FSANZ ultimately deciding on a case-by-case basis how to categorise a product. For example, application "A1186 – soy leghemogoblin in meat analogue products",<sup>48</sup> which concerned a protein similar to hemoglobin meant to mimic

<sup>&</sup>lt;sup>44</sup> FSANZ, 'A1175 - Rapeseed Protein Isolate as a Novel Food | Food Standards Australia New Zealand' (12 November 2018) <a href="https://mta-sts.foodstandards.govt.nz/food-standards-code/applications/A1175">https://mta-sts.foodstandards.govt.nz/food-standards-code/applications/A1175</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>45</sup> FSANZ, 'A1269 - Cultured Quail as a Novel Food | Food Standards Australia New Zealand' (2 March 2023) <a href="https://www.foodstandards.gov.au/code/applications/Pages/A1269---Cultured-Quail-as-a-Novel-Food.aspx">https://www.foodstandards.gov.au/code/applications/Pages/A1269---Cultured-Quail-as-a-Novel-Food.aspx</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>46</sup> FSANZ, 'A1263 - *Rhodomonas Salina* Biomass and Extract as a Novel Food | Food Standards Australia New Zealand' (4 January 2023) <<u>https://mta-sts.foodstandards.govt.nz/food-standards-code/applications/A1263-Rhodomonas-salina-biomass-and-extract-as-a-novel-food> accessed 19 September 2024.</u>

<sup>&</sup>lt;sup>47</sup> FSANZ (n 37).

<sup>&</sup>lt;sup>48</sup> FSANZ, 'Application A1186 Soy Leghemoglobin in Meat Analogue Products' (12 July 2019) <a href="https://www.foodstandards.gov.au/sites/default/files/food-standards-142">https://www.foodstandards.gov.au/sites/default/files/food-standards-142</a>

the taste and appearance of meat in plant-based alternatives was submitted to be approved as a novel food and as a genetically modified food, but the FSANZ decided to assess it only as a nutritive substance produced from a genetically modified organism.<sup>49</sup> Consequently, the food was not included in the list of approved novel foods.

For all applications recorded in the database of novel food applications, the time required by FSANZ to publish the final report was 469 days from the date of application, which is approximately 15 months (see Table 4). The final approval of political authorities was almost always obtained in the prescribed two-month period.

Table /	I. Novel	foods on	nnoval timali	no (onnli	actions or	ailabla in	tha da	tabacas a	fonn	instiana)
rable -	i: INUVEL	roous ap	provai unien	пе (аррп	cations av	anable m	the ua	itabases u	а аррі	ications)

Application	Submission	First public	Final assessment	
		consultation	report	
Application A578 -	27/04/2006	9/08/2006	23 May 2007	
Isomaltulose				
Application A522 -	05/12/2003	18/02/2004	23/03/2005	
DHA-rich micro-				
algal oil from				
Ulkenia sp.				
Application A494 -	7/03/2003	26/05/2004	20/10/2004	
Alpha-Cyclodextrin				
Application A1024 -	02/03/2009	01/10/2009	19/02/2010	
Equivalence of Plant				
Stanols, Sterols &				
their Fatty Acids				
Esters				
A1134 - Increased	22/06/2016	13/12/2016	23/03/2017	
Concentration of				

code/applications/Documents/A1186%201st%20CFS%20report.pdf> accessed 19 September 2024. Executive Summary.

<sup>&</sup>lt;sup>49</sup> Jessica Freitag, 'Producing Food Through Precision Fermentation - The Opportunity For Australia' (*Cellular Agriculture Australia*, 2024) < https://www.cellularagricultureaustralia.org/publications/producing-food-through-precision-fermentation---the-opportunity-for-australia> accessed 19 September 2024.

Plant Sterols in			
Breakfast Cereals			
A1123 - Isomalto-	04/11/2015	13/12/2016	16/05/2017
oligosaccharide			
Application A1019 -	14/11/2008	23/09/2009	19/02/2010
Phytosterol esters in			
low fat cheese			
A1175 - Rapeseed	21/02/2019	31/07/2020	15/12/2020
protein isolate			

Despite being the first application for cultivated meat submitted in AUSNZ, the timeline for the "A1269 - Cultured Quail as a Novel Food" application is in line with the average novel food application. The application was originally submitted on January 20, 2023, and the first round of public consultation was opened in December 11<sup>th</sup>, 2023 and closed on February 5<sup>th</sup>, 2024.<sup>50</sup>

#### 4. Results of the qualitative interviews

In this section, I now present the key themes identified during the interviews with stakeholders active in the alternative protein sector in the EU and AUSNZ. The themes were organised into four main topics to explore stakeholders' perceptions of regulatory barriers within the novel food frameworks in the EU and AUSNZ, as well as potential solutions. The topics include regulatory obstacles in authorisation procedures, interaction between applicants and authorities, political influence in the authorisation procedure, and suggestions for improving the framework.

#### 4.1. Regulatory barriers in the authorisation procedures

The authorisation procedure is the most relevant feature of novel food frameworks in both the EU and the AUSNZ. The regulatory obstacles in the authorisation procedure are mainly related to three aspects: the production of required data, costs, and duration.

The costs were perceived differently in the two jurisdictions. EU costs are only due to the acquisition of scientific data required in the process and to specialised consultancy. For

<sup>&</sup>lt;sup>50</sup> 'FSANZ (n 45). A1269 first call for submissions - 11 December 2023.

example, participant EU 6 estimated that the cost of obtaining the required data is around  $\notin$ 100.000 and lamented that such costs make the procedure a formidable obstacle for small and medium enterprises (SMEs). In the AUSNZ, the cost of obtaining the data adds to the processing fee for the assessment of the application, which is free in the EU.

The duration of the procedure was considered by stakeholders as the main barrier in both the EU and AUSNZ, despite the differences between the two jurisdictions. The authorisation procedure lasts on average 15 months in the AUSNZ, but more than three years in the EU. Participants in Australia were sympathetic to the difficulties of the FSANZ, but highlighted how the timeline, even when it is as fast as one year, can be critical for companies as it delays the opportunity to earn revenue.

Similarly, EU participants clarified that the duration of the authorisation procedure can be difficult to overcome, especially for SMEs. They emphasised that the promised timeline is often not respected because of the power of the EFSA to put the procedure on hold when requiring further data. As participant EU 5 explained:

"the approval timelines in reality are so long that basically you have very little chance of getting funding, if you need to go through that process. (...). And I mean, on the website it says 18 months. We all know with all the clock stops and so on that are a given in any process, it's more three years. (...). It's an absolute killer for collecting capital."

The absence of legal certainty over the duration of the procedure and the substantially longer approval process in the EU are two of the main differences between the two frameworks and contribute significantly to the negative opinion that EU stakeholders generally have over the EU framework.

#### 4.2. Communication between applicants and regulatory authorities

Perceptions on the interaction with authorities vary greatly between the two jurisdictions. For AUSNZ, FSANZ acts as a proactive institution, willing to engage with companies, even informally, prior to the official submission of the dossiers. In the words of AUSNZ 6:

"(FSANZ) make themselves available to companies to have a pre-application conversation so that you can actually get a sense of how much information they're

going to need, how long they think it will take, whether they think you've got a chance based on you know, your technology and your product."

Through these consultations, applicants can work together with the FSANZ to fill in the dossier according to the agency's requirements, speeding up the overall process. The only negative feedback centred on the perception that the authorisation procedure in AUSNZ is designed to favour established companies with sufficient human resources and capital rather than SMEs.

In the EU, interaction with regulatory authorities is described as difficult and demotivating, particularly for start-ups and innovative companies. Institutions do not show interest in supporting innovation and tend to have an obstructive approach to novel products and technologies, especially compared with other jurisdictions. In the words of EU 5:

"(In Singapore) they are really interested in technologies, so they proactively drive the discussion towards, okay, how can we make it happen? and what I like are the points that you need to address if you want us to approve your product? And this is something that I don't see happening proactively in Europe, where we are generally saying like, first step is like, block it. And then I let you come with whatever data you have. And then I tell you what is wrong in your data. That's a bit the different logic of not supporting, but judging. At least this is my my perspective at the moment of the ecosystem, which for start-up that comes with a lot of innovation and motivation is, to say the least, a bit frustrating."

In particular, the absence of pre-submission consultations with the EFSA over which information should be included in the dossier is frequently identified as causing major delays and exacerbating the difficulties faced by applicants. Meaningful dialogue with the authorities is always referred to by EU stakeholders as the number one reason why other jurisdictions, such as Singapore and the United States, are perceived as more innovation-friendly. According to EU participants, this often results in a process of evasion of EU companies, who prefer to migrate overseas to obtain regulatory approvals and enter other markets before engaging with EU authorities at a later stage (if ever).

#### 4.3. Political influence in the authorisation procedure and role of traditional sectors

Both the EU and AUSNZ authorisation procedures separate scientific risk assessment from the final political decision. In the AUSNZ, it is the FSANZ that formulates the regulatory measures

upon which the final decision is based, whereas in the EU, this responsibility lies with the Commission.

EU participants, while acknowledging the importance of addressing the socio-economic impact of innovations such as alternative proteins, criticised the political element of the authorisation procedure advocating for a process solely focused on safety considerations. As EU 3 stated:

"I think if we say products on the market must be safe, then there should not be politician A, B, C and D who say EFSA said this is safe, the science says it's safe, but then I don't want to accept it because I'm against some kind of products as we see is happening in a lot of member states."

Stakeholders are afraid that controversial products such as cultivated meat might be rejected by the PAFF Committee, even when deemed safe by the EFSA. These concerns are exacerbated by the lack of transparency in the functioning of the PAFF Committee, which is perceived as antithetical to the risk assessment phase of the procedure. As EU 1 described it:

"It's a bit like the conclave when we elect the pope in Rome. You know, they do that behind closed doors. You have no idea what they're talking about."

On the contrary, in AUSNZ, stakeholders almost always perceive approval in the ministerial forum as a pro forma. As AUSNZ 6 stated, *"The common practice is for the food ministers to sign what is put in front of them."* 

The main concern of AUSNZ stakeholders is the potential antagonism of the meat and dairy industries towards alternative proteins. In their view, the traditional sectors might lobby against alternative protein companies. To face this concern, AUSNZ companies adopted different strategies: while some still espouse the traditional stance of alternative proteins as opening up a new future for food production, others aim to present themselves as somewhat complementary to traditional industries: *"if we're going to say any label we prefer for cultured meat "complementary protein"*, declared AUSNZ 2. Alongside this strategy, companies are also focusing on high-value or unusual products, such as lactoferrin or quail meat, to enter the market.

Thus, the concerns of the EU and AUSNZ stakeholders are slightly different. While the AUSNZ innovators are more afraid of their relationship with the traditional meat and dairy industries,

the EU interviewees often referred directly to the negative political stance of some member states' governments, which could potentially be reflected in a negative vote in the PAFF committee.<sup>51</sup>

#### 4.4. Suggestions for improving the EU and AUSNZ frameworks

In the EU, suggestions to improve novel food framework have focused on the interaction between applicants and authorities to improve regulatory certainty. Pre-submission consultations with the EFSA were seen as critical for reducing the duration, costs, and uncertainty of the authorisation procedure. Participants identified the main obstacles as the limited amount of resources of EFSA and the introduction of stricter rules on transparency following the adoption of Regulation (EU) 2019/1381<sup>52</sup> on the transparency and sustainability of the EU risk assessment in the food chain.

The creation of "regulatory sandboxes" and special programs to improve dialogue between authorities and applicants was referred to as a potential solution, as they give companies the opportunity to show earlier results to investors and invest them with ownership of the regulatory frameworks.

In both the EU and the AUSNZ, participants advocated for the implementation of support mechanisms for SMEs, aiding them in preparing their applications and navigating the regulatory framework. The creation of contact points for start-ups at the EU and/or national levels could facilitate the development of SMEs and reduce the costs associated with consultancy.

Finally, participants from both countries expressed their interest in the implementation of a mutual recognition procedure between jurisdictions, or in the inclusion of approvals from other jurisdictions in the application material to shorten the timeline of the authorisation procedures.

<sup>&</sup>lt;sup>51</sup> The vote in the PAFF Committee should take into account the opinion of the EFSA, relevant EU law provisions, the precautionary principle and other legitimate factors. Recital 19 of the GFL specifies offers an overview of factors that might be considered "(during risk analysis) other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls."

<sup>&</sup>lt;sup>52</sup> 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, PE/41/2019/REV/1, OJ L 231, 6.9.2019, p. 1–28.

#### **5.** Discussion

Despite the increasing number of novel food approvals, including several alternative proteins, the EU is often described as the most difficult jurisdiction to succeed. Stakeholders particularly criticise the absence of clear guidelines for the preparation of dossiers for innovative products, such as cultivated meat.<sup>53</sup> Additionally, strict transparency rules hinder meaningful presubmission consultations with the EFSA, which can only be generic and conducted by EFSA personnel not involved in the actual assessment, leading to longer and costlier authorisation procedures.<sup>54</sup>

Recently, the EU NFR has been the focus of public and political scrutiny following the approval of the first novel food from insects and due to the increased attention paid to products of cellular agriculture, specifically cultivated meat. In December 2023, Italy became the first country to ban the production and commercialisation of cultivated meat, referring directly to potential risks for human health and to the threat the product poses to the Italian gastronomic heritage.<sup>55</sup> In January 2024, in a note to the Council of the EU, the governments of Italy, France, Austria, and eleven other countries called for the adoption of a more comprehensive regulatory framework than the NFR, citing the impact that products like cultivated meat might have on the lifestyle of Europeans and their potential effects on human health.<sup>56</sup> Similar concerns regarding the limits of the NFR for assessing innovative products and processes were already raised in the European Protein Strategy adopted in October 2023 by the European Parliament.<sup>57</sup> This political environment is alarming for the alternative proteins industry, which fears political backlash could lead to EU-wide bans on products and processes such as cultivated meat and

<sup>&</sup>lt;sup>53</sup> On September 30<sup>th</sup> 2024, specific guidelines on dossiers concerning products of cellular agriculture have been published in the new guidance for novel food applications. EFSA Panel on Nutrition, Novel Foods and Food Allergens and others, 'Guidance on the Scientific Requirements for an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283' (2024) 22 EFSA Journal e8961.

<sup>&</sup>lt;sup>54</sup> Giulia Torre, 'The Novel Foods Authorisation Procedure After Regulation (EU) 2019/1381: Transparency versus Innovation?' (2023) 18 European Food and Feed Law Review 131.

<sup>&</sup>lt;sup>55</sup> LEGGE 1° dicembre 2023, n. 172. Disposizioni in materia di divieto di produzione e di immissione sul mercato di alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o di tessuti derivanti da animali vertebrati nonché di divieto della denominazione di carne per prodotti trasformati contenenti proteine vegetali. Article 1 outlines the objectives of the legislation; Article 2 directly refers to the precautionary principle.

<sup>&</sup>lt;sup>56</sup> General Secretariat of the Council 'Note to Council: The CAP's role on safeguarding high-quality and primary farm-based food production' (2024), 5469/1/24 REV 1.

<sup>&</sup>lt;sup>57</sup> European Parliament, 'Resolution of 19 October 2023 European protein strategy' (2023/2015(INI)).

precision fermentation. Although no novel food has been rejected by the PAFF Committee so far, stakeholders worry that some novel foods will eventually face the same hostility as genetically modified organisms.<sup>58</sup>

Interestingly, while EU academic scholarship on novel foods echoes stakeholders' concerns,<sup>59</sup> in AUSNZ, scholars tend to criticise their novel food framework because of its narrow scope and focus on safety.<sup>60</sup> This criticism mirrors the stance of EU governments and opponents of the EU novel food framework. According to this perspective, novel food authorisation procedures would ignore the major impact on food systems and food consumption patterns that alternative proteins might cause.<sup>61</sup> It is noteworthy that these concerns are mainly raised in the AUSNZ literature, as the AUSNZ system already includes features such as public consultations and economic cost-benefit analysis, which expand the scope of authorisation procedures beyond simple safety assessment.

Alternative proteins have the potential to transform food systems significantly. To facilitate their adoption and consumer acceptance, regulators must avoid past mistakes and foster the sustainability potential of businesses in the sector.<sup>62</sup> Supporting the growth of diverse participants by facilitating the innovative work of SMEs is an essential component in the creation of new, diverse food systems based on a plurality of actors.

Compared to other jurisdictions, in both the EU and AUSNZ, there is no direct public support for innovators working on novel foods in the form of regulatory, technical, and economic

<sup>&</sup>lt;sup>58</sup> Joseph Mohorčich and Jacy Reese, 'Cell-Cultured Meat: Lessons from GMO Adoption and Resistance' (2019) 143 Appetite 104408.

<sup>&</sup>lt;sup>59</sup> Martin Holle, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), Regulating and Managing Food Safety in the EU (Springer International Publishing, 2018) pp. 291-330; Lähteenmäki-Uutela and others (n 9); Alessandro Monaco and Kai 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 219.

<sup>&</sup>lt;sup>60</sup> Hope Johnson, Christine Parker and Brodie Evans, "Don't Mince Words": Analysis of Problematizations in Australian Alternative Protein Regulatory Debates' (2023) 40 Agriculture and Human Values 1581; Katherine Sievert and others, 'What's Really at "Steak"? Understanding the Global Politics of Red and Processed Meat Reduction: A Framing Analysis of Stakeholder Interviews' (2022) 137 Environmental Science & Policy 12.

<sup>&</sup>lt;sup>61</sup> Hope Johnson and Christine Parker, 'An Impossible Task? Australian Food Law and the Challenge of Novel Meat Analogues' (2022) 50 Federal Law Review 331.

<sup>&</sup>lt;sup>62</sup> Christine Parker, 'From "Corporate Governance" to Ecological Regulation: Flipping the Regulatory Story on Climate Change' (2022) SSRN Electronic Journal: <a href="https://papers.ssrn.com/abstract=4184911">https://papers.ssrn.com/abstract=4184911</a>> accessed 19 September 2024.

assistance. For example, in Singapore, the Future Ready Food Safety Hub (FRESH) is an initiative of the Singaporean Food Authority directly referred to in the regulatory guidance for novel foods' application.<sup>63</sup> Through FRESH, companies can access regulatory consultancy services to outline their regulatory roadmap, review safety data on novel foods, and obtain a pre-submission risk assessment. In December 2023, the British Food Standards Agency created a regulatory sandbox for cultivated meat as part of the National Vision for Engineering Biology.<sup>64</sup>

Interviewed stakeholders in both the EU and AUSNZ have advocated for similar systems, where companies and SMEs can test and develop novel foods in a controlled environment, allowing them to navigate the complex approval process more flexibly. Regulatory sandboxes would facilitate a more collaborative approach between regulators and innovators, offering guidance and feedback throughout the development phase and ultimately accelerating the introduction of innovations into the market without compromising regulatory supervision.

#### 6. Limitations

While this study provides valuable insights into the challenges and perspectives of the alternative protein sectors in the EU and AUSNZ, and on stakeholders' perceptions of the EU and AUSNZ novel food frameworks, it is important to acknowledge certain limitations inherent to the research design.

First, due to differences between the EU and AUSNZ regulatory frameworks, the scope of novel food regulations varies between the two jurisdictions, leading to potential disparities in the novel food status of specific products and different regulatory classifications. Currently, the number of approved novel foods in AUSNZ is significantly lower than in the EU, as is the number of active applications. The data included in this study must be interpreted considering the differences in size, institutional settings, and regulatory implementation between the two jurisdictions.

<sup>&</sup>lt;sup>63</sup> FRESH, 'Future Ready Food Safety Hub' < https://www.ntu.edu.sg/fresh/about> accessed 19 September 2024.

<sup>&</sup>lt;sup>64</sup> Good Food Institute, 'Cultivated Meat Backed by UK Government's New National Vision for Engineering Biology' (2023) <a href="https://gfieurope.org/blog/cultivated-meat-backed-by-uk-governments-new-national-vision-for-engineering-biology/">https://gfieurope.org/blog/cultivated-meat-backed-by-uk-governments-new-national-vision-for-engineering-biology/</a>> accessed 19 September 2024.

Second, the sample of participants in the interviews was drawn from either the EU or AUSNZ alternative protein sector, with only one participant possessing expertise and knowledge in both systems.

Finally, the depth of understanding of the framework varied among the participants. Interviews in the EU were primarily conducted with consultants who helped with dossier submission and possessed good knowledge of the framework, while in AUSNZ, the sample of participants was mainly formed by company representatives who exhibited different levels of familiarity with their regulatory framework. This discrepancy in expertise and focus may introduce biases in the interpretation of the findings and hinder a balanced comparative analysis. For this reason, the interviews focused on the stakeholders' individual perspectives and perceptions of the framework within which they operate, rather than their specific legal knowledge.

#### 7. Conclusion

A comparison between the EU and AUSNZ novel food frameworks reveals distinct approaches that influence the development of the two alternative protein sectors. The AUSNZ framework is generally perceived as more innovation-friendly, particularly regarding breakthrough innovations such as cultivated meat, due to the opportunity of pre-submission consultations with the FSANZ. The EU novel food framework is viewed as challenging because of its long authorisation procedures and the lack of support from regulatory authorities, especially the EFSA in the pre-submission consultation phase.

The political stances of governments and society are likely to affect the development of the alternative protein sector in both the EU and the AUSNZ. While the EU grapples with heated debates surrounding insects and cultivated meat, AUSNZ alternative protein companies have not yet faced the same political backlash. Nonetheless, a common challenge persists: fostering acceptance among the general population and integrating these products into the gastronomy of the two countries, a challenge that regulation cannot win by itself, but for which it could create the right conditions, especially favouring the proliferation of SMEs.

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### **Chapter 6**

## Data Protection under the Novel Food Regulation: valuable instrument or barrier to Innovation? Insights from the insect sector

Based on: Alessandro Monaco. "Data Protection Under the Novel Food Regulation: Valuable Instrument or Barrier to Innovation? Insights from the Insect Sector." *European Food and Feed Law Review*, 18, 172-178 (2023). Available at: <u>https://effl.lexxion.eu/article/EFFL/2023/3/7</u>

#### Abstract

The data protection clause under Regulation (EU) No 2283/2015 on novel foods (NFR) is the instrument chosen by the legislator to reward innovators for their efforts in obtaining authorisation for novel food products in the European Union. Authorisations under the NFR are, in principle, horizontal. However, an exclusive right to place novel foods on the market can be granted to the applicants in case they include in their applications proprietary, unpublished data essential for the good outcome of the authorisation procedure. This chapter hypothesises the potential impact of data protection in the novel foods sector. Insights from the insect industry, considered the first real test for the NFR, and the data protection clause are used to provide a valuable case study.

#### **1. Introduction**

Innovation in the food sector is one of the key drivers to accelerate the transition of the current food production systems towards a sustainable, healthy and inclusive future and to meet the European Green Deal's objectives.<sup>1</sup> Insects are among the most promising alternative proteins, due to their nutritional properties and sustainability potential.<sup>2</sup>

Insects are categorised as novel foods in the European Union (EU).<sup>3</sup> Despite their history of consumption in Asia, Africa and South America, insects have not been consumed to a large extent in any EU Member States before 1997. As a consequence, insects fall under the scope of Regulation (EU) 2283/2015 on novel foods (hereafter "the Novel Food Regulation" or "NFR") and they are subject to a pre-market authorisation procedure before entering the market.

In June 2021, the dried Tenebrio molitor larva was the first insect product authorised for human

<sup>&</sup>lt;sup>1</sup> European Commission, Food 2030 pathways for action - Research and innovation policy as a driver for sustainable, healthy and inclusive food systems (2020) https://research-and-innovation.ec.europa.eu/knowledge-publications-tools-and-data/publications/all-publications/food-2030-pathways-action-research-and-innovation-policy-driver-sustainable-healthy-and-inclusive\_en accessed 19 September 2024

<sup>&</sup>lt;sup>2</sup> Andrea M Liceaga and others, 'Insects as an Alternative Protein Source' (2022) 13 Annual Review of Food Science and Technology 19.

<sup>&</sup>lt;sup>3</sup> 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, p. 1–22. Hereinafter referred to as "NFR". The novel food status of insects is specified in Recital 8.

consumption in the EU.<sup>4</sup> In the next year and a half, three more insects species, *Locusta migratoria*, *Acheta domesticus* and *Alphitobius diaperinus*, have received positive opinions from the European Food Safety Authority (EFSA) and, at the moment of writing (January 2023), a total of six authorisations have been granted.<sup>5</sup> Such developments are expected to continue in the near future due to a large number of applications currently submitted covering products obtained also from *Hermetia lucens*, *Apis mellifera* male pupae, and *Gryllodes sigillatus*.<sup>6</sup>

Authorisations granted under the Novel Food Regulation are in principle horizontal, meaning that an authorisation, once granted, applies to everyone and not only to the applicant. However, if scientific studies provided by the applicants are recognised as necessary for the positive outcome of the application, the applicants can obtain the exclusive right to place the product on the market for a period of five years.<sup>7</sup> Other food business operators can seek and obtain authorisations that overlap partially or entirely with the first one, providing that they also present original scientific data or find an agreement with the original applicant.

The data protection clause and the resulting exclusive authorisations are the designated tool to promote innovation under the NFR.<sup>8</sup> The investment made by innovators for placing novel foods on the market is rewarded, giving them a certain amount of market power over their novel products.

#### 1.1. Objectives and methodology

This chapter considers the positive and negative aspects of the data protection system in the context of the NFR to make predictions of its future impact on innovation and novel foods'

<sup>&</sup>lt;sup>4</sup> Commission Implementing Regulation (EU) 2021/882 of 1 June 2021 authorising the placing on the market of dried Tenebrio molitor larva as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470, OJ L 194, 2.6.2021, p. 16–20.

<sup>&</sup>lt;sup>5</sup> Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, C/2017/8878, OJ L 351, 30.12.2017, p. 72–201.

<sup>&</sup>lt;sup>6</sup> European Commission, 'Summary of Applications and Notifications' <a href="https://food.ec.europa.eu/safety/novel-food/authorisations/summary-applications-and-notifications\_en">https://food.ec.europa.eu/safety/novel-food/authorisations/summary-applications-and-notifications\_en</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>7</sup> NFR (n 3). Article 26.

<sup>&</sup>lt;sup>8</sup> ibid. Recital 30.

development. To do so, the insect sector is used as a case study. The insect sector was chosen because of three reasons: it encompasses a homogenous class of novel foods, at least in terms of consumer perception; there is currently a huge number of companies willing to enter the market; data protection has so far been granted to each authorised insect product.

The chapter analyses the criteria for receiving data protection under the NFR and its theoretical implications. It then clarifies the categorisation of insects as novel foods, highlighting the peculiarities of their regulatory history in the EU. Finally, the impact of data protection in the insect sector is investigated, to make relevant predictions on how it will affect the novel foods sector in general. Anecdotal evidence provides relevant insights on the topic.

#### 2. Data protection under the Novel Food Regulation

The Novel Food Regulation requires a pre-market authorisation procedure for foods that were not used for human consumption to a significant degree within the Union before the 15<sup>th</sup> of May, 1997 and which fall under one of the novel food categories.<sup>9</sup>

The authorisation procedure for novel food is based on risk analysis, which is divided into two consecutive steps, risk assessment and risk management.<sup>10</sup> The EFSA first conducts an assessment of available scientific data to prove that the novel food is not harmful to human health. Afterwards, the European Commission drafts an implementing regulation to authorise the novel food, considering (a) the scientific opinion of the authority, (b) whether or not the food misleads consumers and whether it is nutritionally disadvantageous compared with foods it intends to replace, (c) general principles of EU law, such as the precautionary principle and (d) other legitimate factors.<sup>11</sup> Member States' representatives then vote on the proposed implementing regulation.

Food business operators willing to obtain a novel food authorisation apply following a centralised procedure at the EU level. The application requires the creation of a dossier with relevant information and data. The name and description of the novel food, the production processes, its detailed composition, each proposed use and any scientific evidence

<sup>11</sup> ibid. Article 12.

<sup>&</sup>lt;sup>9</sup> ibid. Article 3(2).

<sup>&</sup>lt;sup>10</sup> ibid. Articles 10 to 12.

demonstrating that the novel food does not pose a safety risk to human health must all be included in the dossier.<sup>12</sup>

The EFSA will only evaluate scientific evidence provided by the applicant and this usually requires an intense dialogue between the Authority and the applicant. The overall procedure should not last more than nine months beginning when the application is validated but can be stopped every time EFSA requires more information.<sup>13</sup> Overall, the time required can be much longer.<sup>14</sup> When the novel food is proven to be safe and authorised, the Commission includes the novel food in the Union List of Novel Foods, where the product specifications, the conditions of use, any additional labelling and post-market requirements are specified.

When all relevant data have been considered, the EFSA publishes a scientific opinion highlighting the application's main features. Upon request of the applicant, certain technical information can be exempted from publication, along with proprietary scientific data. In its Opinion, the EFSA must also indicate whether the proprietary, unpublished scientific data included in the application were essential to conduct the risk assessment. The EU Commission will then decide on awarding data protection, based on the opinion of EFSA. If granted, data protection results in an exclusive right to place the novel food on the market for a non-renewable period of five years.<sup>15</sup> Other food business operators are authorised to apply for a very similar, or even the same novel food and obtain their exclusive authorisations if they provide unpublished, proprietary scientific data. This creates a system under which authorisations might partially or entirely overlap in scope and duration.

#### 2.1. Data protection and innovation

Under the previous novel food regulation, Regulation (EC) No 258/97<sup>16</sup> concerning novel foods and novel food ingredients, authorisations were product and applicant-specific. When the novel

<sup>&</sup>lt;sup>12</sup> ibid. Article 10.

<sup>&</sup>lt;sup>13</sup> ibid. Article 11(4).

<sup>&</sup>lt;sup>14</sup> Martin Holle, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing, 2018) pp. 291-330.

<sup>&</sup>lt;sup>15</sup> NFR (n 3). Article 27.

<sup>&</sup>lt;sup>16</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p.1 1997.

foods framework was reformed in 2015 each authorisation under the new NFR became horizontally applicable.<sup>17</sup> At the same time, the data protection provision was also introduced.

The decision of binding the protection of proprietary data with exclusive authorisations was taken to reward innovators for their efforts in financing scientific studies required during the authorisation procedures and to avoid the free-riding of competitors. However, to keep the authorisation system as open as possible and favouring the development of the overall sector, the data protection clause does not preclude other food business operators from applying for authorisations covering the same novel food with equal or very similar conditions of use, providing that the other applicants also produce proprietary scientific data, or find an agreement with the first applicant for the use of their protected data.<sup>18</sup>

Despite not being an explicit objective of the NFR, the promotion of innovation can be identified as one of the goals of the novel food framework.<sup>19</sup> Data protection is the chosen instrument through which the NFR rewards innovators and therefore incentivises the innovation process.<sup>20</sup> The exclusive authorisation creates rights which are, from a view of its protective scope, similar to patents, offering food business operators a limited market power over the authorised novel foods. The five-year duration of the exclusivity has been determined as the right compromise between rewarding the applicants and the necessity to open the market to other enterprises after a reasonable period.<sup>21</sup>

However, the data protection clause may cause unwanted consequences. Exclusive authorisations could make the market entrance for smaller companies less attractive, slowing down the development of the innovation sector. Start-ups and small-sized companies may not have the scientific capability or the economic power to provide the required data by

<sup>&</sup>lt;sup>17</sup> Annalisa Volpato, 'Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective' in Lucia Scaffardi and Giulia Fornici (eds), *Novel Foods and Edible Insects in the European Union* (Springer Nature Switzerland, 2022) pp. 15-36.

<sup>&</sup>lt;sup>18</sup> NFR (n 3). Recital 30.

<sup>&</sup>lt;sup>19</sup> Alessandro Monaco and Kai 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 219.

<sup>&</sup>lt;sup>20</sup> Martin Holle, 'The Protection of Proprietary Data in Novel Foods – How to Make It Work' (2014) 9 European Food and Feed Law Review 280.

<sup>&</sup>lt;sup>21</sup> Craig Simpson, 'Data Protection under Food Law Post: In the Aftermath of the Novel Foods Regulation' (2016) 11 European Food and Feed Law Review 309.

themselves.<sup>22</sup> Furthermore, data protection can only be granted to unpublished scientific data, leading to a delay in building scientific knowledge in a given sector.<sup>23</sup> If several novel foods were authorised and received data protection, the regulatory landscape applicable to specific classes of novel food products might become increasingly complicated to navigate for all actors involved. Not surprisingly, when a novel food is approved as a "traditional food from a third country", a class of novel foods that enjoys a simplified authorisation procedure, the data protection system is not applicable,<sup>24</sup> since this would give one single company the exclusive right to sell a product commonly consumed and produced in countries outside the EU. Finally, whether data protection results in appealing advantages for the applicants is also debatable, considering that the same authorisation can be granted to others, the duration is limited to a non-renewable period of five years and the scope of the provision is limited to unpublished data.

Based on these considerations, I hypothesise the following scenarios regarding the impact of data protection in the novel foods sector:

# Data protection and exclusive authorisations constitute a valuable system for companies, without jeopardising the growth of any given novel foods sub-sector.

Under this scenario, innovators perceive exclusive authorisations as significant rewards for undergoing the authorisation procedures. In particular, companies obtaining exclusive authorisations might gain significant advantages in terms of market power, capacity to attract investors and partnerships with retailers and actors along the supply chain. Companies can defend their exclusive rights but still maintain good relationships with one another. Start-ups and established companies are willing to collaborate and achieve mutual objectives through the exchange of knowledge, partnerships and the creation of consortiums. Investors would recognise exclusive authorisation as a valuable asset which drives their choices towards those companies able to obtain one or more authorisations. Retailers recognise the exclusive authorisation as proof of safety and quality, and thanks to a widespread market presence, consumers approach the novel food without fear, limiting the impact of disgust sensitivity and

<sup>&</sup>lt;sup>22</sup> Anu Lähteenmäki-Uutela and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336.

<sup>&</sup>lt;sup>23</sup> Holle (n 14).

<sup>&</sup>lt;sup>24</sup> NFR (n 3). Article 26(3).

cultural rejection.<sup>25</sup> Data protection initially limits the supply of products on the market, but over the five years period and especially after the expiration of the exclusive authorisation, more and more companies enter a given novel foods sub-sector either as producers or transformers. The sector grows accordingly.

The data protection system is valuable for companies obtaining exclusive authorisations but hinders innovation in a given novel foods sub-sector.

According to this hypothesis, data protection would create an environment where small and medium-size companies cannot compete with more prominent companies. Exclusive authorisations would be an obstacle for small companies because they lack the resources to undergo the procedure by themselves and will have to wait five years to enter the market when the authorisations are no longer exclusive. In the meantime, the market advantage of companies benefiting from the authorisations becomes unbridgeable also due to the willingness of the authorisation holders to defend their rights in court. The data protection clause would then lead to oligopolies which potentially jeopardise the innovation process. Consumers are confused because the supply of novel food is limited and this slows down the creation of a proper market able to sustain all stakeholders in the sector.

The data protection system and the exclusive authorisations do not bring additional value for the authorisation's holder nor cause particular problems to other companies, proving to be almost useless and causing no visible impact on a given novel foods sub-sector.

Exclusive authorisations are not enforced due to a lack of will (and resources) by the companies and the competent authorities in the Member States. Under this scenario, authorisations holders are not interested in lengthy disputes and prefer to favour the growth of the sector overall. Sporadically, companies might defend their rights but mostly prefer to dialogue with competitors. Investors appreciate the authorisation, but their choices are driven mainly by other factors. The data protection system proves to have little or no impact on a given novel food sector, due to its intrinsic drawbacks: the limit to unpublished data, the difficulty of enforcement and the proliferation of authorisations that slowly erodes the exclusivity.

<sup>&</sup>lt;sup>25</sup> Tieneke Kröger and others, 'Acceptance of Insect-Based Food Products in Western Societies: A Systematic Review' (2022) 8 Frontiers in Nutrition 759885.

#### 3. Categorisation of insects as novel foods

The categorisation of insects as novel foods in the EU has been heavily disputed in the European Union. The current Novel Food Regulation explicitly clarifies in Recital 8 that "*whole insects and their parts*" are considered novel foods, under the novel food category (iii) "whole or part of animals". Regulation (EC) No 258/97 considered novel foods "food ingredients isolated from animals", not clarifying whether whole insects fell under its scope.<sup>26</sup> As a result of this legal uncertainty, since 1997, some Member States have admitted the commercialisation of insects, and others did not. The situation has, on the one hand, favoured the creation of "regulatory sandboxes" in countries such as Belgium or the Netherlands, while on the other hand, it has jeopardised the free circulation of goods within the Union.<sup>27</sup> Only in 2020, the Court of Justice of the European Union clarified that whole insects did not fall within the scope of Regulation (EC) No 258/97.<sup>28</sup>

Due to this problematic categorisation, when the NFR was adopted, transitional measures have been implemented to give food business operators the right to keep their products on the market, provided that a proper application under the new NFR was filled in before the 2<sup>nd</sup> January, 2020.<sup>29</sup> This decision was taken to avoid the recall of products and to ensure that companies already legally present on the market in several Member States could keep consumers' trust and not lose their market shares.<sup>30</sup> At the moment of writing, in January 2023, specific uses of four insect species have been authorised in the EU and a total of six authorisations have been granted

<sup>29</sup> NFR (n 3). Article 35(2).

<sup>&</sup>lt;sup>26</sup> Corrado Finardi and Christophe Derrien, 'Novel Food: Where Are Insects (and Feed...) in Regulation 2015/2283?' (2016) 11 European Food and Feed Law Review 119.

<sup>&</sup>lt;sup>27</sup> Giulia Formici, 'Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 99-122.

<sup>&</sup>lt;sup>28</sup> Court of Justice of the European Union, Case C-526/19 - Entoma SAS v Ministre de l'Économie et des Finances, Ministre de l'Agriculture et de l'Alimentation, [2020] ECLI:EU:C:2020:769; For a thorough analysis of the judgement see: Valeria Paganizza, 'Are Insects Novel Foods?: An Enlightenment on the Scope of Regulation (EC) No 258/97 after the Judgment of the Court in Case C-526/19' (2020) 15 European Food and Feed Law Review 579.

<sup>&</sup>lt;sup>30</sup> IPIFF, 'Regulation (EU) 2015/2283 on Novel Foods - Briefing Paper on the Provisions Relevant to the Commercialisation of Insect-Based Products Intended for Human Consumption in the EU' (2021) V. 3 <a href="https://ipiff.org/wp-content/uploads/2019/08/ipiff\_briefing\_update\_03.pdf">https://ipiff.org/wp-content/uploads/2019/08/ipiff\_briefing\_update\_03.pdf</a>> accessed 19 September 2024.

to four companies.

#### 4. Data protection in the insect sector

Insects are likely the first benchmark for the data protection system under the NFR. First of all, they constitute a relatively homogenous sample of novel foods both taxonomically and in terms of market perception. Second, several companies and start-ups are already on the market. Consequently, the market presence of insects, both currently and potentially, is more prominent than other novel foods. Third, virtually all companies require data protection for their applications. This will result in a regulatory landscape with overlapping exclusive authorisations. Finally, several companies are and will be on the market without authorisation due to the food business operators' poor knowledge of EU provisions, lack of enforcement from national authorities and national legislation created in response to the previous legal uncertainty.

To develop valuable theories on the impact of the data protection system and of the exclusive authorisations in the insect sector, I conducted non-recorded, informal conversations with entrepreneurs and stakeholders via Zoom calls, to collect anecdotal evidence and insights. The following aspects emerged as the most prominent.

#### 4.1. Potential consequences of the data protection clause in the insect sector

#### Exclusive authorisations usually make companies leaders in the sector

Companies obtaining exclusive authorisations at this early stage are seen as pioneers of the sector. Their names are largely present in the media and informed consumers recognise their role. This means that smaller companies and start-ups are likely to consider them as models, opening huge opportunities for collaboration.

#### Benefits obtained through data protection are limited

The data protection and exclusive authorisation system are limited by all the conditions set in the NFR. The five-year exclusivity period is shorter than other similar systems adopted in the EU legislation e.g. health claims.<sup>31</sup> Other business operators can obtain similar authorisations,

<sup>&</sup>lt;sup>31</sup> Simpson (n 21).

and even though some specifics might differ, the progressive expiration of the first exclusive authorisations will slowly erode the rights of the authorisation holders. It is debatable whether companies obtaining exclusive authorisations will enforce their right consistently for mainly two reasons. First, there are several companies active on the market across the Union. Costs to monitor and eventually prosecute them in court would require massive resources. Second, competent authorities in Member States may vary in their knowledge of the novel food framework and on how to apply the transitional measures. This might cause even more issues when dealing with different judicial systems across the Union. Only major violations of the right are likely to trigger legal disputes.

# The sector's overall growth is perceived as more important than enforcing exclusive authorisations

Considering the potential of the industry, but also how controversially insects are perceived in western countries, the development of the overall sector seems more important for authorisation holders than protecting individual rights. If insect products are available to consumers, consumers are more likely to appreciate them. Adopting this perspective, enforcing data protection seems less crucial than the advantages derived from the overall growth of the market.

#### Appreciation of business partners and investors for exclusive authorisations

The novel food authorisation proves that the product is safe. Partners in the supply chain, particularly huge manufacturers and retailers, are willing to work only by following the conditions of use set by the authorisations. They are thus more likely to collaborate with authorisation holders. Similarly, investors appreciate the exclusive authorisations granted by the data protection system. This is because authorisations grant a certain amount of market power, and in case of extreme violations and consequent legal disputes, exclusive authorisations could be effective instruments in courts.

#### Data protection can be a problem for innovation

Data protection could potentially drive out of the market start-ups and companies unable to obtain authorisations. Exclusive authorisations might directly or indirectly disincentivise the creation or development of smaller companies. The fear of being legally prosecuted likely scares small-scale innovators in the insect sector and so does the duration and difficulty of obtaining their authorisations. If small-scale companies are driven out of the market for not

obtaining their authorisations and only a small amount of larger companies shapes the development of the sector, this might result in a serious loss of innovative ideas. The Novel Food Regulation is already a huge burden for smaller enterprises.<sup>32</sup> A sector heavily controlled by larger corporations through exclusive authorisations could be an insurmountable obstacle

#### Data protection is not ethically acceptable when it comes to insects

The authorisation granted with data protection leads to five years of exclusivity for novel food products obtained from insects, setting precise conditions of use and production rules. Considering how largely insects are consumed worldwide and that they are living organisms, it is debatable whether exclusive authorisations should be granted to novel foods obtained from animals and living organisms. This interpretation follows the argumentation of "No Patents on life!" already seen about genetically modified organisms,<sup>33</sup> and it would be in line with the choice made with "traditional foods from third countries", which cannot receive data protection and whose authorisations are therefore generic.<sup>34</sup>

#### 4.2. Potential future developments

All these considerations seem to categorise insects somewhere in between the second and third scenarios presented above. Some insect companies might enjoy market advantage due to the exclusive authorisations, but several questions on the extent of this advantage remain. First, the feasibility of enforcing the authorisations is debatable: insect products have been on the market for a while in several European countries, and the prosecution of competitors would require a considerable amount of resources. Second, the fact that other companies are allowed to obtain very similar or even the same authorisations might erode the market advantage of the first applicants.

From the perspective of small-scale companies, exclusive authorisations are another obstacle to their development. The fear of being sued and the request for proper authorisations from

<sup>&</sup>lt;sup>32</sup> Holle (n 14).

<sup>&</sup>lt;sup>33</sup> Joseph Mohorčich and Jacy Reese, 'Cell-Cultured Meat: Lessons from GMO Adoption and Resistance' (2019) 143 Appetite 104408.

<sup>&</sup>lt;sup>34</sup> Lucia Scaffardi, 'A Peculiar Category of Novel Foods: Traditional Foods Coming from Third Countries and the Regulatory Issues Involving Sustainability, Food Security, Food Safety, and the Free Circulation of Goods' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 37-58.

partners along the supply chain, mainly retailers and distributors, might drive them out of the market. The innovation process in the insect sector would then be hindered, and so would the growth of the market as a whole. This is particularly bothersome since the promotion of innovation was the main reason behind the creation of the data protection clause.

#### **5.** Conclusion

Insects are a valuable case study to investigate the impact of data protection on the development of specific novel food sectors. In addition to all the reasons listed in the previous section, insects are also fascinating because they are opening the path for alternative proteins in the EU and are likely the most debated novel foods ever by the general public. The controversies over the latest authorisations for crickets and buffalo worms in countries like Italy and Germany are a perfect example of such impact.<sup>35</sup> Neither microalgae nor fungal mycelium or cultured meat are likely to achieve the same market size, number of active companies, and products availability anytime soon.

The long-term role of data protection and exclusive authorisations in the novel food sector cannot yet be predicted with certainty. The case study on the insect sector shows that small-scale companies will likely see data protection and exclusive authorisation as another bureaucratic barrier to their growth. They risk being prosecuted by larger companies and they are not likely to have the resources to obtain their authorisations. On the other hand, larger companies enjoy only limited benefits from exclusive authorisations due to the limited scope and duration of the exclusivity and enforcement difficulties.

Companies are more likely to invest their resources in protecting their technical innovations and technological developments in the production processes through the traditional patent systems instead of focusing on novel food data protection. For industries such as cultured meat, precision fermentation, insect breeding or microalgae cultivation, the technology behind their novel food products will be more valuable to ensure market advantage than exclusive novel foods authorisations. The objective of promoting innovation, the main reason behind the

<sup>&</sup>lt;sup>35</sup> See for example: Solvejg Hoffmann, 'Grillenmehl in Lebensmitteln: EU Erlaubt Beimischung von Insektenpulver' (GEO, 19 January 2023) < https://www.geo.de/wissen/ernaehrung/insekten-in-lebensmitteln-jetztin-der-eu-zugelassen-33115156.html> accessed 19 September 2024 ; Marco Leardi, 'Gli insetti arrivano al Un attacco dieta mediterranea' supermercato. alla (II)Giornale, 24 January 2023) <https://www.ilgiornale.it/news/europa/attacco-dieta-mediterranea-insetti-tavola-ora-sono-commercio-2108431.html> accessed 19 September 2024.

introduction of the data protection clause and exclusive authorisations, does not seem to be adequately pursued by the current NFR.

### Chapter 7

## Design thinking principles in the regulation of novel foods in the European Union and Singapore: A comparison

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#### Abstract

This chapter relies on a comparative analysis of the regulatory frameworks governing novel foods in the European Union (EU) and Singapore, employing design thinking as a theoretical framework and methodological lens. The chapter delves into the authorisation procedures for novel foods in the two jurisdictions to investigate their capacity to encourage innovation. In particular, the research focuses on the instruments adopted to facilitate communication between the authorities (the "designers") and the applicants (the "users") during the authorisation procedure (the "service"). Taking alternative proteins as a focal point, the divergent approaches and regulatory outcomes in the EU and Singapore are discussed. The ultimate objective is to formulate policy recommendations that could enhance the EU framework's perception among innovators and stakeholders, and foster its ability to stimulate innovation within the novel food sector.

#### **1. Introduction**

"Alternative proteins" is an umbrella term that encompasses all products meant to substitute traditional animal proteins and facilitate the transition toward more sustainable and environmentally friendly food systems.<sup>1</sup> Alternative proteins can be produced from plants, animal cells, or fermentation.<sup>2</sup> In some contexts, insects are also classified as alternative proteins due to the lack of significant human consumption.<sup>3</sup>

Alternative proteins are categorised as novel foods in various jurisdictions across the globe.<sup>4</sup> Because of the potential safety risks they may present, novel foods typically necessitate premarket approval before being introduced to the market.<sup>5</sup> While these authorisation procedures

<sup>&</sup>lt;sup>1</sup> Mario Herrero and others, 'Innovation Can Accelerate the Transition towards a Sustainable Food System' (2020) 1 Nature Food 266; Rachel 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.

<sup>&</sup>lt;sup>2</sup> Good Food Institute, 'Defining Alternative Protein' <a href="https://gfi.org/defining-alternative-protein/">https://gfi.org/defining-alternative-protein/</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>3</sup> Andrea M Liceaga and others, 'Insects as an Alternative Protein Source' (2022) 13 Annual Review of Food Science and Technology 19.

<sup>&</sup>lt;sup>4</sup> Jessica Vapnek, Kai Purnhagen and Ben Hillel, 'Regulatory and Legislative Framework for Novel Foods', in Shivani Pathania and Brijesh Tiwari (eds), *Food Formulation* (John Wiley & Sons, Ltd 2021) pp. 285-308.

<sup>&</sup>lt;sup>5</sup> Malsha Samarasiri, Kong Fei Chai and Wei Ning Chen, 'Forward-Looking Risk Assessment Framework for Novel Foods' (2023) 1 Food and Humanity 500.

traditionally focus on consumer safety, this chapter explores the ability of the European Union (EU) and Singapore's regulatory framework to encourage innovation.

In the EU, Regulation (EU) 2015/2283<sup>6</sup> on novel foods (hereinafter "the Novel Food Regulation" or "NFR") regulates the market entry of food products categorised as novel foods. Novel foods are those foods that were not significantly consumed within the Union before the 15<sup>th</sup> of May, 1997.<sup>7</sup> By introducing an authorisation procedure based on risk analysis, the regulation aims to ensure that novel foods do not pose safety risks to human health and consumer interests.<sup>8</sup> Scholars have criticised the NFR due to its broad regulatory capture and the length and cost of the authorisation procedure.<sup>9</sup> Additionally, novel foods, particularly alternative proteins, often encounter a trend of rejection from the general public.<sup>10</sup> As an example, the Italian government recently banned the production and commercialisation of cultivated meat in the country, even though no application for approval has been filed in the EU yet.<sup>11</sup>

The Singapore Food Agency (SFA) considers novel food to be food and food ingredients that do not have a history of safe use.<sup>12</sup> The development of novel foods is considered a key part of the strategy "30 by 30" promoted by Singapore's government, which aims to produce 30% of

<sup>8</sup> ibid. Article 1(2).

<sup>9</sup> Anu Lähteenmäki-Uutela and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336.

<sup>&</sup>lt;sup>6</sup> 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, p. 1–22. Hereinafter referred to as the "NFR".

<sup>&</sup>lt;sup>7</sup> ibid. Article 3(2).

<sup>&</sup>lt;sup>10</sup> Alessandro Monaco and others, 'Consumers' Perception of Novel Foods and the Impact of Heuristics and Biases: A Systematic Review' (2024) 196 Appetite 107285; Elena Faccio and Lucrezia Guiotto Nai Fovino, 'Food Neophobia or Distrust of Novelties? Exploring Consumers' Attitudes toward GMOs, Insects and Cultured Meat' (2019) 9 Applied Sciences 4440; Alexandra E Sexton, Tara Garnett and Jamie Lorimer, 'Framing the Future of Food: The Contested Promises of Alternative Proteins' (2019) 2 Environment and Planning E: Nature and Space 47.

<sup>&</sup>lt;sup>11</sup> Francesco Planchestainer, 'Meat Me in Italy: The Italian Ban on Sounding Names and Cell-Cultured Meat' (2024) 19 European Food and Feed Law Review 66.

<sup>&</sup>lt;sup>12</sup> Singapore Food Agency, 'Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients' (2023) <a href="https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-food-and-novel-food-ingredients.pdf">https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-food-and-novel-food-ingredients.pdf</a>> accessed 19 September 2024. Article 1.1. For the scope of this chapter, I relied on the official translation retrievable from the website of the SFA in January 2024.

the country's nutritional needs domestically by 2030.<sup>13</sup> The SFA, similarly to the EU, requires a pre-market authorisation procedure for novel foods.<sup>14</sup> The authorisation procedure in Singapore is based on a case-by-case approach, where regulators collaborate with applicants to ensure a favourable outcome of the process.<sup>15</sup> Singapore is often described by stakeholders as the frontrunner in the regulation of food innovations, due to its early approvals of cultivated meat products, and has been praised as an innovation-friendly regulatory environment.<sup>16</sup>

When considering the similarities and differences between the EU and Singapore, one has to consider that the EU is a supranational union comprising 27 Member States, 448 million citizens and a Gross Domestic Product (GDP) of 15.9 trillion euros,<sup>17</sup> while Singapore is a city-state with less than 6 million citizens and a GDP of circa 599 billion dollars.<sup>18</sup> Nevertheless, the distinct achievements and experiences of Singapore can be employed to formulate recommendations for enhancing the ability of the EU framework to regulate novel foods and to improve the perception of stakeholders involved in the authorisation procedure.

The purpose of this chapter is to compare the regulatory approaches of the EU and Singapore towards novel foods, to ultimately provide policy suggestions on how to improve the EU framework's ability to encourage innovation in the novel food sector. To do so, the chapter uses design thinking as a theoretical framework and methodological lens to examine the authorisation procedures for novel foods in the two jurisdictions, with the aim to explain the

<sup>15</sup> Flora Southey, 'Dissecting Cultivated Meat Regulation Part 2: What's Working in the US and Singapore, and What's Not?' (*Food Navigator*, 16 February 2023)

<a href="https://www.foodnavigator.com/Article/2023/02/16/dissecting-cultivated-meat-regulation-part-2-what-s-working-in-the-us-and-singapore-and-what-s-not">https://www.foodnavigator.com/Article/2023/02/16/dissecting-cultivated-meat-regulation-part-2-what-s-working-in-the-us-and-singapore-and-what-s-not</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>13</sup> Singapore Food Agency, '30 by 30 -Strengthening Our Food Security' (2020) <a href="https://www.ourfoodfuture.gov.sg/30by30/">https://www.ourfoodfuture.gov.sg/30by30/</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>14</sup> Singapore Food Agency (n 12). Article 3(1).

<sup>&</sup>lt;sup>16</sup> Shabana Begum, 'More Companies Entering the Novel Food Space Offering Alternative Protein' (*The Straits Times*, 26 April 2021) <a href="https://www.straitstimes.com/singapore/environment/more-companies-entering-the-novel-food-space">https://www.straitstimes.com/singapore/environment/more-companies-entering-the-novel-food-space</a> accessed 19 September 2024; The Economist, 'Singapore Is the World Leader in Selling Cultivated Meat' (*The Economist*, 20 July 2023) <a href="https://www.economist.com/asia/2023/07/20/singapore-is-the-world-leader-in-selling-cultivated-meat">https://www.economist.com/asia/2023/07/20/singapore-is-the-world-leader-in-selling-cultivated-meat</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>17</sup> Statista, 'Gross Domestic Product of the European Union from 2011 to 2022' (*Statista*, 2023) <https://www.statista.com/statistics/279447/gross-domestic-product-gdp-in-the-european-union-eu/#:~:text=In%202022%20the%20gross%20domestic,economic%20strength%20of%20a%20country> accessed 19 September 2024.

<sup>&</sup>lt;sup>18</sup> World Economics, 'Singapore's Gross Domestic Product (GDP)' (2023) <a href="https://www.worldeconomics.com/Country-Size/Singapore.aspx">https://www.worldeconomics.com/Country-Size/Singapore.aspx</a> accessed 19 September 2024.

differences between the EU and Singapore in their approach toward innovation and in their regulatory achievements.

In the following sections, I first introduce the methodology applied throughout the chapter and the principles of design thinking. I then clarify the scope of the EU Novel Food Regulation and Singapore's regulatory framework. Afterwards, I examine the differences between the EU and Singapore's authorisation procedures in light of design thinking theory, to highlight the extent to which design principles are directly or indirectly reflected. Finally, I elaborate on which lessons can be learned from the comparison of the two systems and their regulatory results in the field of alternative proteins and formulate policy suggestions for improving the EU framework's perception among stakeholders and its ability to encourage innovation.

#### 2. Theoretical framework and methodology

#### 2.1. Design thinking theory

Design thinking is a solution-focused method derived from design theory, whose starting points are the users' implicit and explicit needs.<sup>19</sup> Design thinking stresses the importance of communication between the designers of a product or a service and the final users. Applying design thinking principles, designers elaborate on the needs, experiences, and viewpoints that future users have and identify which problems are to be solved, favouring the creation of solutions to be tested under real-life conditions, collecting feedback and repeating the cycle until the optimal result is achieved.<sup>20</sup>

Design thinking is commonly represented as based on five steps.<sup>21</sup> First, designers must understand the real needs of the future users of their products and services (**empathise**).<sup>22</sup> Then,

<sup>&</sup>lt;sup>19</sup> Pietro Micheli and others, 'Doing Design Thinking: Conceptual Review, Synthesis, and Research Agenda' (2019) 36 Journal of Product Innovation Management 124.

<sup>&</sup>lt;sup>20</sup> Julia von Thienen, Christoph Meinel and Claudia Nicolai, 'How Design Thinking Tools Help To Solve Wicked Problems' in Larry Leifer, Hasso Plattner and Christoph Meinel (eds), *Design Thinking Research: Building Innovation Eco-Systems* (Springer International Publishing, 2014) pp. 97-102.

<sup>&</sup>lt;sup>21</sup> Walter Brenner, Falk Uebernickel and Thomas Abrell, 'Design Thinking as Mindset, Process, and Toolbox' in Walter Brenner and Falk Uebernickel (eds), *Design Thinking for Innovation: Research and Practice* (Springer International Publishing, 2016) pp. 3-21.

<sup>&</sup>lt;sup>22</sup> Eva Köppen and Christoph Meinel, 'Empathy via Design Thinking: Creation of Sense and Knowledge' in Hasso Plattner, Christoph Meinel and Larry Leifer (eds), *Design Thinking Research: Understanding Innovation* (Springer International Publishing, 2015) pp. 15-28.

designers have to identify which objectives are to be achieved and which problems have to be solved, avoiding a too-narrow or too-broad focus (**define the problem**). Afterward, designers work on how to achieve the defined goals, considering all potential options (**ideate**). Once a number of feasible options are identified, prototypes are created to assess on a pilot scale which ones are more promising (**prototype**). Finally, the remaining prototypes are presented to reallife users, who are required to assess their functionality and give feedback. The process then goes back to the ideation phase to incorporate such feedback (**test**), until the optimal outcome is achieved.

#### 2.2. Design thinking as a lens to analyse regulation

The use of principles derived from design thinking theory has been proposed to regulate disruptive innovations.<sup>23</sup> Adopting this perspective, the authorisation procedures for novel foods are to be regarded as a legal service directed to "users", mainly innovative companies seeking approval for their products, which ensures that consumer health and interests are protected. The "designers" are the regulators that define the principles of the authorisation procedures for novel foods, and the regulatory agencies determining the necessary scientific requirements for the risk assessment.<sup>24</sup>

The use of design thinking principles in the authorisation procedures for novel foods might offer effective instruments to tackle the traditional challenges of safety and trust associated with novel foods, while considering the needs of innovators.<sup>25</sup> Engagement between authorities and innovators affected by the regulation can help define the legislation's scope, identify critical issues and determine which aspects are more problematic.<sup>26</sup> This would reduce the regulatory burden on the innovators, cutting down costs for both businesses and public authorities and

<sup>&</sup>lt;sup>23</sup> Alice Armitage, Andrew Cordova and Rebecca Siegel, 'Design Thinking: The Answer to the Impasse Between Innovation and Regulation' (2017) 2 Georgetown Law Technology Review 3.

<sup>&</sup>lt;sup>24</sup> ibid.

<sup>&</sup>lt;sup>25</sup> Nikolas Martelaro and others, 'The Personal Trait Myth: A Comparative Analysis of the Innovation Impact of Design Thinking Tools and Personal Traits' in Hasso Plattner, Christoph Meinel and Larry Leifer (eds), *Design Thinking Research: Building Innovators* (Springer International Publishing, 2015) pp. 41-57.

<sup>&</sup>lt;sup>26</sup> Brahim Benichou Vranckaert Thomas Gils, Koen, 'Design Thinking in the Legislative Process: The Key to Useable Legislation?' (*CITIP blog*, 2021) <a href="https://www.law.kuleuven.be/citip/blog/design-thinking-in-the-legislative-process/">https://www.law.kuleuven.be/citip/blog/design-thinking-in-the-legislative-process/</a> accessed 19 September 2024.

facilitating the adoption of innovation.<sup>27</sup> Social trust among all stakeholders would also increase.<sup>28</sup>

Adopting design thinking as a methodology to examine the differences between Singapore and the EU, I consider whether the two authorisation procedures for novel foods stipulate provisions on: communication and consultation between authorities and stakeholders (empathise); objectives to be achieved and obstacles deemed to be critical during the authorisation procedure (define the problem); instruments and tools available to overcome such obstacles during the authorisation procedures (ideate, prototype); how easily such requirements and strategies can be amended when needed (test). The incorporation of design thinking principles is then used to explain differences in the regulatory achievements and the stakeholder perception in the two jurisdictions.

#### 3. The novel food regulatory frameworks in the EU and Singapore

#### 3.1. The authorisation procedure for novel foods in the EU

Novel foods are foods not consumed to a significant degree within the Union before the 15<sup>th</sup> of May, 1997 and that fall under one of the ten novel food categories.<sup>29</sup> Due to their novelty and lack of history of consumption in the EU, novel foods are considered potentially risky and are subject to an authorisation procedure. The authorisation procedure aims to ensure that the following criteria are respected: the novel food does not pose a risk to human health, and, when the novel food is intended to replace another food, its consumption would not be disadvantageous and misleading for the consumers.<sup>30</sup> It is up to food business operators to determine the novel food status of their products.<sup>31</sup>

<sup>&</sup>lt;sup>27</sup> Allan Lind and Christiane Arndt, 'Perceived Fairness and Regulatory Policy: A Behavioural Science Perspective on Government-Citizen Interactions' (OECD Publishing, 2016) <a href="https://www.oecdilibrary.org/governance/perceived-fairness-and-regulatory-policy\_1629d397-en">https://www.oecdilibrary.org/governance/perceived-fairness-and-regulatory-policy\_1629d397-en</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>28</sup> OECD, *Better Regulation Practices across the European Union* (OECD Publishing, 2019) < https://doi.org/10.1787/9789264311732-en > accessed 19 September 2024.

<sup>&</sup>lt;sup>29</sup> NFR (n 6). Article 3(2).

<sup>&</sup>lt;sup>30</sup> ibid. Article 7.

<sup>&</sup>lt;sup>31</sup> ibid. Article 8.

Applicants willing to place a novel food on the market must submit a dossier including the name and description of the novel food, its detailed composition, scientific evidence demonstrating the safety of the novel food, and appropriate analysis and detection methods.<sup>32</sup> The authorisation procedure is based on risk analysis, and it is divided into a risk assessment phase and a risk management phase. Throughout the procedure, authorities maintain a high level of communication with the public and the involved stakeholders.

The risk assessment conducted by the European Food Safety Authority (EFSA) aims to assess that the novel food is safe, its composition does not pose safety risks to human health, and that the novel food does not differ from the non-novel foods that it intends to replace in a way that its normal consumption would be a disadvantage for consumers.<sup>33</sup> Once the opinion of the EFSA has been published, the European Commission prepares a draft implementing regulation, where the regulatory requirements applicable to the novel food are specified. The proposed measures take into consideration the outcomes of the risk assessment, the precautionary principle and other legitimate factors. The proposal is then voted by Member States' representatives.<sup>34</sup>

The authorisation is in principle generic unless the applicant invokes the application of the data protection clause, which, in case the applicant presented proprietary scientific studies deemed necessary for the good outcome of the application, grants the applicant a five years-exclusivity for placing the product on the market.<sup>35</sup> Other applicants can still obtain a very similar, or even the same authorisation by providing their own scientific data.<sup>36</sup>

Overall, the novel food authorisation procedure is supposed to last for eighteen months, of which nine months are required for the risk assessment, but in practice, the overall time needed

<sup>&</sup>lt;sup>32</sup> ibid. Article 10(2).

<sup>&</sup>lt;sup>33</sup> ibid. Article 11.

<sup>&</sup>lt;sup>34</sup> ibid. Article 12. A positive vote requires a qualified majority voting as specified in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

<sup>&</sup>lt;sup>35</sup> ibid. Article 26.

<sup>&</sup>lt;sup>36</sup> ibid. Article 27(1)(d).
can be much longer, since the EFSA is allowed to "stop the clock" every time new information is requested to the applicant.<sup>37</sup>

### 3.2. The authorisation procedure for novel foods in Singapore

The SFA considers novel foods to be foods and food ingredients that do not have a history of safe use. This means that they do not have at least 20 years of regular consumption without adverse effects on health by a significant human population in any part of the globe.<sup>38</sup> Companies are responsible for determining the novel food status of their products,<sup>39</sup> and must obtain pre-market approval before placing a novel food on the market.<sup>40</sup>

When applying for the authorisation, the applicants should provide the following information: data on the identity and source of the novel food and on its expected purity, information on the tests conducted, background information on the safety and purity of all inputs used for novel food production and on any potential metabolite, any safety assessment reports conducted in other jurisdiction, the proposed use levels and anticipated intake amounts, data showing the absence of toxicity, and information on allergenicity.<sup>41</sup> Differently than in the EU, genetic modifications can be used to produce a novel food.<sup>42</sup> Despite the general scope of the regulatory framework, in the "Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients", additional guidance and checklists for alternative proteins obtained through biomass and precision fermentation, and cell-tissue cultivation are included.<sup>43</sup>

Once the application is received, the SFA Novel Food Safety Expert Working Group reviews the evidence and eventually approves or rejects the novel food. This approach differs from the EU, as the final decision is taken by the SFA, which is a governmental agency and not an elected

<sup>&</sup>lt;sup>37</sup> ibid. Article 11(4).

<sup>&</sup>lt;sup>38</sup> Singapore Food Agency (n 12). Article 1(1). The category also covers compounds chemically identical to naturally occurring substances.

<sup>&</sup>lt;sup>39</sup> ibid. Article 1(3).

 $<sup>^{40}</sup>$  ibid. Article 3(1).

<sup>&</sup>lt;sup>41</sup> ibid. Article 3(6).

<sup>&</sup>lt;sup>42</sup> ibid. Article 3(10).

<sup>&</sup>lt;sup>43</sup> ibid. Chapter 4.

body.<sup>44</sup> The procedure is free from costs and is expected to last from nine to twelve months after the required data is submitted.<sup>45</sup> SFA approvals are always applicant-specific.<sup>46</sup> The SFA does not publish the details of the scientific evaluation nor the details of the applications.<sup>47</sup>

# **4.** Design thinking principles in the authorisation procedures for novel foods in the EU and Singapore

### Empathise

The first step of design thinking requires the achievement of an optimal knowledge of the user needs. The first task of the competent authorities would then be to explore the applicant's perspective and foster communication regarding the objectives to achieve through the authorisation procedures. The way of engaging with stakeholders is one of the major differences between the EU and Singapore. The EFSA and EU authorities adopted a collective and general strategy, while the SFA tends towards an individual, case-by-case approach.

The EFSA provides scientific advice and technical support to EU institutions and member states, and it is the agency responsible for conducting the risk assessment during the authorisation procedure for novel foods.<sup>48</sup> The EFSA deals with the scientific aspects of the authorisation procedure for novel foods but does not take part in the final decisions over authorisations. When the EFSA receives the mandate to deal with a specific topic, for example which aspects should be included in the applications concerning a specific category of novel foods, the EFSA organises symposiums where companies, associations, competent authorities from member states, and academic experts can present their views and opinions on the topic. Following these consultation processes, guidelines on how the risk assessments of these products and processes will be conducted are published. These guidelines can be general, like

<sup>&</sup>lt;sup>44</sup> Singapore Food Agency, 'What We Do' <a href="https://www.sfa.gov.sg/about-sfa/what-we-do">https://www.sfa.gov.sg/about-sfa/what-we-do</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>45</sup> Singapore Food Agency (n 12). Article 8(6).

<sup>&</sup>lt;sup>46</sup> ibid. Article 9(3).

<sup>&</sup>lt;sup>47</sup> ibid. Article 9(4).

<sup>&</sup>lt;sup>48</sup> 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. Hereinafter referred to as "GFL". Article 22.

the "Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283"<sup>49</sup> or more specific, as the "Guidelines on the allergenicity assessment of insect proteins".<sup>50</sup> The EFSA would then organise public webinars to clarify the content of the guidelines.

Concerning the communication with single applicants, following the adoption of Regulation (EU) No 1381/2019<sup>51</sup> on the transparency and sustainability of the EU risk assessment in the food chain (the "Transparency Regulation"), applicable as of 27 March 2021, the EFSA cannot discuss in advance the specifics of applications or comment on the study design proposed by applicants but only answer questions on the published guidelines and provide advice that is transposable to all potential applicants.<sup>52</sup> Applicants are also required to notify in advance each study included in the application before conducting them.<sup>53</sup>

On the contrary, the SFA encourages early engagement of applicants and pre-submission consultation, to discuss the design of studies to be included in the application.<sup>54</sup> Through this case-by-case approach, the SFA and the applicants define which data are required for the safety assessments,<sup>55</sup> and applicants provide parts of their safety assessment dossier in phases,<sup>56</sup> to avoid delays in the approval.<sup>57</sup>

<sup>&</sup>lt;sup>49</sup> European Food Safety Authority, 'Administrative Guidance for the Preparation of Applications on Novel Foods Pursuant to Article 10 of Regulation (EU) 2015/2283' (2021) 18 EFSA Supporting Publications e6488.

<sup>&</sup>lt;sup>50</sup> Biase Liguori and others, 'Novel Foods: Allergenicity Assessment of Insect Proteins' (2022) 20 EFSA Journal e200910.

<sup>&</sup>lt;sup>51</sup> 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, PE/41/2019/REV/1, OJ L 231, 6.9.2019, p. 1–28.

<sup>&</sup>lt;sup>52</sup> GFL (n 48). Article 6(2).

<sup>&</sup>lt;sup>53</sup> ibid. Article 32b.

<sup>&</sup>lt;sup>54</sup> Singapore Food Agency (n 12). Article 3(6).

<sup>55</sup> ibid.

<sup>&</sup>lt;sup>56</sup> ibid. Annex A: FAQs for Novel Food Companies, Q1.5.

<sup>&</sup>lt;sup>57</sup> ibid. Article 8(6).

As additional support, the SFA organises an online bimonthly Novel Foods Virtual Clinic, where businesses can participate and exchange views.<sup>58</sup> Companies can also contact the SFA directly or engage with the Future Ready Food Safety Hub (FRESH), a joint initiative of the SFA, the Nanyang Technological University and the Agency for Science Technology and Research. Through FRESH, companies receive regulatory consultancy in order to define the regulatory roadmap, review the company's safety data on the novel food, and even receive a pre-submission risk assessment on the novel food to structure the dossier according to the SFA guidelines.<sup>59</sup>

#### Define the problems

The design process continues with the determination of the objectives to achieve and, through continuous communication with the stakeholders, the identification of the obstacles to overcome during the procedure.

The main objective of the EU and Singapore's framework is to ensure that novel foods are safe for human consumption. In EU primary law, the NFR has its legal basis in Article 114 of the Treaty on the Functioning of the European Union<sup>60</sup> and explicitly recognises the functioning of the internal market as its main objective together with the provision of a high level of protection of human health and consumer interests.<sup>61</sup> Likewise, the main objective of the SFA is ensuring that food on the market is safe.<sup>62</sup> The two frameworks differ in the way they consider transparency and the promotion of innovation.

Transparency towards the public in the form of risk communication throughout the procedure is a cornerstone of the EU framework and one of the key principles of EU food law.<sup>63</sup> Citizens and stakeholders must have the opportunity to access relevant information on the authorised

<sup>&</sup>lt;sup>58</sup> ibid. Article 11(1).

<sup>&</sup>lt;sup>59</sup> ibid. Articles 11(2) and 11(3).

<sup>&</sup>lt;sup>60</sup> Consolidated version of the Treaty on the Functioning of the European Union, OJ C 202, 7.6.2016, p. 1–388.

<sup>&</sup>lt;sup>61</sup> NFR (n 6). Article 1(2).

<sup>&</sup>lt;sup>62</sup> Singapore Food Agency, 'Vision, Mission and Values' <a href="https://www.sfa.gov.sg/about-sfa/who-we-are-accessed 19">https://www.sfa.gov.sg/about-sfa/who-we-are-accessed 19</a> September 2024.

<sup>&</sup>lt;sup>63</sup> GFL (n 48). Article 8a. Recital 2 of the NFR, also recognize the need to ensure transparency during the authorisation procedure.

products and receive access to the specifics of the authorisations, with the objective of increasing the legitimacy of the process. In Singapore, transparency throughout the process is not as important and is not addressed in the novel food framework. The SFA does not advertise the approvals or publish the details of the submitted applications.<sup>64</sup>

The promotion of innovation is not listed among the objectives of the NFR. The importance of new technologies and innovation is underlined in Recital 29 of the NFR, as they could "*reduce the environmental impact of food production, enhance food security and bring benefits to consumers*".<sup>65</sup> Thus, the promotion of innovation can, at best, be considered an implicit objective of the legislation.<sup>66</sup> In Singapore, innovation in the novel food sector is seen as a critical instrument to achieve the goals of the "30 by 30" strategy. Singapore explicitly considers the development of novel foods as a key component of the larger national strategy to reduce imports of foods from neighbouring countries and ensure future food security.<sup>67</sup> Promotion of innovation is thus a key objective of the framework alongside food safety.

To achieve the stated objectives, the problems to be solved can be defined as follows: the production of the scientific data required to ensure that the novel foods are safe; in the EU, the development of tools to communicate the results of the scientific assessments of the applications and the specifics of the authorisations; in both the EU and Singapore, but mainly in the latter, the creation of procedures that do not negatively affect the willingness of the applicants to engage with novel foods development and incentive them to seek approval in the jurisdiction.

### Ideate and Prototype

The ideate phase of the design thinking process focuses on finding the best solutions to achieve the defined objectives, while the prototype phase calls for their early implementation. For the

<sup>&</sup>lt;sup>64</sup> Singapore Food Agency (n 12). Sub-chapter 9(4).

<sup>&</sup>lt;sup>65</sup> While non-binding, recitals can help to interpret the respective articles of the legislative act, for example clarifying their nature or scope. For further reference, see Todas Klimas and Jurate Vaiciukaite, 'The Law of Recitals in European Community Legislation' (2008) 15 ILSA Journal of International & Comparative Law 61.

<sup>&</sup>lt;sup>66</sup> Alessandro Monaco and Kai 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 219.

<sup>&</sup>lt;sup>67</sup> Hallam Stevens and Yvonne Ruperti, 'Smart Food: Novel Foods, Food Security, and the Smart Nation in Singapore' (2023) 27 Food, Culture & Society 754.

scope of this research, I am addressing these steps simultaneously as the frameworks have already been established and applied.

Both the Singapore and EU frameworks present applicants with similar challenges in their authorisation procedures. These challenges include the production of data that prove the safety of novel foods, as well as the lengthy, uncertain, and costly nature of the process, which can discourage innovators.

To overcome the technical difficulties in the dossier preparation, the EU and Singapore's frameworks clarify which data must be presented and how these data must be produced. To ensure that companies can overcome the length and costs of the procedure, or at least can be compensated for it, the two frameworks establish ways to communicate with the applicants and to reward and facilitate the job of innovators before, during, and after the authorisation procedures.

### a. Food safety, communication and transparency

Both the EFSA and the SFA rely on authorisation procedures where they assess the data presented by the applicants. Neither the EFSA nor the SFA engage in active research on their own. The two authorities publish general and product-specific guidelines on how the data should be produced and presented.

Where the two approaches differ is in the opportunity to discuss the details of the submissions and how the dossier is evaluated. While the EFSA cannot engage in individual consultations, the SFA stresses the need for dialogue on a case-by-case basis with companies and encourages them to communicate from the early stages of development. The EFSA reviews the application only when all required documents are submitted and asks for clarifications when needed, but only after the procedure has started. On the other hand, the SFA is open to receiving the dossier in phases to avoid delays, following the "Do-It-Right-the-First-Time" principle.<sup>68</sup>

When dealing with foods commonly consumed elsewhere but not in the country, the EU and Singapore also have different approaches, reflected in the novel food definition. In the EU, the definition of novel food is euro-centric and requires authorisation for all novel foods consumed in third countries. To facilitate the approval of traditional foods from other countries, the EU

<sup>&</sup>lt;sup>68</sup> Singapore Food Agency (n 12). Annex A: FAQs for Novel Food Companies, Q1.5.

introduced a notification procedure for foods with a history of safe use in third countries, but the procedure still lasts at least five to ten months.<sup>69</sup> In Singapore, there is no distinction between safe consumption in the country or abroad, as long as a history of safe use can be demonstrated.

To ensure transparency throughout the procedure, the EU publishes the summaries of applications, the scientific opinions of the EFSA and the details of each authorisation in the form of implementing regulations that update the Union List of Novel Foods. In Singapore, there are no official lists of applications or summaries of the scientific aspects of the applications. The SFA does not communicate when authorisations are granted.<sup>70</sup> Companies willing to communicate they received approvals for their products are encouraged to contact the SFA and release a joint statement.

b. Rewarding and incentivising innovation

The main difference between the two frameworks is the amount of support and incentives that the SFA and the Singapore government offer to companies willing to apply for authorisation in the country. In addition to the regulatory support provided through initiatives like FRESH, the SFA offers connections to facilities such as labs and pilot-scale plants.<sup>71</sup> Technical support can be found at the Centre for Remote Imaging Sensing and Processing of the National University of Singapore, a research centre dedicated to supporting companies active in the alternative proteins sector.<sup>72</sup> Enterprise Singapore and the Economic Development Board provide start-ups with advice and support mechanisms.<sup>73</sup> Some of these initiatives are only partially related to the authorisation procedure but attract companies and innovators by offering them support in the first vital stages of development. The direct reference to these initiatives in the Annex of the "Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients" proves Singapore's holistic strategy on novel foods and alternative proteins.

<sup>&</sup>lt;sup>69</sup> NFR (n 6). Section II.

<sup>&</sup>lt;sup>70</sup> Singapore Food Agency (n 12). Annex A: FAQs for Novel Food Companies, Q4.2.

<sup>&</sup>lt;sup>71</sup> ibid. Annex A: FAQs for Novel Food Companies, Q8.4.

<sup>&</sup>lt;sup>72</sup> ibid. Annex A: FAQs for Novel Food Companies, Q8.3.

<sup>&</sup>lt;sup>73</sup> ibid. Annex A: FAQs for Novel Food Companies, Q8.1.

In contrast, the EU framework and the NFR provide little or no incentive for companies to work with novel foods and seek approval in the EU. The data protection clause is the only reward mechanism for compensating the costs of going through the authorisation procedure. However, the real impact of the data protection is debatable since the five-year length is limited compared with other systems of protection of intellectual property since other applicants can potentially obtain the same or a very similar authorisation by producing their own proprietary data.<sup>74</sup> The data protection clause might even reduce the willingness of companies to engage in the procedure before their competitors.<sup>75</sup> In Singapore, every authorisation is applicant-specific, without time limits, and companies working with similar products have to obtain a distinct authorisation.<sup>76</sup>

Test

According to design thinking principles, the service offered should be regularly updated based on the users' feedback. This is particularly true when considering regulations and scientific guidelines that apply to innovations like novel foods.

The EU framework applicable to novel foods has been reformed only once since its first introduction in 1997. The Novel Food Regulation adopted in 2015 explicitly refers to the need to review, clarify and update the procedure on the basis of scientific and technological developments,<sup>77</sup> but some provisions have been criticised for being already outdated at their adoption.<sup>78</sup> Regarding the scientific requirements for the authorisation procedure, the EFSA is in charge of publishing and regularly updating guidelines on how dossiers for novel food

<sup>&</sup>lt;sup>74</sup> NFR (n 6). Article 26.

<sup>&</sup>lt;sup>75</sup> Alessandro Monaco, 'Data Protection Under the Novel Food Regulation: Valuable Instrument or Barrier to Innovation? Insights from the Insect Sector' (2023) 18 European Food and Feed Law Review 172.

<sup>&</sup>lt;sup>76</sup> Singapore Food Agency (n 12). Article 9(3).

<sup>&</sup>lt;sup>77</sup> NFR (n 6). Recital 8.

<sup>&</sup>lt;sup>78</sup> Martin Holle, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), Regulating and Managing Food Safety in the EU (Springer International Publishing, 2018) pp. 291-330.

approvals should be organised and submitted. Normally, the review happens every three years.<sup>79</sup>

In Singapore, the novel food framework was adopted in 2019. Since then, the "Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients" have been updated six times until July 2023,<sup>80</sup> according to the feedback collected from early applicants.

### 5. Discussion

# **5.1. Regulatory achievements in the EU and Singapore: the case study of alternative proteins**

Both the European Union (EU) and Singapore feature a distinct framework dedicated to novel foods. Looking at the two definitions of novel food, the differences are the geographical delimitation specified in the EU definition (consumption "*within the Union*") and the different approach to the time condition: "*consumption by a significant human population for at least 20 years*" in Singapore, and "*before 15 May 1997*" in the EU. Both frameworks require pre-market approval for novel foods based on the scientific assessment of data presented by applicants. However, while the EU framework involves the EFSA and the political institutions, dividing the scientific risk assessment from the final decision over the authorisations, Singapore adopts an agency-based system, where the SFA assesses and eventually authorises novel foods. The SFA'ghbhs more comprehensive role is also why regulatory provisions can be changed more easily in Singapore than in the EU. Food safety and consumer protection are the key objectives of the two frameworks, with Singapore's having a stronger focus on the role of innovation for boosting food security and the EU emphasising the need for transparency throughout the process.

In the EU and Singapore, novel foods are a wide and heterogeneous group of products. Despite similarities in the definitions, drawing a comparison between the regulatory accomplishments of the two jurisdictions is a challenging task. Alternative proteins, defined as all products meant

<sup>&</sup>lt;sup>79</sup> EFSA Scientific Committee, 'Guidance on the Review, Revision and Development of EFSA's Cross-Cutting Guidance Documents' (2015) 13 EFSA Journal e4080.

<sup>&</sup>lt;sup>80</sup> Singapore Food Agency (n 12). Article 13.

to substitute traditional animal proteins,<sup>81</sup> stand out as the most widely recognised sub-group within novel foods, given their potential to influence traditional diets and contribute positively to the shift towards sustainable food systems.<sup>82</sup> As the most uniform category of novel foods, alternative proteins emerge as the appropriate category to use as a benchmark for comparison.

Since 2018, the year of entry into force of the Novel Food Regulation, forty-two applications concerning alternative proteins have been submitted for approval under the NFR.<sup>83</sup> The number of applications and approved alternative proteins has been determined by considering whole foods and food ingredients that fall under the novel food regulation, and are meant to substitute traditional animal proteins in the food categories "meat", "milk" and "dairy analogues".<sup>84</sup> At the moment of writing, ten alternative protein products have been included in the Union List for Novel Foods. Six concern insects, three plants, and one a mycelium fermented substrate.<sup>85</sup> In September 2024, the EFSA implemented specific guidelines for the risk assessment for products of precision fermentation and cell tissue cultivation.<sup>86</sup> To date, no applications concerning cultivated meat products, defined as animal tissues grown under laboratory conditions, or dairy proteins produced via precision fermentation have been submitted.<sup>87</sup>

<sup>84</sup> Isolates to be used exclusively in food supplements were not considered.

<sup>&</sup>lt;sup>81</sup> Good Food Institute (n 2).

<sup>&</sup>lt;sup>82</sup> Sexton, Garnett and Lorimer (n 10).

<sup>&</sup>lt;sup>83</sup> At the moment of writing thirty-six applications concerning alternative proteins are available in the "Summary of applications and notifications" on the website of the European Commission. However, by examining the list of terminated procedures, nine concerned novel alternative proteins. For six of them, it was not possible to find the related application in the "Summary of Applications and Notifications". Considering the additional six, the total number of applications is deemed to be at least forty-two.

<sup>&</sup>lt;sup>85</sup> Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, C/2017/8878, OJ L 351, 30.12.2017, p. 72–201. As of May 2024, the approved novel foods are: *Acheta domesticus* (house cricket) partially defatted powder, Pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia, Frozen, dried and powder forms of *Acheta domesticus* (house cricket), Frozen, dried and powder forms of *Locusta migratoria* (migratory locust), Frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva), Partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L., Mung bean (*Vigna radiata*) protein, Dried *Tenebrio molitor* Larva (yellow mealworm).

<sup>&</sup>lt;sup>86</sup> EFSA Panel on Nutrition, Novel Foods and Food Allergens and others, 'Guidance on the Scientific Requirements for an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283' (2024) 22 EFSA Journal e8961.

<sup>&</sup>lt;sup>87</sup> Commission Implementing Regulation (EU) 2017/2470 (n 85). Five products of cell culture from plant cells have been authorized as novel foods, all of which are used in food supplements, while eight novel food ingredients produced via precision fermentation have been approved and included in the Union List of Authorized Novel Foods. The company Gourmey has announced the first submission for a cultivated meat product, a cultivated foie 186

Currently, Singapore does not systematically communicate when applications are received and authorisations are granted.<sup>88</sup> This makes the collection of certain data difficult. According to the public statements of companies, Singapore has already given the green light to products of precision<sup>89</sup> and biomass<sup>90</sup> fermentation, one cultivated meat product in 2020,<sup>91</sup> the use of a serum-free medium growth for cell cultivation in 2022.<sup>92</sup> In addition, sixteen species of insects are approved for consumption, because they are traditionally consumed in other countries.<sup>93</sup>

# **5.2.** Different perceptions among innovators: design thinking principles in the authorisation procedures

Although there may not be a significant difference in actual accomplishments, stakeholders tend to view Singapore more positively, due to its approach towards innovation.<sup>94</sup> Singapore has successfully established itself as a trailblazer in food innovations, with a particular emphasis on alternative proteins.<sup>95</sup> The ambitious "30 by 30" strategy promoted by Singapore's government, which aims to produce domestically 30% of the country's nutritional needs by

<sup>91</sup> Southey (n 15). One other approval for the Australian company Vow followed in 2024.

gras, in July 2024. As of October 2024, no official summary or official documents concerning the application are publicly available.

<sup>&</sup>lt;sup>88</sup> Singapore Food Agency (n 12). Article 9(4).

<sup>&</sup>lt;sup>89</sup> Remilk, 'Remilk Racking up Regulatory Approvals' (*Press release*, 23 February 2023) <a href="https://www.prnewswire.com/news-releases/remilk-racking-up-regulatory-approvals-301753694.html">https://www.prnewswire.com/news-releases/remilk-racking-up-regulatory-approvals-301753694.html</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>90</sup> Solar Foods 'Solar Foods Receives Novel Food Regulatory Approval for a Protein Grown with CO2 and Electricity' (*Press Release*, 26 October 2022) <a href="https://solarfoods.com/solar-foods-receives-novel-food-regulatory-approval/">https://solarfoods.com/solar-foods-receives-novel-food-regulatory-approval/</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>92</sup> ibid. Despite not being a novel food per se, the medium growth is a key component in the production of cultivated meat and will be a key component for any future authorization of novel foods in the EU. For this reason, it was included in this list.

<sup>&</sup>lt;sup>93</sup> Singapore Food Agency, 'Factsheet on Insect Regulatory Framework' (2023) <https://www.sfa.gov.sg/docs/default-source/default-document-library/sfa-insect-regulatory-frameworkfactsheet.pdf> accessed 19 September 2024. The insect species listed in the factsheet have been allowed into the market because of their history of consumption in other countries.

<sup>&</sup>lt;sup>94</sup> Arthur Neslen, 'Europe Lags behind in Lab-Grown Meat Race' (*Politico*, 27 December 2020) <https://www.politico.eu/article/as-cultured-nuggets-go-on-sale-in-singapore-industry-fears-that-eu-will-chicken-out-of-global-tech-race/> accessed 19 September 2024.

<sup>&</sup>lt;sup>95</sup> Suyu Khor, 'How Novel Foods Are Bolstering Singapore's Food Security' (*GovInsider*, 14 April 2023) <a href="https://govinsider.asia/intl-en/article/how-novel-foods-are-bolstering-singapores-food-security">https://govinsider.asia/intl-en/article/how-novel-foods-are-bolstering-singapores-food-security</a> accessed 19 September 2024

2030,<sup>96</sup> explains the country's efforts to position as a regulatory hub for novel foods, particularly for breakthrough innovations like cultivated meat. By positioning itself as an innovation-friendly regulator, Singapore aims to attract the attention of innovators worldwide, offering them regulatory clarity, resources, and support. The streamlined authorisation process allows companies to showcase initial results to investors and the public, paving the way for expansion into other jurisdictions. In return, Singapore gains a "first mover advantage", potentially reaping benefits that other regions may wait years to realise, fostering expertise within the SFA and leading the effort towards the harmonisation of international regulation of novel foods.

The EU, despite the general commitment to the transition towards sustainable food systems of the European Green Deal,<sup>97</sup> has not demonstrated a comparable level of interest and support for novel foods. This is especially notable in the case of alternative proteins, often perceived as a potential threat to the traditional food industry and food culture.<sup>98</sup> Despite the efforts to ensure transparency on the specifics of the authorisation, the general public acceptance of novel foods remains low.<sup>99</sup>

The comparative analysis of the two authorisation procedures using design thinking as a methodological lens explains why innovators prefer Singapore's approach. In line with the principles set in design thinking, the SFA adopts an individual communication approach with the applicants. Continuous communication starting in the early stages of the application gives them the opportunity to clarify which data are needed and how they should be produced. Applicants perceive that they are accompanied by the authorities, enhancing their accountability. Applicants receive support to navigate the obstacles of the authorisation procedure economically and technically, answering most of their "needs". On the contrary, the EU authorities do not offer specific support for innovators: from the perspective of the applicants, the authorisation procedure is perceived as more intricate to navigate and

<sup>&</sup>lt;sup>96</sup> Singapore Food Agency (n 13).

<sup>&</sup>lt;sup>97</sup> European Commission, Communication on the European Green Deal (2019) COM/2019/640.

<sup>&</sup>lt;sup>98</sup> Hannah Roberts, 'Lab-Grown Meat Threatens Italian Culture — Meloni Minister' (*Politico*, 16 November 2023)<a href="https://www.politico.eu/article/italy-environment-lab-grown-meat-threatens-culture-meloni-minister/">https://www.politico.eu/article/italy-environment-lab-grown-meat-threatens-culture-meloni-minister/</a>> accessed
19 September 2024.

<sup>&</sup>lt;sup>99</sup> Monaco and others (n 10); Christina Hartmann and Michael Siegrist, 'Consumer Perception and Behaviour Regarding Sustainable Protein Consumption: A Systematic Review' (2017) 61 Trends in Food Science & Technology 11.

challenging to confront.<sup>100</sup> The limits of the EFSA's mandate are defined in Article 22 of Regulation (EU) No 178/2022, the General Food Law. These rules are meant to ensure that the authorisation procedures respect the principles of EU food law: transparency of the assessment process, protection of consumer interests, and clear separation of risk assessment and risk management during risk analysis. The SFA is a statutory board whose functioning resembles closely to the US agency-based system. The SFA's mission is to ensure a supply of safe food. To do so, the SFA enjoys a higher degree of autonomy in its decision-making than the EFSA, overseeing the entire process of authorisation, which does not separate the adoption of risk management measures from the risk assessment. The SFA also does not have any specific obligations for transparency towards the public.

Such a system is undoubtedly faster in addressing breakthrough innovations and in dealing with applicants' feedback and demands. Two examples can be given. First, while Singapore has positioned itself as the pioneer for regulating cultivated meat, being the first country to grant approval to products of cell-culture and thus attracting the attention of all start-ups and companies active in the sector, the EFSA adopted specific guidelines only in September 2024. Such delay makes it difficult for applicants to even plan to submit a dossier for the approval of these products.

A second example is the recent adoption of guidelines for commercial tastings. Conducting tastings of novel foods with a consumer panel is critical for product development and to attract investors. Currently, the NFR does not contain provisions on how to legally conduct a tasting of novel foods with pending approvals in the EU. Among member states' competent authorities, only the Dutch competent authority has adopted guidelines on how to conduct non-commercial tastings of novel foods, specifically cultivated meat.<sup>101</sup> In Singapore, since July 2023, following the companies' feedback and requests, the novel food framework was updated by clarifying the conditions under which sensory evaluation and tasting of unassessed novel food can be

<sup>&</sup>lt;sup>100</sup> Marc Cervera, 'Mosa Meat Eyes Regulatory Clearance in Europe While Beefing up Partnership in Singapore' (*Food Ingredients 1st*, 2 November 2022) <a href="https://fif.cnsmedia.com/a/nwXOILdQNEU=">https://fif.cnsmedia.com/a/nwXOILdQNEU=">https://fif.cnsmedia.com/a/nwXOILdQNEU=</a> 2024

<sup>&</sup>lt;sup>101</sup> Rijksoverheid, 'Code of Practice Safely Conducting Tastings Cultivated Foods Prior to EU Approval' (2023) https://open.overheid.nl/documenten/39127f7e-b18b-4ddf-95a7-0be5ff660aed/file accessed 19 September 2024

conducted. The SFA requires companies willing to conduct sensory evaluations for novel foods to apply for an administrative exemption at least 8 weeks before the session.<sup>102</sup>

The different degrees of complexity of the two legal frameworks and the EU's emphasis on transparency explains the differences in approach and the number of institutions and steps required to authorise a novel food successfully in the EU. However, these factors do not preclude the potential for improvements in the EU system to attract more applicants and improve their experience during the authorisation procedure.

### 5.3. EU framework's ability to encourage innovation

Despite not being an explicit objective of the NFR in the EU, the importance of innovation in the food sector for the transition toward sustainable food systems is recognised in several policy documents, reports, and official declarations by representatives of EU institutions.<sup>103</sup> The following policy and regulatory options are developed based on the results of this analysis, in the spirit of design thinking principles. The suggestions aim to make the EU novel food framework friendlier towards "users/innovators" and to facilitate the work of the "designers/regulators".

First, the EU Transparency Regulation could be amended to give EFSA the opportunity to work closer with the individual applicants, following the case-by-case approach adopted in Singapore. Since the entry into force of the Transparency Regulation, nineteen applications have been evaluated, and 53% of them were terminated due to mistakes in the notification of studies, leading to delays for companies who have to wait six months before submitting a new dossier.<sup>104</sup> To guarantee the transparency of the process, pre-submission consultations in the EU are only meant to clarify which rules apply to the submission of the application, and any advice from the EFSA is non-committal as to any subsequent assessment of the application.

<sup>&</sup>lt;sup>102</sup> Singapore Food Agency (n 12). Article 10.

<sup>103</sup> European Parliament, 'Debates -Novel Foods Wednesday, 28 October 2015' <a href="https://www.europarl.europa.eu/doceo/document/CRE-8-2015-10-28-ITM-005">https://www.europarl.europa.eu/doceo/document/CRE-8-2015-10-28-ITM-005</a> EN.html> accessed 19 September 2024. As an example of the importance of Novel Food Regulation for promoting innovation, consider the interventions from James Nicholson, rapporteur for the proposal of the Novel Food Regulation, and Commissioner Vytenis Povilas Andriukaitis.

<sup>&</sup>lt;sup>104</sup> Andrea Almagro and Luis Gosálbez, 'Novel Foods: Half of New Applications Terminated for the Same Reason' (*Nutraingriedents* 8 June 2023) <a href="https://www.nutraingredients.com/Article/2023/06/08/Novel-Foods-Half-of-new-applications-terminated-for-the-same-reason">https://www.nutraingredients.com/Article/2023/06/08/Novel-Foods-Half-of-new-applications-terminated-for-the-same-reason</a> accessed 19 September 2024.

Moreover, the staff of the EFSA providing the advice is not involved in the assessment of the applications.<sup>105</sup> The Transparency Regulation could be revised to find a balance between the transparency requirements and the needs of innovators to discuss the specificities of their products, particularly for those innovations that cannot be related to previously authorised products, such as cultivated meat. Similar changes could be adopted without jeopardising the high level of transparency required in the authorisation process by continuing to publish the EFSA's opinions, the summaries of applications and the details of the authorisations.

Second, regulatory sandboxes, already proposed in the context of GMO legislation,<sup>106</sup> could be created to foster collaboration between the authorities and the innovators. This collaborative approach between public authorities and the private sector was already tested in the EU through the "Innovation Deals", voluntary agreements between the European Commission and innovators, to help the latter overcome regulatory hurdles and bring their ideas to the market.<sup>107</sup> Implementing a comparable system, possibly tailored per novel food category, could provide valuable insights to EU authorities regarding the regulatory obstacles of the novel foods authorisation procedures, benefitting future applicants and augmenting the expertise of authorities involved. The Farm to Fork Strategy<sup>108</sup> objectives, or the specific indicators for the Sustainable Development Goals adopted by the General Assembly of the United Nations,<sup>109</sup> could be used as a base to develop measurable metrics to justify which companies should be part of these programs because of the potential benefits of their products.

Third, rewarding mechanisms other than the data protection clause could be introduced to attract innovators inside and outside the EU jurisdictions. Such mechanisms could consist of ex

<sup>&</sup>lt;sup>105</sup> Giulia Torre, 'The Novel Foods Authorisation Procedure After Regulation (EU) 2019/1381: Transparency versus Innovation?' (2023) 18 European Food and Feed Law Review 131.

<sup>&</sup>lt;sup>106</sup> Tomasz Zimny and Dennis Eriksson, 'Exclusion or Exemption from Risk Regulation?: A Comparative Analysis of Proposals to Amend the EU GMO Legislation' (2020) 21 EMBO reports e51061.

<sup>&</sup>lt;sup>107</sup> European Commission, 'Identifying Barriers to Innovation' (2016) <https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers\_en> accessed 19 September 2024.

<sup>&</sup>lt;sup>108</sup> European Commission, 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 (2020) COM/2020/381.

<sup>&</sup>lt;sup>109</sup> United Nations, Resolution adopted by the General Assembly on Work of the Statistical Commission pertaining to the 2030 Agenda for Sustainable Development (A/RES/71/313) 2017.

*ante* incentives, such as technical support for the preparation of the dossier, on the model of Singapore's FRESH program, or in *ex post* rewards, by rethinking the data protection system.

Fourth, international collaboration with other regulatory authorities across the globe could be used to reduce the burden on companies seeking approval in several jurisdictions. For example, Singapore has always advocated for international collaboration.<sup>110</sup> Approvals received in other jurisdictions are required to be submitted as part of the dossier in the authorisation procedure,<sup>111</sup> and in October 2023, the SFA organised a "Roundtable for Novel Food Regulations", where scientific authorities from all around the world discussed the opportunity to adopt a global "white list" of authorised growth media components for cultivated meat production and the requirements to characterise cell line genetic and phenotypic sustainability during the cultivation process.<sup>112</sup>

Finally, a more radical approach to the topic would require extensive modifications of the EU novel food framework, for example, changing the novel food definition to reduce the regulatory capture of the NFR by eliminating the geographical condition and reconsidering the role of the EFSA, but changes of this extent are unlikely to happen in the near future and would require massive political will.

### 6. Conclusion

Differences in regulatory requirements applicable to novel foods will determine which countries and jurisdictions will be able to enjoy the "first mover" advantage when dealing with innovative and potentially history-changing innovations.<sup>113</sup> While prioritising food safety remains critical, there is a growing recognition of the significance of promoting innovation,

<sup>&</sup>lt;sup>110</sup> FAO and WHO, *Food Safety Aspects of Cell-Based Food* (2023) <a href="https://www.fao.org/documents/card/en/c/cc4855en">https://www.fao.org/documents/card/en/c/cc4855en</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>111</sup> Singapore Food Agency (n 12). Article 3(6)(5).

<sup>&</sup>lt;sup>112</sup> Singapore Food Agency, 'Factsheet on Roundtable for Novel Food Regulations' (2023) <https://www.sfa.gov.sg/docs/default-source/default-document-library/factsheet-roundtable-for-novel-food-regulations-2023\_31oct23.pdf> accessed 19 September 2024.

<sup>&</sup>lt;sup>113</sup> Kaihua Zhang and others, 'Development of Meat Analogs: Focus on the Current Status and Challenges of Regulatory Legislation' (2023) 22 Comprehensive Reviews in Food Science and Food Safety 1006.

driven by concerns about the environmental impact of food systems and issues related to food security.

The frameworks pertaining to novel foods in both the EU and Singapore exhibit similarities and differences. Although they have achieved relatively comparable regulatory outcomes, Singapore is often perceived as a more dynamic and innovation-driven environment. Incorporating some of the principles from Singapore's framework could enable EU regulators and policymakers to streamline the authorisation processes for novel foods and enhance the experience for innovators, without compromising on the traditional objectives of consumer safety and transparency.

### Chapter 8

### General discussion and conclusions

### **1. Introduction**

This dissertation enhances the understanding of the regulatory landscape for novel foods in the European Union. It investigates whether and how the regulatory framework proportionally pursues the objectives of ensuring the functioning of the internal market and protecting human health and safety, while balancing these goals with the promotion of innovation in the food sector. The dissertation first examines which risk factors trigger the application of Regulation (EU) No 2015/2283 on novel foods (hereinafter: Novel Food Regulation), and how these factors relate to heuristics and biases that shape consumer perception of novel foods. It then focuses on the ability of the novel food framework to support innovation in the EU food sector, using alternative proteins as a case study. Through comparative analyses with other jurisdictions, the dissertation advances proposals to facilitate the development and adoption of food innovations in the EU.

This final chapter begins by addressing the core research questions of the dissertation. It then outlines the key academic and practical contributions made by this research, while also acknowledging its limitations and providing recommendations for future research. The chapter concludes by exploring potential future directions for the regulation of novel foods within the European Union.

### 2. Answering the research questions

The following overarching research question has guided the whole dissertation:

How does the EU regulatory framework for novel foods proportionally balance the promotion of innovation with its established objectives of ensuring the functioning of the internal market and protecting human health and safety, considering the risk triggers prompting the application of the legislation and the effects of subsequent regulatory provisions?

Four sub-questions have been formulated to operationalise the overarching research question of the dissertation. Each chapter has individually addressed the specific research sub-questions. Chapter 1 discussed the first research sub-question on which risk triggers are employed for novel food regulation in the EU, while Chapters 2 and 3 explored the connection between risk triggers and consumer perception of novel foods. Chapter 4 addressed the third research question on which regulatory barriers are introduced by the Novel Food Regulation, and 196

Chapters 5 and 6 investigated how to improve the ability of the framework to promote innovation. The answers to the research sub-questions are summarised in the following sections.

### • Which risk triggers are currently employed for regulating novel foods in the *EU*?

For the purposes of this dissertation, risk triggers refer to distinct characteristics of products and/or processes that distinguish novel foods from traditional foods and may undermine the objectives of the legislation, thereby prompting the application of its regulatory requirements. The Novel Food Regulation relies on two main risk triggers: "novelty" and "unnaturalness". The "novelty" risk trigger is embedded in the novel food definition, which comprises every food not consumed to a significant degree within the Union before 15 May 1997, while the preferential treatment granted to novel foods derived from primary production underscores the preference of the legislator for natural products. However, "novelty" and "unnaturalness" do not necessarily signal a direct or well-established threat to consumer interests, public health, or the environment. Instead, even when scientific evidence supports the safety of a product or a process, their classification as "novel" or "unnatural" subjects them to stringent regulatory controls. Ultimately, the use of "novelty" and "unnaturalness" as risk triggers reflects a biased approach that imposes significant hurdles for the approval of novel foods.

# • How do these risk triggers relate to the psychological factors shaping consumer perception and acceptance of novel foods?

Heuristics are mental shortcuts that enable individuals to make decisions in uncertain situations. However, these shortcuts can also give rise to biases that impair decision-making. A range of psychological factors and cultural influences shape heuristics and biases guiding consumer perception of novel foods. Emotions like fear and disgust, personality traits such as food neophobia, and perceptions of unnaturalness, coupled with a lack of familiarity, consistently lead to the formation of heuristic cues such as the "affect", the "natural-is-better", and the "trust" heuristics, which drive Western consumers to reject novel foods like insects, cultivated meat, and nanofoods.

The use of "novelty" and "unnaturalness" as risk triggers in the regulation of novel foods reflects the same heuristics and cognitive biases that shape consumer perception of novel foods. This occurs for two main reasons. First, public concerns, however biased, often drive the political agenda, with citizens' perceptions of risk influencing government priorities. Second,

legislators and policymakers are not immune to the same cognitive processes as the general public. As for common people, alongside political, economic, and social factors, their personal perception of risk is shaped by heuristics and biases. In a repetition of what happened with genetically modified organisms, negative biases lead European legislators to underestimate the benefits of novel foods, while overestimating the potential risks of novel and unnatural innovations.

# • What impact do risk triggers have on the innovation process, and what are the resulting regulatory barriers for novel foods in the EU compared to other jurisdictions?

This dissertation identifies and justifies the promotion of innovation as an implicit goal of the Novel Food Regulation. References to innovation in the regulation's recitals, its legislative history, and the broader academic and political discussions underscore the regulation's role in influencing the innovation process within the EU food sector. Additionally, the development and adoption of novel foods are acknowledged as instrumental in achieving the legislation's explicit objectives, notably the protection of human health and safety.

Risk triggers initiate the application of the Novel Food Regulation, subjecting novel foods and related processes to its regulatory requirements. Through semi-structured interviews with stakeholders, this dissertation examined the regulatory barriers that adversely impact the development and adoption of novel foods within the EU.

The comparative analyses conducted between the EU and Australia-New Zealand (AUSNZ), and between the EU and Singapore, reveal notable differences in how novel foods are regulated. While all three jurisdictions mandate authorisation procedures to ensure consumer safety, the definitions of novel foods differ, affecting their regulatory scope. In Singapore, the geographical and temporal scopes of the definition are less stringent than in the EU. In AUSNZ, non-traditional foods that do not raise safety issues are not considered novel foods. The novel food definition in the EU, defined by its risk triggers, is the broadest and most general, subjecting more products and processes to the novel food framework.

Moreover, while some criticisms are common across jurisdictions, particularly regarding the treatment of small and medium-sized enterprises in the EU and AUSNZ, stakeholders generally view the approval processes in AUSNZ and Singapore more favourably. A key difference with the EU lies in the levels of communication provided by regulatory authorities during the pre-198

submission consultation phase. In the EU, pre-submission consultations are limited to general advice and do not extend to discussing the specifics of individual applications.<sup>1</sup> Many innovative companies find this inadequate.<sup>2</sup> In contrast, regulatory authorities in AUSNZ and Singapore are noted for their proactive communication and collaborative approach with companies. In Singapore, companies can also benefit from regulatory and even economic support throughout the authorisation process, while the EU framework lacks effective reward mechanisms for innovators.

In summary, the use of "novelty" and "unnaturalness" as risk triggers expands the regulatory scope of the framework, subjecting numerous products and processes to stringent regulatory barriers, in particular the lengthy and costly authorisation procedures. Within the EU, stakeholders find these procedures particularly onerous due to the limited dialogue and support from regulatory authorities. These regulatory challenges hinder the development and adoption of novel foods, thereby delaying the realisation of their potential benefits.

### • Which proposals can be advanced to amend the existing regulatory framework to facilitate the market entrance and the adoption of novel foods, while still ensuring a high level of consumer protection?

### Fostering the innovation process in the EU

In the EU, the primary regulatory mechanism to incentivise innovators is the partial market exclusivity afforded by the data protection clause. This provision grants companies the exclusive right to market a product for a period of five years if the proprietary scientific data submitted with their application is deemed crucial for its approval. During this exclusivity period, other companies must submit their own data to obtain the authorisations for the same or closely related products.

<sup>&</sup>lt;sup>1</sup> European Food Safety Authority, 'EFSA's Catalogue of Support Initiatives during the Life-Cycle of Applications for Regulated Products' (2021) 18 EFSA Supporting Publications e6472.

<sup>&</sup>lt;sup>2</sup> Alie de Boer, Marta Morvillo and Sabrina Röttger-Wirtz, 'Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation' (2023) 14 European Journal of Risk Regulation 313.

Given the questionable efficacy of the data protection clause in incentivising innovators, this dissertation investigated alternative approaches to facilitate novel food approval, taking inspiration from design thinking principles and the practices adopted in AUSNZ and Singapore.

Applying design thinking principles to the regulation of novel foods could provide practical solutions for reducing regulatory barriers to their development and adoption in the EU. This approach views authorisation procedures as legal services tailored to users, particularly innovators. Design thinking emphasises the importance of effective communication between regulators and innovators, and advocates for iterative learning and continuous improvement of processes and services. Both Singapore and AUSNZ have incorporated similar principles into their regulatory frameworks. In Singapore, the combination of regulatory, practical, and economic support, along with a more adaptable approval process, fosters an environment conducive to innovation. In AUSNZ, stakeholders appreciate the openness of the process, which includes public consultations and adherence to official timelines by regulatory authorities.

#### Suggestions to improve the capacity of the EU novel food framework to facilitate innovation

This dissertation advances several proposals aimed at enhancing the novel food framework's capacity to support the innovation process and improving innovators' perception of the regulatory environment in the EU.

These suggestions can be categorised based on their potential for legal disruption: those necessitating substantial legislative changes, those requiring minor amendments, and those that could be integrated within the current novel food framework. The proposals address procedural requirements of the authorisation process as well as potential support and reward mechanisms.

Suggestions that do not cause significant legal disruption primarily focus on enhancing support for innovators outside the authorisation procedure and improving the availability of relevant guidelines for dossier preparation. Regulatory support could be tailored for small and mediumsized enterprises. Although the EU is praised for its transparency and access to relevant documents, there is a lack of centralised regulatory support for start-ups in crucial areas like alternative proteins. Currently, advice on the novel food status of products is left to the discretion of regulatory authorities in member states, resulting in inconsistent and sometimes contradictory opinions.<sup>3</sup> Establishing a centralised contact point for regulatory support could streamline resources and reduce reliance on private consultants. Additionally, support for companies engaged in critical innovations could be strengthened by enhancing existing funding schemes and developing accelerators inspired by Singapore's model.

The revision and publication of guidance documents by EFSA concerning new products and processes could be quickened. For example, the first initiative to set guidelines for dossiers relating to cellular agriculture only happened in May 2023, years after the first approval of cultivated meat in Singapore and the United States. The guidelines have been adopted only in September 2024.<sup>4</sup> Although consulting relevant stakeholders is time-consuming and the capacity constraints of EFSA staff are understandable, more rapid procedures for setting and updating the requirements for innovative products and processes should nevertheless be in place.

Innovators could also benefit from the adoption of uniform rules for non-commercial tasting of novel foods not yet approved. For example, the EU lacks a unified approach to how to conduct consumer studies involving the tasting of cultivated meat products. Only the Dutch competent authority has issued specific guidelines for conducting such studies with cultivated meat products.<sup>5</sup>

Changes necessitating varying degrees of regulatory adaptation primarily involve establishing collaborative frameworks to enhance communication between innovators and regulators. Regulatory sandboxes, which are already implemented in EU legislation for sectors like finance, energy, and artificial intelligence, could be adapted for novel foods.<sup>6</sup> Regulatory

<sup>&</sup>lt;sup>3</sup> Katharina Niewalda, 'Systematics of the Novel Food Regulation - An Analysis of the Consultation Results to Date' (2023) 18 European Food and Feed Law Review 10.

<sup>&</sup>lt;sup>4</sup> EFSA Panel on Nutrition, Novel Foods and Food Allergens and others, 'Guidance on the Scientific Requirements for an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283' (2024) 22 EFSA Journal e8961.

<sup>&</sup>lt;sup>5</sup> Rijksoverheid, 'Code of Practice Safely Conducting Tastings Cultivated Foods Prior to EU Approval' (2023) <a href="https://www.rijksoverheid.nl/documenten/rapporten/2023/07/05/bijlage-cop-safely-conducting-tastings-cultivated-foods-prior-to-eu-approval">https://www.rijksoverheid.nl/documenten/rapporten/2023/07/05/bijlage-cop-safely-conducting-tastings-cultivated-foods-prior-to-eu-approval > accessed 19 September 2024.</a>

<sup>&</sup>lt;sup>6</sup> European Commission, 'Commission Launches European Regulatory Sandbox for Blockchain | Shaping Europe's Digital Future' (2023) <https://digital-strategy.ec.europa.eu/en/news/commission-launches-european-regulatory-sandbox-blockchain> accessed 19 September 2024; European Commission, 'Regulatory Sandboxes in the Energy Sector - European Commission' (2023) <https://energy.ec.europa.eu/publications/regulatory-sandboxes-energy-sector\_en> accessed 19 September 2024. Similar collaborative approaches between public authorities and the private sector were already tested in the EU through the "Innovation Deals", voluntary agreements between the European Commission and innovators, to help the latter overcome regulatory hurdles and

sandboxes for specific novel foods, like cultivated meat, could be introduced in member states strongly inclined to support innovation, such as the Netherlands. These sandboxes could operate on an opt-in basis, as previously suggested for GMO regulation,<sup>7</sup> to facilitate the innovation process within the Union and bypass opposition from hostile member states.

The critical element for regulatory sandboxes is the collaboration between regulators and innovators. Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain imposed strict limits on pre-submission dialogue between EFSA and innovators on novel food applications.<sup>8</sup> Regulatory sandboxes could facilitate the application of design thinking principles in novel food regulation and offer some flexibility regarding transparency rules,<sup>9</sup> following the models of Singapore and AUSNZ.

A complete overhaul of the transparency rules would require significant major legislative changes.<sup>10</sup> Other substantial changes could involve the amendment of the novel food definition. By adopting a revised definition with less constrained geographical limitations and updated temporal parameters, risk triggers would change and better reflect actual risks, focusing more on product characteristics rather than production processes. Another significant legislative change could be the shift to an agency-based mechanism enhancing EFSA's authority and reducing the political influence on the risk management phase, as it happens in AUSNZ and Singapore. Finally, EU regulators could lead a broader international initiative to standardise novel food regulation, facilitating concurrent approvals across multiple jurisdictions.

bring their ideas to the market. European Commission, 'Identifying Barriers to Innovation' (2016) <a href="https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers">https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers</a> en> accessed 19 September 2024.

<sup>&</sup>lt;sup>7</sup> Dennis Eriksson and others, 'Why the European Union Needs a National GMO Opt-Inmechanism' (2018) 36 Nature Biotechnology 18.

<sup>&</sup>lt;sup>8</sup> 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. Article 32a.

<sup>&</sup>lt;sup>9</sup> Alexandra Molitorisová and Kai Purnhagen, "Regulatory sandboxes for novel foods as a geographical space with borders" (ex. 2024). Upcoming. On file with author.

<sup>&</sup>lt;sup>10</sup> 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, PE/41/2019/REV/1, OJ L 231, 6.9.2019, p. 1–28.

#### Figure 1: Potential amendments to the novel foods' framework and degree of legal disruption



### 3. Contributions to the field

This dissertation contributes to academic scholarship and provides practical insights into the regulation of novel foods. It delivers an interdisciplinary analysis combining legal methodologies with psychological research, incorporating behavioural studies, consumer perception literature, and legal scholarship. The key contributions of the dissertation can be summarised as follows.

### 3.1. Academic contributions

The academic contributions of the dissertation include justifying innovation as an objective of the Novel Food Regulation, assuming the perspective of innovators when analysing the novel food framework, considering the role of psychological factors on the decision-making of legislators and policymakers, and applying design thinking principles to develop policy and regulatory recommendations.

Despite not being listed among the explicit objectives of the Novel Food Regulation, innovation is justified throughout the dissertation as an implicit and critical goal of the framework. The importance of new technologies is recognised in the recitals of the legal text, and the effects of the Novel Food Regulation on innovation have been debated extensively during the legislation's drafting and after its adoption. Innovation is also recognised as instrumental in achieving the Novel Food Regulation's explicit objective of protecting consumer health and interests and in pursuing the goals of EU policies such as the European Green Deal and the Farm-to-Fork Strategy.

Positioning innovation as an objective of the novel food framework leads to a new perspective in the analysis of the Novel Food Regulation. Traditionally the novel food framework has been considered a regulatory tool only aimed at protecting consumers,<sup>11</sup> in line with the precautionary approach of EU institutions towards food innovation.<sup>12</sup> This dissertation aimed to adopt and examine the perspectives of innovators, equating consumer protection with the

<sup>&</sup>lt;sup>11</sup> Jessica Vapnek, Kai Purnhagen and Ben Hillel, 'Regulatory and Legislative Framework for Novel Foods', in Shivani Pathania and Brijesh Tiwari (eds), *Food Formulation* (John Wiley & Sons, Ltd 2021) pp. 285-308.

<sup>&</sup>lt;sup>12</sup> Ludivine Petetin, 'The Precautionary Principle and Non-Scientific Factors in the Regulation of Biotech Foods' (2017) 8 European Journal of Risk Regulation 106.

promotion of innovation. This point of view complements and extends the existing scholarship on the regulation of novel foods.

The dissertation also enriches the understanding of the interplay between consumer biases and regulatory barriers. While traditionally behavioural studies focused on the opportunity to nudge consumer behaviour by influencing choice architecture,<sup>13</sup> this dissertation explores the role of heuristics and biases in legislative processes. It investigates the psychological pathways that shape the actions of legislators and policymakers, specifically in their identification of "novelty" and "unnaturalness" as risk triggers for novel foods, providing a behavioural interpretation of regulatory decisions. By linking lawmakers' choices with consumer perception of novel foods, it provides a new path for understanding regulatory choices, aside from the traditional economic and political explanations.

Finally, the dissertation uses design thinking principles for developing proposals aiming at improving the ability to promote innovation of the novel food framework. While the use of design thinking principles has been explored before in legal scholarship,<sup>14</sup> this dissertation is the first example of applying design thinking principles for regulating innovation in the food sector.

### **3.2. Practical contributions**

In the dynamic landscape of novel food regulation, this research offers a theoretical foundation and empirical evidence to inform and guide the development of future regulatory measures.

Firstly, the dissertation offers a qualitative examination of stakeholders' opinions of the novel food framework in the EU and beyond. While these individual perspectives often tend to highlight the negative aspects of the legal framework, exploring the motivations behind stakeholders' entrepreneurial decisions, as this research does, provides policymakers with valuable insights into how regulation impacts innovation development in the novel food sector.

<sup>&</sup>lt;sup>13</sup> For an overview of the power of heuristics and their use to nudge consumer behaviour see: Cass Sunstein and Lucia Reisch, *The Economics of Nudging* (Routledge, 2016).

<sup>&</sup>lt;sup>14</sup> Alice Armitage, Andrew Cordova and Rebecca Siegel, 'Design Thinking: The Answer to the Impasse Between Innovation and Regulation' (2017) 2 Georgetown Law Technology Review 3.

The findings are especially pertinent to the regulation of alternative proteins such as cultivated meat and insects.

Secondly, this dissertation draws a connection between the regulatory approaches for GMOs and novel foods. The GMO regulatory framework has faced persistent criticism in the literature for stifling innovation and imposing excessive regulatory barriers.<sup>15</sup> The portrayal of GMOs as unnatural and harmful to human health and the environment has significantly nudged the EU regulator to adopt a restrictive regulatory framework.<sup>16</sup> By analysing the framing errors associated with GMOs, this dissertation aims to identify and avoid similar pitfalls in the regulation of novel foods, especially for contentious products like cultivated meat.<sup>17</sup>

Ultimately, this dissertation highlights the importance of interdisciplinary analyses in legal scholarship. Such an approach is crucial for identifying potential regulatory issues in advance, allowing the adoption of a proactive approach. By uncovering the principles driving regulatory decisions and recognising biases in political and regulatory practices, this work enriches our understanding and paves the way for more balanced and innovative regulation of novel foods.

### 4. Limitations

In addition to the methodological limitations addressed in each chapter, this dissertation acknowledges three primary theoretical limitations that warrant explicit attention.

The first limitation is the challenge of empirically demonstrating how biases influence legislators and linking consumer studies to specific risk triggers in novel food regulation. Public actors, such as legislators and policymakers, are influenced by a complex array of factors, including broader political and economic contexts, constraints imposed by legal frameworks, and their personal objectives and beliefs. As a result, establishing a definitive causal relationship between risk triggers and biases affecting consumer perceptions of novel foods is inherently difficult. Consequently, the findings of this dissertation should be viewed as a

<sup>&</sup>lt;sup>15</sup> Andreas T Christiansen, Martin Marchman Andersen and Klemens Kappel, 'Are Current EU Policies on GMOs Justified?' (2019) 28 Transgenic Research 267.

<sup>&</sup>lt;sup>16</sup> Stefaan Blancke and others, 'Fatal Attraction: The Intuitive Appeal of GMO Opposition' (2015) 20 Trends in Plant Science 414.

<sup>&</sup>lt;sup>17</sup> Joseph Mohorčich and Jacy Reese, 'Cell-Cultured Meat: Lessons from GMO Adoption and Resistance' (2019) 143 Appetite 104408.

contribution to the understanding of the role of psychological factors in risk perception for innovative products and processes, according to the cognitive psychology theory, rather than as providing a singular explanation for regulatory decisions.

The second conceptual limitation pertains to the perspective adopted throughout the dissertation. The analysis often reflects the viewpoints of innovators, particularly when criticising the regulatory barriers faced by novel foods. The semi-structured interviews conducted for this research predominantly capture stakeholders' concerns, which frequently highlight the challenges posed by the regulatory framework rather than its positive aspects. To address this limitation, the dissertation incorporates doctrinal analysis of the legal framework and empirical data, such as the number of novel food approvals. The primary objective was to explore the relationship between stakeholders' perceptions of regulatory barriers and their actual, practical impacts. By contextualising stakeholders' opinions, this dissertation offers a realistic perspective on how regulation affects the development of the novel food sector.

Finally, this research lacks a large econometric analysis to precisely determine the consequences of regulatory choices on the novel food sector, because of the different expertise of the author, the lack of funding to conduct such an analysis and the difficulty in accessing precise data from companies active in the sector.

### 5. Recommendations for future research

Future research building on this dissertation should investigate the impact of technological advancements in the field, the evolving political contexts surrounding novel foods, and the economic effects of these innovations.

Technological advancements in the food industry will accelerate in the next years.<sup>18</sup> It is crucial to monitor these developments closely to assess their potential to cause legal disruption and adopt proactive regulatory strategies so that the benefits of innovation are maximised.

Scholars should also closely monitor evolving regulatory approaches both within the EU and internationally. Within the EU, factors such as new elections to the European Parliament and political shifts in member states could significantly influence novel food regulation. On a global

<sup>&</sup>lt;sup>18</sup> Jen L Banach and others, 'Alternative Proteins for Meat and Dairy Replacers: Food Safety and Future Trends' (2023) 63 Critical Reviews in Food Science and Nutrition 11063.

scale, jurisdictions are actively working on the approval of innovative products like cultivated meat. Beyond traditional innovation hubs like the United States, countries such as Singapore, Israel, the United Kingdom, and Saudi Arabia are also seeking to attract innovators to bolster the sustainability and reliability of their food supply chains.<sup>19</sup>

The public debate in several EU member states increasingly juxtaposes traditional foods with novel foods, claiming that the latter will have a negative economic impact on local food production. As highlighted in the limitations, there is a lack of research on the economic consequences of adopting novel foods within the EU.<sup>20</sup> This topic is significantly underresearched, compared, for example, to the economic consequences of the regulation of genetically modified crops.<sup>21</sup> Integrating an economic perspective with the psychological insights explored in this dissertation could offer a comprehensive understanding of the diverse factors influencing novel food regulation, supporting more informed and balanced policy decisions.

<sup>&</sup>lt;sup>19</sup> So far, comparative legal research or scholarship studying the impact of new actors in the food space is lacking. Most of the available material is anecdotal or based on journalistic reports: Flora Southey, 'Dissecting Cultivated Meat Regulation Part 1: What's Working in Europe and Israel, and What's Not?' (*Food Navigator*, 8 February 2023) <https://www.foodnavigator.com/Article/2023/02/08/Dissecting-cultivated-meat-regulation-part-1-What-s-working-in-Europe-and-Israel-and-what-s-not> accessed 19 September 2024; Flora Southey, 'Dissecting Cultivated Meat Regulation Part 2: What's Working in the US and Singapore, and What's Not?' (*Food Navigator*,16 February 2023) <https://www.foodnavigator.com/Article/2023/02/16/dissecting-cultivated-meat-regulation-part-2-what-s-working-in-the-us-and-singapore-and-what-s-not> accessed 19 September 2024.

 $<sup>^{20}</sup>$  To the knowledge of the author, currently no article has been published on this topic. Only one pre-print awaiting publication treats comparable aspects: Alessandro Varacca and others, 'Relationship between regulations and firm investment decisions: the case of novel foods in the European Union' (2023) available at: https://www.realoptions.org/programAbstracts2023/1/33.pdf accessed 19 September 2024. In a report entitled 'Can the EU regulatory environment help deliver food innovation?' written in 2017, Graham Brookes and Chris Downes addressed the impact of the novel food authorisation procedure, but based on the 1997 Novel Food Regulation. The report was originally prepared for the Specialty Food Ingredient Industry Association. The findings accessed form scientific available were in the of а poster. at: https://www.pgeconomics.co.uk/pdf/BrookesandDownesNUT%20119%2017%20-att%20-%20ESFI%20article%20on%20innovation.pdf accessed 19 September 2024.

<sup>&</sup>lt;sup>21</sup> Kai Purnhagen and Justus Wesseler, 'EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2020) 43 Applied Economic Perspective and Policy 1621; Justus Wesseler and others, '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 839; Ewa Woźniak, Tomasz Zimny and Tomasz Twardowski, 'Agri-Biotechnology: Legal and Economic Aspects of Using GMOs in EU' in Chetan Keswani (ed), *Bioeconomy for Sustainable Development* (Springer, 2020) pp. 21-41.

### 6. The regulation of novel foods: an uncertain future

While this dissertation focused on the ability of the Novel Food Regulation to support innovation in the EU and criticised several of its regulatory barriers, the louder voices against the current novel food framework argue against the adoption of measures facilitating the innovation process. Opponents of the Novel Food Regulation often advocate that the novel food framework is unsuitable for assessing the socio-economic impact that the new generations of novel foods will cause, calling for a more restrictive framework.

Critics fear that novel foods such as cultivated meat will threaten the cultural heritage associated with the traditional diets of European people. They fear that introducing novel foods could undermine the existence of high-quality foods that characterise the EU food landscape.<sup>22</sup>

These concerns have justified several initiatives at the member-state level. Italy banned the production and sale of cultivated meat.<sup>23</sup> Similar bills have been proposed in France.<sup>24</sup> Both France and Italy adopted or proposed laws prohibiting meat-sounding names for plant-based products.<sup>25</sup> Proposals to slow down the diffusion of alternative proteins and cultivated meat have also been proposed in other member states such as Hungary, Poland and Romania.<sup>26</sup> At the Union level, in January 2024, the Commissioner for Agriculture Stella Kyriakides had to

<sup>&</sup>lt;sup>22</sup> Massimiliano Paoloni, 'Il Cibo Artificiale è Fuorilegge, Ha Vinto Coldiretti' (*Il punto Coldiretti*, 17 November 2023) <a href="https://www.ilpuntocoldiretti.it/attualita/economia/il-cibo-artificiale-e-fuorilegge-ha-vinto-coldiretti/">https://www.ilpuntocoldiretti.it/attualita/economia/il-cibo-artificiale-e-fuorilegge-ha-vinto-coldiretti/</a> accessed 19 September 2024; Confédération paysanne, 'Viande in Vitro: Pour La Confédération Paysanne c'est Non !' (*Press release*, 2 February 2023) <a href="https://www.confederationpaysanne.fr/actu.php?id=13176">https://www.confederationpaysanne.fr/actu.php?id=13176</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>23</sup> LEGGE 1° dicembre 2023, n. 172. Disposizioni in materia di divieto di produzione e di immissione sul mercato di alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o di tessuti derivanti da animali vertebrati nonché di divieto della denominazione di carne per prodotti trasformati contenenti proteine vegetali. Article 2.

 <sup>&</sup>lt;sup>24</sup> Anay Mridul, 'Following Italy's Footstep, The French Propose Their Own Cultivated Meat Ban' (*Green Queen*, 19 December 2023) <a href="https://www.greenqueen.com.hk/france-cultivated-meat-lab-grown-ban-italy/">https://www.greenqueen.com.hk/france-cultivated-meat-lab-grown-ban-italy/</a> accessed 19 September 2024.

<sup>&</sup>lt;sup>25</sup> In Italy, the ban on cultivated meat also prohibits the use of meat sounding names for plant-based products (LEGGE 1° Dicembre 2023, n. 172, Article 3). In France, two proposed decrees have attempted in 2022 and 2024 to ban use of meat sounding names for non animal products. The first one of them referred for a preliminary ruling (Court of Justice of the European Union, Case *C-438/23, Protéines France and Others [2023]* ECLI:EU:C:2024:826) to the Court of Justice of the European Union on July 23<sup>rd</sup> 2023. On October 4<sup>th</sup> 2024, the Court has ruled against the French decree.

<sup>&</sup>lt;sup>26</sup> Francesco Planchestainer, 'Meat Me in Italy: The Italian Ban on Sounding Names and Cell-Cultured Meat' (2024) 19 European Food and Feed Law Review 66.

reiterate her confidence that the novel food framework is capable of addressing the concerns raised by these governments.<sup>27</sup>

These developments are in line with the findings of this dissertation. Biases such as fear of novelty, preference for products perceived as natural, and distrust towards technological advancement all contribute to the resistance against novel foods. This negative perception may not only influence public opinion but also result in new political and regulatory challenges.

The criticisms of modern food systems should not be denied.<sup>28</sup> Problems related to food safety and food security, social justice, and environmental sustainability cannot easily be solved. New food sources such as cultivated meat and new processes like precision fermentation or genetic engineering are not silver bullets. They cannot be simple solutions to complex problems. What they can do is be part of a holistic strategy addressing these problems.

The EU has long been a leader in food regulation, but if it continues to stifle the innovation process, other jurisdictions will take this role. Countries like Singapore, Israel, the United States, and Australia-New Zealand, as well as Switzerland and the United Kingdom, are increasingly seen as more welcoming environments for novel food technologies. This shift could lead to a loss of ideas and resources that might not return. The EU should strive to become a proactive leader in food sector innovation, guiding and shaping developments rather than merely reacting to them.

<sup>&</sup>lt;sup>27</sup> 'Council of the European Union, "Opening Remarks by Commissioner Stella Kyriakides at the Agrifish Council Meeting - High quality and Primary Farm-Based Food Production", <a href="https://Ec.Europa.Eu/Commission/Presscorner/Detail/En/SPEECH\_24\_384">https://Ec.Europa.Eu/Commission/Presscorner/Detail/En/SPEECH\_24\_384</a>> accessed 19 September 2024.

<sup>&</sup>lt;sup>28</sup> Priti Khatri and others, 'Understanding the Intertwined Nature of Rising Multiple Risks in Modern Agriculture and Food System' (2024) 26 Environment, Development and Sustainability 24107.

### References

### **Bibliography**

Ademola A., and others, 'Two Decades of GMOs: How Modern Agricultural Biotechnology Can Help Meet Sustainable Development Goals', in Ademola A. Adenle, and others (eds), *Science, Technology, and Innovation for Sustainable Development Goals: Insights from Agriculture, Health, Environment, and Energy* (Oxford Academic, 2020) pp. 401–422. DOI: https://doi.org/10.1093/oso/9780190949501.003.0020

Aghion P, Bergeaud A and Van Reenen J, 'The Impact of Regulation on Innovation' (2021) National Bureau of Economic Research. DOI: https://doi.org/10.3386/w28381

Alba JW and Hutchinson JW, 'Dimensions of Consumer Expertise' (1987) 13 Journal of Consumer Research 411. DOI: https://doi.org/10.1086/209080

Ammann K, '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. DOI: https://doi.org/10.1016/j.nbt.2013.04.008

Annosi MC and others, 'Digitalization within Food Supply Chains to Prevent Food Waste. Drivers, Barriers and Collaboration Practices' (2021) 93 Industrial Marketing Management. 208 DOI: https://doi.org/10.1016/j.indmarman.2021.01.005

Arber W, 'Genetic Engineering Compared to Natural Genetic Variations' (2010) 27 New Biotechnology 517. DOI: https://doi.org/10.1016/j.nbt.2010.05.007

Armitage A, Cordova A and Siegel R, 'Design Thinking: The Answer to the Impasse Between Innovation and Regulation' (2017) 2 Georgetown Law Technology Review 3. Available at: https://repository.uclawsf.edu/faculty\_scholarship/1569

Banach JL and others, 'Alternative Proteins for Meat and Dairy Replacers: Food Safety and Future Trends' (2023) 63 Critical Reviews in Food Science and Nutrition 11063. DOI: https://doi.org/10.1080/10408398.2022.2089625

Becher S, 'The Alternative Meat of the Matter' (2024) 98 Tulane Law Review 99. Preprint available in SSRN Electronic Journal: http://dx.doi.org/10.2139/ssrn.4386459

211

Berggren Å, Jansson A and Low M, 'Approaching Ecological Sustainability in the Emerging Insects-as-Food Industry' (2019) 34 Trends in Ecology & Evolution 132. DOI: https://doi.org/10.1016/j.tree.2018.11.005

Blancke S and others, 'Fatal Attraction: The Intuitive Appeal of GMO Opposition' (2015) 20 Trends in Plant Science 414. DOI: https://doi.org/10.1016/j.tplants.2015.03.011

Boer A de, Morvillo M and Röttger-Wirtz S, 'Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation' (2023) 14 European Journal of Risk Regulation 313. DOI: https://doi.org/10.1017/err.2022.47

Bradford A, 'The False Choice Between Digital Regulation and Innovation' (2024) 118 Northwestern University Law Review. Preprint available in SSRN Electronic Journal: https://dx.doi.org/10.2139/ssrn.4753107

Braun V and others, 'Thematic Analysis' in Pranee Liamputtong (ed), *Handbook of Research Methods in Health Social Sciences* (Springer, 2019) pp. 843-860. DOI: https://doi.org/10.1007/978-981-10-5251-4\_103

Brenner W and others, 'Design Thinking as Mindset, Process, and Toolbox' in Walter Brenner and Falk Uebernickel (eds), *Design Thinking for Innovation: Research and Practice* (Springer International Publishing, 2016) pp. 3-21.

DOI: http://dx.doi.org/10.1007/978-3-319-26100-3\_1

Brooke-Taylor S and Grinter K, 'Novel Food and Ingredients: Laws and Regulations Australia and New Zealand' in Pasquale Ferranti (ed), *Sustainable Food Science - A Comprehensive Approach* (Elsevier, 2023) pp. 75–85.

DOI: https://doi.org/10.1016/B978-0-12-823960-5.00040-8

Brownsword R, 'Law Disrupted, Law Re-Imagined, Law Re-Invented' (2019) 2019 Technology and Regulation 10. DOI: https://doi.org/10.26116/techreg.2019.002

Brownsword R, *Law, Technology and Society: Re-Imagining the Regulatory Environment* (Routledge, 2019). ISBN: 9780815356455
Calabrese MG and Ferranti P, 'Novel Foods: New Food Sources' in Pasquale Ferranti, Elliot Berry and Jock Anderson (eds), *Encyclopedia of Food Security and Sustainability* (Elsevier, 2019) pp. 271-275. DOI: https://doi.org/10.1016/B978-0-08-100596-5.22128-8

Canavari M, Castellini A and Xhakollari V, 'Chapter 2 - A Short Review on Willingness to Pay for Novel Food' in Cristina Santini, Stefania Supino and Lucia Bailetti (eds), *Case Studies on the Business of Nutraceuticals, Functional and Super Foods* (Woodhead Publishing, 2023) pp.21-30. DOI: https://doi.org/10.1016/B978-0-12-821408-4.00003-1

Caspi A, Roberts BW and Shiner RL, 'Personality Development: Stability and Change' (2005) 56 Annual Review of Psychology 453. DOI: https://doi.org/10.1146/annurev.psych.55.090902.141913

Chen P-J and Antonelli M, 'Conceptual Models of Food Choice: Influential Factors Related to Foods, Individual Differences, and Society' (2020) 9 Foods 1898. DOI: https://doi.org/10.3390/foods9121898

Christiansen AT, Andersen MM and Kappel K, 'Are Current EU Policies on GMOs Justified?' (2019) 28 Transgenic Research 267. DOI: https://doi.org/10.1007/s11248-019-00120-x

Clancy KA and Clancy B, 'Growing Monstrous Organisms: The Construction of Anti-GMO Visual Rhetoric through Digital Media' (2016) 33 Critical Studies in Media Communication 279. DOI: https://doi.org/10.1080/15295036.2016.1193670

Collman JP, *Naturally Dangerous: Surprising Facts about Food, Health, and the Environment* (University Science Books, 2001). ISBN: 9781938787041

Cooper RG and Kleinschmidt EJ, 'Winning Businesses in Product Development: The Critical Success Factors' (1996) 39 Research-Technology Management 18. DOI: http://dx.doi.org/10.1080/08956308.2007.11657441

Curtis V, 'Why Disgust Matters' (2011) 366 Philosophical Transactions of the Royal Society B: Biological Sciences 3478. DOI: https://doi.org/10.1098%2Frstb.2011.0165

Dale S, 'Heuristics and Biases: The Science of Decision-Making' (2015) 32 Business Information Review 93. DOI: http://dx.doi.org/10.1177/0266382115592536

Davis SJ and others, 'Food without Agriculture' (2024) 7 Nature Sustainability 90 DOI: https://doi.org/10.1038/s41893-023-01241-2

Davison J and Ammann K, 'New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology' (2017) 8 GM Crops & Food 13. DOI: https://doi.org/10.1080/21645698.2017.1289305

de Boer A and Bast A, 'Demanding Safe Foods – Safety Testing under the Novel Food Regulation (2015/2283)' (2018) 72 Trends in Food Science & Technology 125. DOI: http://dx.doi.org/10.1016/j.tifs.2017.12.013

De Coninck J, 'The Functional Method of Comparative Law: "Quo Vadis"?' (2010) 74 Rabels Zeitschrift für ausländisches und internationales Privatrecht 318. DOI: https://doi.org/10.1628/003372510791090238

Dederer H-G, '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. DOI: https://doi.org/10.1017/ilm.2019.51

Deliza R and others, 'Cultured Meat: A Review on Accepting Challenges and Upcoming Possibilities' (2023) 52 Current Opinion in Food Science 101050. DOI: https://doi.org/10.1016/j.cofs.2023.101050

Dries L, 'Future Developments in the EU Food Sector' in Liesbeth Dries and others (eds), *EU Bioeconomy Economics and Policies: Volume II* (Springer International Publishing, 2019) pp. 83-90. DOI: https://doi.org/10.1007/978-3-030-28642-2\_6

Edelman LB and Stryker R, '23. A Sociological Approach to Law and the Economy' in Neil J. Smelser and Richard Swedberg (eds), *The Handbook of Economic Sociology* (Princeton University Press, 2010) pp. 527-551. ISBN: 9781400835584

Ehrlinger J, Readinger WO and Kim B, 'Decision-Making and Cognitive Biases', in Howard S Friedman (ed), *Encyclopedia of Mental Health* (Elsevier, 2016) pp. 5-12. DOI: http://dx.doi.org/10.1016/B978-0-12-397045-9.00206-8

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

Eriksson D and Chatzopoulou S, 'Responsible Decision-Making for Plant Research and Breeding Innovations in the European Union' (2018) 9 GM Crops & Food 39. DOI: https://doi.org/10.1080%2F21645698.2017.1388496

Eriksson D and others, 'Why the European Union Needs a National GMO Opt-In mechanism' (2018) 36 Nature Biotechnology 18. DOI: https://doi.org/10.1038/nbt.4051

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

Everett JAC, Faber NS and Crockett M, 'Preferences and Beliefs in Ingroup Favoritism' (2015)9FrontiersinBehavioralNeuroscience15.DOI: https://doi.org/10.3389/fnbeh.2015.00015

Faccio E and Guiotto Nai Fovino L, 'Food Neophobia or Distrust of Novelties? Exploring Consumers' Attitudes toward GMOs, Insects and Cultured Meat' (2019) 9 Applied Sciences 4440. DOI: https://doi.org/10.3390/app9204440

Finardi C and Derrien C, 'Novel Food: Where Are Insects (and Feed...) in Regulation 2015/2283?' (2016) 11 European Food and Feed Law Review 119.

Finucane ML and others, 'The Affect Heuristic in Judgments of Risks and Benefits' (2000) 13 Journal of Behavioral Decision Making 1. DOI: https://doi.org/10.1002/(SICI)1099-0771(200001/03)13:1%3C1::AID-BDM333%3E3.0.CO;2-S

Florença SG and others, 'The Motivations for Consumption of Edible Insects: A Systematic Review' (2022) 11 Foods 3643. DOI: https://doi.org/10.3390/foods11223643

Folkes VS, 'The Availability Heuristic and Perceived Risk' (1988) 15 Journal of Consumer Research 13. DOI: https://psycnet.apa.org/doi/10.1086/209141

Formici G, 'Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 99-122. DOI: https://dx.doi.org/10.1007/978-3-031-13494-4\_6

Frewer LJ and others, 'Public Perceptions of Agri-Food Applications of Genetic Modification
A Systematic Review and Meta-Analysis' (2013) 30 Trends in Food Science & Technology
142. DOI: https://doi.org/10.1016/j.tifs.2013.01.003

Garnett K, Calster GV and Reins L, 'Towards an Innovation Principle: An Industry Trump or Shortening the Odds on Environmental Protection?' (2018) 10 Law, Innovation and Technology 1. DOI: http://dx.doi.org/10.1080/17579961.2018.1455023

Gaskell G and others, 'GM Foods and the Misperception of Risk Perception' (2004) 24 Risk Analysis: An Official Publication of the Society for Risk Analysis 185. DOI: https://doi.org/10.1111/j.0272-4332.2004.00421.x

Gorissen K and Weijters B, 'The Negative Footprint Illusion: Perceptual Bias in Sustainable Food Consumption' (2016) 45 Journal of Environmental Psychology 50. DOI: https://doi.org/10.1016/j.jenvp.2015.11.009

Gough D, Stewart R and Tripney J, 'Using Research Findings' in Sandy Oliver and James Thomas (eds), *An Introduction to Systematic Reviews* (Sage, 2012) pp. 279-296.ISBN: 9781473929432

Haggard S, MacIntyre A and Tiede L, 'The Rule of Law and Economic Development' (2008)11AnnualReviewofPoliticalScience205.DOI: https://doi.org/10.1146/annurev.polisci.10.081205.100244

Hartmann C and Siegrist M, 'Consumer Perception and Behaviour Regarding Sustainable Protein Consumption: A Systematic Review' (2017) 61 Trends in Food Science & Technology 11. DOI: https://doi.org/10.1016/j.tifs.2016.12.006

Hartung F and Schiemann J, 'Precise Plant Breeding Using New Genome Editing Techniques: Opportunities, Safety and Regulation in the EU' (2014) 78 The Plant Journal 742. DOI: https://doi.org/10.1111/tpj.12413

Herman RA and others, 'Transparency in Risk-Disproportionate Regulation of Modern Crop-Breeding Techniques' (2021) 12 GM Crops & Food 376. DOI: https://doi.org/10.1080/21645698.2021.1934353 Hermann M, 'The Impact of the European Novel Food Regulation on Trade and Food Innovation Based on Traditional Plant Foods from Developing Countries' (2009) 34 Food Policy 499. DOI: https://doi.org/10.1016/j.foodpol.2009.08.005

Herrero M and others, 'Innovation Can Accelerate the Transition towards a Sustainable Food System' (2020) 1 Nature Food 266. DOI: https://doi.org/10.1038/s43016-020-0074-1

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

Holle M, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing, 2018) pp. 291-330. DOI: https://doi.org/10.1007/978-3-319-77045-1\_14

Holle M, 'The Protection of Proprietary Data in Novel Foods – How to Make It Work' (2014) 9 European Food and Feed Law Review 280.

Hutchinson T and Duncan N, 'Defining and Describing What We Do: Doctrinal LegalResearch'(2012)17DeakinLawReview83.DOI: https://doi.org/10.21153/dlr2012vol17no1art70

Hutchinson T, 'The Doctrinal Method: Incorporating Interdisciplinary Methods in Reforming the Law' (2015) 3 Erasmus Law Review 130. DOI: https://doi.org/10.5553/ELR.000055

Hutchinson T, 'Vale Bunny Watson? Law Librarians, Law Libraries, and Legal Research in thePost-InternetEra'Era'(2014)106LawLibraryJournal579.Available at: https://api.semanticscholar.org/CorpusID:148880721

Ichim MC, 'The More Favorable Attitude of the Citizens toward GMOs Supports a New Regulatory Framework in the European Union' (2021) 12 GM Crops & Food 18. DOI: https://doi.org/10.1080/21645698.2020.1795525

Igartua J-J and Cheng L, 'Moderating Effect of Group Cue While Processing News on Immigration: Is the Framing Effect a Heuristic Process?' (2009) 59 Journal of Communication 726. DOI: http://dx.doi.org/10.1111/j.1460-2466.2009.01454.x Jensen NH and Lieberoth A, 'We Will Eat Disgusting Foods Together – Evidence of the Normative Basis of Western Entomophagy-Disgust from an Insect Tasting' (2019) 72 Food Quality and Preference 109. DOI: https://doi.org/10.1016/j.foodqual.2018.08.012

Johnson H and Parker C, 'An Impossible Task? Australian Food Law and the Challenge of Novel Meat Analogues' (2022) 50 Federal Law Review 331. DOI: https://doi.org/10.1177/0067205X221107411

Johnson H, Parker C and Evans B, "Don't Mince Words": Analysis of Problematizations in Australian Alternative Protein Regulatory Debates' (2023) 40 Agriculture and Human Values DOI: 1581. https://doi.org/10.1007/s10460-023-10441-7

Kahneman D, 'A Perspective on Judgment and Choice: Mapping Bounded Rationality' (2003) 58 American Psychologist 697. DOI: https://psycnet.apa.org/doi/10.1037/0003-066X.58.9.697

Kahneman D, *Thinking, Fast and Slow* (Farrar, Straus and Giroux, 2013) ISBN: 978-0374275631

Kantono K and others, 'Consumer Acceptance and Production of In Vitro Meat: A Review' (2022) 14 Sustainability 4910. DOI: https://doi.org/10.3390/su14094910

Keekok L, The Natural and the Artefactual: The Implications of Deep Science and Deep Technology for Environmental Philosophy (Lexington Books, 1999) ISBN: 9780739100615

Khatri P and others, 'Understanding the Intertwined Nature of Rising Multiple Risks in Modern Agriculture and Food System' (2023) 26 Environment, Development and Sustainability 24107. DOI: https://doi.org/10.1007/s10668-023-03638-7

Kim B and Schuldt JP, 'Judging the Environmental Impact of Green Consumption: Evidence of Quantity Insensitivity' (2018) 60 Journal of Environmental Psychology 122 DOI: https://doi.org/10.1016/j.jenvp.2018.10.005

King J and Slovic P, 'The Affect Heuristic in Early Judgments of Product Innovations' (2014) 13 Journal of Consumer Behaviour 411. DOI: https://doi.org/10.1002/cb.1491

Klimas T and Vaiciukaite J, 'The Law of Recitals In European Community Legislation' (2008) 15 ILSA Journal of International & Comparative Law 61. Koch JA, Bolderdijk JW and van Ittersum K, 'No Way, That's Gross! How Public Exposure Therapy Can Overcome Disgust Preventing Consumer Adoption of Sustainable Food Alternatives' (2021) 10 Foods 1380. DOI: https://doi.org/10.3390/foods10061380

Köppen E and Meinel C, 'Empathy via Design Thinking: Creation of Sense and Knowledge' in Hasso Plattner, Christoph Meinel and Larry Leifer (eds), *Design Thinking Research: Understanding Innovation* (Springer International Publishing, 2015) pp. 15-28. DOI: https://doi.org/10.1007/978-3-319-01303-9

Korobkin RB, 'The Problems with Heuristics for Law' in Gerd Gigerenzer and Christoph Engel (eds), *Heuristics in the Law* (MIT Press, 2006) pp. 45-60. ISBN: 9780262072755

Krapohl S, 'Thalidomide, BSE and the Single Market: An Historical-Institutionalist Approach to Regulatory Regimes in the European Union' (2007) 46 European Journal of Political Research 25. DOI: https://doi.org/10.1111/j.1475-6765.2006.00643.x

Kröger T and others, 'Acceptance of Insect-Based Food Products in Western Societies: A Systematic Review' (2022) 8 Frontiers in Nutrition 759885. DOI: https://doi.org/10.3389/fnut.2021.759885

Kuran T and Sunstein CR, 'Availability Cascades and Risk Regulation' (1999) 51 Stanford Law Review 683. DOI: https://doi.org/10.2307/1229439

Lähteenmäki-Uutela A and others, 'Alternative Proteins and EU Food Law' (2021) 130 Food Control 108336. DOI: https://doi.org/10.1016/j.foodcont.2021.108336

Lassoued R and others, 'Expert Opinions on the Regulation of Plant Genome Editing' (2021) 19 Plant Biotechnology Journal 1104. DOI: https://doi.org/10.1111/pbi.13597

Lerner JS and others, 'Emotion and Decision Making' (2015) 66 Annual Review of Psychology 799. DOI: https://doi.org/10.1146/annurev-psych-010213-115043

Levenstein H, Fear of Food: A History of Why We Worry about What We Eat (University of Chicago Press, 2012). ISBN: 9780226473734

Liceaga AM and others, 'Insects as an Alternative Protein Source' (2022) 13 Annual Review of Food Science and Technology. 19 DOI: https://doi.org/10.1146/annurev-food-052720-112443

Lietzow J, Luckert C and Schäfer B, Julika Lietzow, Claudia Luckert and Bernd Schäfer, 'Novel and Traditional Foods: Novel Food Regulation in the EU' in Franz Reichl and Michael Schwenk (eds), *Regulatory Toxicology* (Springer Berlin Heidelberg, 2020) pp. 1-28. DOI: https://doi.org/10.1007/978-3-642-36206-4\_144-1

Lind EA and Arndt C, 'Perceived Fairness and Regulatory Policy: A Behavioural Science Perspective on Government-Citizen Interactions' *OECD Regulatory Policy Working Papers*, No. 6 (OECD Publishing, 2016). DOI: http://dx.doi.org/10.1787/1629d397-en

Liu RW, Lapinski MK, Kerr JM, Zhao J, Bum T and Lu Z 'Culture and Social Norms: Development and Application of a Model for Culturally Contextualized Communication Measurement (MC<sup>3</sup>M)' (2022) 6 Frontiers in Communication 770513. DOI: 10.3389/fcomm.2021.770513

Loken B, Barsalou L and Joiner C, 'Categorization Theory and Research in Consumer Psychology: Category Representation and Category-Based Inference' in Curtis P Haugtvedt, Paul M Herr and Frank R Kardes (eds), *Handbook of consumer psychology* (Taylor & Francis Group/Lawrence Erlbaum Associates, 2008) pp. 133-163. ISBN: 9780805856033

Loken B and John DR, 'Diluting Brand Beliefs: When Do Brand Extensions Have a Negative Impact?' (1993) 57 Journal of Marketing 71. DOI: https://doi.org/10.1177/002224299305700305

Marrani D, 'Nanotechnologies and Novel Foods in European Law' (2013) 7 NanoEthics 177. DOI: https://doi.org/10.1007/s11569-013-0176-4

Martelaro N and others, Nikolas Martelaro and others, 'The Personal Trait Myth: A Comparative Analysis of the Innovation Impact of Design Thinking Tools and Personal Traits' in Hasso Plattner, Christoph Meinel and Larry Leifer (eds), *Design Thinking Research: Building Innovators* (Springer International Publishing, 2015) pp. 41-57. DOI: https://doi.org/10.1007/978-3-319-06823-7\_4

Mastroeni M, Mittra J and Tait J, 'Political Influences on Biotechnology-Based Innovation for European Agriculture: Risk-Assessment and Risk Management' (2019) 33 Technology Analysis & Strategic Management 271. DOI:https://doi.org/10.1080/09537325.2019.1573983

Mazac R 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. DOI: https://doi.org/10.1038/s43016-022-00489-9

McGrath C, Palmgren PJ and Liljedahl M, 'Twelve Tips for Conducting Qualitative Research Interviews' (2019) 41 Medical Teacher 1002. DOI: https://doi.org/10.1080/0142159X.2018.1497149

Meier BP, Dillard AJ and Lappas CM, 'Naturally Better? A Review of the Natural-Is-Better Bias' (2019) 13 Social and Personality Psychology Compass e12494. DOI: https://doi.org/10.1111/spc3.12494

Michaels R, 'The Functional Method of Comparative Law' in Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law* (Oxford University Press, 2005) pp. 339-382. DOI: https://doi.org/10.1093/oxfordhb/9780199296064.013.0011

Micheli P and others, 'Doing Design Thinking: Conceptual Review, Synthesis, and Research Agenda' (2019) 36 Journal of Product Innovation Management 124. DOI: https://doi.org/10.1111/jpim.12466

Mina G, Peira G and Bonadonna A, 'The Potential Future of Insects in the European Food System: A Systematic Review Based on the Consumer Point of View' (2023) 12 Foods 646. DOI: https://doi.org/10.3390/foods12030646

Mohorčich J and Reese J, 'Cell-Cultured Meat: Lessons from GMO Adoption and Resistance' (2019) 143 Appetite 104408. DOI: https://doi.org/10.1016/j.appet.2019.104408

Molitorisová A, Monaco A and Purnhagen K, 'An Analysis of the Regulatory Framework Applicable to Products Obtained from Mushroom and Mycelium' (2021). Available in SSRN Electronic Journal: https://dx.doi.org/10.2139/ssrn.3955899 Monaco A and others, 'Consumers' Perception of Novel Foods and the Impact of Heuristics and Biases: A Systematic Review' (2024) 196 Appetite 107285. DOI: http://dx.doi.org/10.1016/j.appet.2024.107285

Monaco A and Purnhagen K, 'Risk Triggers as Innovation Triggers? Risk Analysis and Innovation's Promotion under the Novel Food Regulation' (2022) 17 European Food and Feed Law Review 219.

Monaco A, 'Data Protection Under the Novel Food Regulation: Valuable Instrument or Barrier to Innovation? Insights from the Insect Sector' (2023) 18 European Food and Feed Law Review 172.

Monterrosa EC and others, 'Sociocultural Influences on Food Choices and Implications for Sustainable Healthy Diets' (2020) 41 Food and Nutrition Bulletin 59. DOI: https://doi.org/10.1177/0379572120975874

Moskowitz GB, *Social Cognition: Understanding Self and Others* (Guilford Press, 2005). ISBN: 9781462515042

Neale J, 'Iterative Categorization (IC): A Systematic Technique for Analysing Qualitative Data' (2016) 111 Addiction 1096. DOI: https://doi.org/10.1111/add.13314

Nestle M and Pollan M, *Food Politics: How the Food Industry Influences Nutrition and Health* (University of California Press, 2013). ISBN: 9780520275966

Nickerson RS, 'Confirmation Bias: A Ubiquitous Phenomenon in Many Guises' (1998) 2 Review of General Psychology 175. DOI: https://doi.org/10.1037/1089-2680.2.2.175

Niewalda K, 'Systematics of the Novel Food Regulation - An Analysis of the Consultation Results to Date' (2023) 18 European Food and Feed Law Review 10.

Noll RG and Krier JE, 'Some Implications of Cognitive Psychology for Risk Regulation' (1990) 19 The Journal of Legal Studies 747. DOI: https://doi.org/10.1086/467870

Oeberst A and Imhoff R, 'Toward Parsimony in Bias Research: A Proposed Common Framework of Belief-Consistent Information Processing for a Set of Biases' (2023) 18 Perspectives on Psychological Science 1464.

DOI: https://doi.org/10.1177/17456916221148147

Paganizza V, 'Are Insects Novel Foods?: An Enlightenment on the Scope of Regulation (EC) No 258/97 after the Judgment of the Court in Case C-526/19' (2020) 15 European Food and Feed Law Review 579.

Pakseresht A, Ahmadi Kaliji S and Canavari M, 'Review of Factors Affecting ConsumerAcceptanceofCulturedMeat'(2022)170Appetite105829.DOI: https://doi.org/10.1016/j.appet.2021.105829

Palmer K, Oates WE and Portney PR, 'Tightening Environmental Standards: The Benefit-Cost or the No-Cost Paradigm?' (1995) 9 Journal of Economic Perspectives. DOI: http://dx.doi.org/10.1257/jep.9.4.119

Parker C, 'From "Corporate Governance" to Ecological Regulation: Flipping the Regulatory Story on Climate Change' (2022) Available in SSRN Electronic Journal: https://dx.doi.org/10.2139/ssrn.4184911

Parodi A and others, 'The Potential of Future Foods for Sustainable and Healthy Diets' (2018) 1 Nature Sustainability 782. DOI: https://doi.org/10.1038/s41893-018-0189-7

Peters BG, Institutional Theory in Political Science, Fourth Edition: The New Institutionalism (Edward Elgar Publishing, 2019). ISBN: 9781786437921

Petetin L, 'The Precautionary Principle and Non-Scientific Factors in the Regulation of Biotech Foods' (2017) 8 European Journal of Risk Regulation 106 DOI: http://dx.doi.org/10.1017/err.2016.18

Petrini C, Slow Food Nation: Why Our Food Should Be Good, Clean, and Fair (Rizzoli Ex Libris 2013). ISBN: 9780847841462

Pilcher JM, Food in World History (Routledge, 2023). ISBN 9781032351490

Planchestainer F, 'Meat Me in Italy: The Italian Ban on Sounding Names and Cell-Cultured Meat' (2024) 19 European Food and Feed Law Review 66.

Pollan M, *The Omnivore's Dilemma: A Natural History of Four Meals* (Penguin Press, 2006). ISBN: 1594200823

Poort LM and others, 'Restore Politics in Societal Debates on New Genomic Techniques' (2022) 39 Agriculture and Human Values 1207. DOI: https://doi.org/10.1007/s10460-022-10328-z

Porter ME, 'America's Green Strategy' (1991) 264 Scientific American 168. DOI: http://dx.doi.org/10.1038/scientificamerican0491-168

Post MJ and others, 'Scientific, Sustainability and Regulatory Challenges of Cultured Meat' (2020) 1 Nature Food 403. DOI: https://doi.org/10.1038/s43016-020-0112-z

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

Purnhagen K and Wesseler J, 'EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2020) 43 Applied Economic Perspective and Policy 1621. DOI: https://doi.org/10.1002/aepp.13084

Purnhagen K, 'The Increasing Overlap of Agricultural, Free Movement and Competition Law in the EU' (2021) 46 European Law Review 20.

Purnhagen K, 'EU Court Casts New Plant Breeding Techniques into Regulatory Limbo' (2018)36 Nature Biotechnology 799. DOI: https://doi.org/10.1038/nbt.4251

Purnhagen K, 'You Want It Extra CRISPERY? Legal Disruption through New Plant Breeding Technologies in the EU' (2021) 40 Yearbook of European Law 374. DOI: http://dx.doi.org/10.1093/yel/yeab003

Rachlinski J and Farina C, 'Cognitive Psychology and Optimal Government Design' (2002) 87 Cornell Law review 549.

Raybould A, 'Improving the Politics of Biotechnological Innovations in Food Security and Other Sustainable Development Goals' (2021) 30 Transgenic Research 613. DOI: https://doi.org/10.1007/s11248-021-00277-4

Read R and O'Riordan T, 'The Precautionary Principle Under Fire' (2017) 59 Environment:ScienceandPolicyforSustainableDevelopment4.DOI: https://doi.org/10.1080/00139157.2017.1350005

Reisch L, 'Shaping healthy and sustainable food systems with behavioural food policy' (2021)48EuropeanReviewofAgriculturalEconomics665.DOI: https://doi.org/10.1093/erae/jbab024

Renda A and Pelkmans J, Does EU Regulation Hinder or Stimulate Innovation? (Centre for European Policy Studies, 2014). Available at: https://www.ceps.eu/ceps-publications/does-euregulation-hinder-or-stimulate-innovation/

Renda A and Simonelli F, 'Study Supporting the Interim Evaluation of the Innovation Principle' (Centre for European Policy Studies, 2019). DOI: https://doi.org/10.2777/620609

Rice S and others, 'What Factors Predict the Type of Person Who Is Willing to Fly in an Autonomous Commercial Airplane?' (2019) 75 Journal of Air Transport Management 131. DOI: https://doi.org/10.1016/j.jairtraman.2018.12.008

Román S, Sánchez-Siles LM and Siegrist M, 'The Importance of Food Naturalness for Consumers: Results of a Systematic Review' (2017) 67 Trends in Food Science & Technology 44. DOI: https://doi.org/10.1016/j.tifs.2017.06.010

Rombach M, Dean DL and Bitsch V, "Got Milk Alternatives?" Understanding Key Factors Determining U.S. Consumers' Willingness to Pay for Plant-Based Milk Alternatives' (2023) 12 Foods 1277. DOI: https://doi.org/10.3390/foods12061277

Ronchetti F, Springer L and Purnhagen K, The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation. (Springer Briefs in Law, 2024). DOI: https://doi.org/10.1007/978-3-031-49692-9

Rozin P and Fallon AE, 'A Perspective on Disgust' (1987) 94 Psychological Review 23. DOI: https://psycnet.apa.org/doi/10.1037/0033-295X.94.1.23

Rozin P and Haidt J, 'The Domains of Disgust and Their Origins: Contrasting Biological and Cultural Evolutionary Accounts' (2013) 17 Trends in Cognitive Sciences 367. DOI: https://doi.org/10.1016/j.tics.2013.06.001

Samarasiri M, Chai KF and Chen WN, 'Forward-Looking Risk Assessment Framework for Novel Foods' (2023) 1 Food and Humanity 500. DOI: https://doi.org/10.1016/j.foohum.2023.06.020

Scaffardi L, 'A Peculiar Category of Novel Foods: Traditional Foods Coming from Third Countries and the Regulatory Issues Involving Sustainability, Food Security, Food Safety, and the Free Circulation of Goods' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 37-58. DOI: https://doi.org/10.1007/978-3-031-13494-4\_3

Schebesta H and Purnhagen K, *EU Food Law* (Oxford University Press, 2024). ISBN: 780198844853

Scheibehenne B, Miesler L and Todd PM, 'Fast and Frugal Food Choices: UncoveringIndividualDecisionHeuristics'(2007)49Appetite578.DOI: https://doi.org/10.1016/j.appet.2007.03.224

Scherer KR, 'What Are Emotions? And How Can They Be Measured?' (2005) 44 Social Science Information 695. DOI: https://doi.org/10.1177/0539018405058216

Scherzberg A, 'EU–US Trade Disputes about Risk Regulation: The Case of Genetically Modified Organisms' (2006) 19 Cambridge Review of International Affairs 121. DOI: https://doi.org/10.1080/09557570500501853

Sexton AE, Garnett T and Lorimer J, 'Framing the Future of Food: The Contested Promises of Alternative Proteins' (2019) 2 Environment and Planning E: Nature and Space 47. DOI: https://doi.org/10.1177/2514848619827009

Sforza S, 'Food (In)Security: The Role of Novel Foods on Sustainability' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union: An Interdisciplinary Analysis* (Springer International Publishing, 2022) pp. 59-79. DOI: https://doi.org/10.1007/978-3-031-13494-4\_4

Shao S and others, 'Environmental Regulation and Enterprise Innovation: A Review' (2020) 29 Business Strategy and the Environment 1465. DOI: https://doi.org/10.1002/bse.2446

Shapiro P, Clean Meat (Gallery Books, 2018). ISBN: 9781501189104

Siddiqui SA and others, 'Consumer Acceptability of Plant-, Seaweed-, and Insect-Based Foods as Alternatives to Meat: A Critical Compilation of a Decade of Research' (2022) 66 Critical Reviews in Food Science and Nutrition 6630. DOI: https://doi.org/10.1080/10408398.2022.2036096

Siddiqui SA and others, 'Marketing Strategies for Cultured Meat: A Review' (2022) 12 Applied Sciences 8795. DOI: https://doi.org/10.3390/app12178795

Siegrist M and Hartmann C, 'Consumer Acceptance of Novel Food Technologies' (2020) 1 Nature Food 343. DOI: https://doi.org/10.1038/s43016-020-0094-x

Sievert K and others, 'What's Really at "Steak"? Understanding the Global Politics of Red and Processed Meat Reduction: A Framing Analysis of Stakeholder Interviews' (2022) 137 Environmental Science & Policy 12. DOI: https://doi.org/10.1016/j.envsci.2022.08.007

Siipi H, 'Dimensions of Naturalness' (2008) 13 Ethics and the Environment 71. DOI: https://doi.org/10.2979/ete.2008.13.1.71

Simpson C, 'Data Protection under Food Law Post: In the Aftermath of the Novel Foods Regulation' (2016) 11 European Food and Feed Law Review 309

Sintov ND and Hurst KF, 'Experimental Support for a Trust Heuristic' (2023) 26 Journal of Risk Research 37. DOI: https://doi.org/10.1080/13669877.2022.2091002

Slovic P and others, 'Affect, Risk, and Decision Making' (2005) 24 Health Psychology 35. DOI: https://psycnet.apa.org/doi/10.1037/0278-6133.24.4.S35

Slovic P and Peters E, 'Risk Perception and Affect' (2006) 15 Current Directions in Psychological Science 322. DOI: https://doi.org/10.1111/j.1467-8721.2006.00461.x

Slovic P, 'Perception of Risk' (1987) 236 Science 280. DOI: https://doi.org/10.1126/science.3563507

227

Smyth SJ and others, 'Removing Politics from Innovations That Improve Food Security' (2021) 30 Transgenic Research 601. DOI: https://doi.org/10.1007/s11248-021-00261-y

Stephens N and others, 'Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture' (2018) 78 Trends in Food Science & Technology 155. DOI: https://doi.org/10.1016/j.tifs.2018.04.010

Stevens H and Ruperti Y, 'Smart Food: Novel Foods, Food Security, and the Smart Nation inSingapore'(2023)27Food,Culture& Society754.DOI: https://doi.org/10.1080/15528014.2022.2163455

Stigler GJ, 'The Theory of Economic Regulation' (1971) 2 The Bell Journal of Economics and Management Science 3. DOI: https://doi.org/10.2307/3003160

Sunstein CR, *Laws of Fear beyond the Precautionary Principle* (Cambridge University Press 2005) DOI: https://doi.org/10.1017/CBO9780511790850

Sunstein CR and Reisch L, *The Economics of Nudging* (Routledge, 2016). ISBN: 9781138938533

Elizabeth A Szabo and others, 'Outcome Based Regulations and Innovative Food Processes: An Australian Perspective' (2008) 9 Innovative Food Science & Emerging Technologies 249. DOI: https://doi.org/10.1016/j.ifset.2007.12.001

Tagliabue G and Ammann K, 'Some Basis for a Renewed Regulation of Agri-Food Biotechnology in the EU' (2018) 31 Journal of Agricultural and Environmental Ethics 39. DOI: https://doi.org/10.1007/s10806-018-9708-9

Tagliabue G, 'Nature as a Totem, "GMOs" as a Contemporary Taboo' (2016) 18 North American Journal of Psychology 283. Preprint available in ResearchGate: https://www.researchgate.net/publication/303909674\_Nature\_as\_a\_totem\_GMOs\_as\_a\_conte mporary\_taboo

Tagliabue G, 'Product, Not Process! Explaining a Basic Concept in Agricultural Biotechnologies and Food Safety' (2017) 13 Life Sciences, Society and Policy 3. DOI: https://doi.org/10.1186/s40504-017-0048-8

Tagliabue G, 'The Precautionary Principle: Its Misunderstandings and Misuses in Relation to "GMOs" (2016) 33 New Biotechnology 437. DOI: https://doi.org/10.1016/j.nbt.2016.02.007

Taylor MR, Rubin ES and Hounshell DA, 'Regulation as the Mother of Innovation: The CaseofSO2Control\*'(2005)27Law& Policy348.DOI: https://doi.org/10.1111/j.1467-9930.2005.00203.x

Torre G, 'The Novel Foods Authorisation Procedure After Regulation (EU) 2019/1381: Transparency versus Innovation?' (2023) 18 European Food and Feed Law Review 131.

Tuorila H and Hartmann C, 'Consumer Responses to Novel and Unfamiliar Foods' (2020) 33 Current Opinion in Food Science 1. DOI: https://doi.org/10.1016/j.cofs.2019.09.004

Tversky A and Kahneman D, 'Judgment under Uncertainty: Heuristics and Biases' (1974) 185 Science 1124. DOI: https://doi.org/10.1126/science.185.4157.1124

Twigg-Flesner C, 'Disruptive Technology - Disrupted Law? How the Digital Revolution Affects (Contract) Law' (2016) in Alberto. De Franceschi, European Contract Law and the Digital Single Market (Intersentia, 2016). DOI: https://doi.org/10.1017/9781780685212

Valor C, Antonetti P and Crisafulli B, 'Emotions and Consumers' Adoption of Innovations: An Integrative Review and Research Agenda' (2022) 179 Technological Forecasting and Social Change 121609. DOI: https://doi.org/10.1016/j.techfore.2022.121609

van der Meulen BMJ and others, 'Structural Precaution: The Application of Premarket Approval Schemes in EU Food Legislation' (2012) 67 Food and Drug Law Journal 453. Available at: https://www.jstor.org/stable/26661233

Van Hoecke M, 'Methodology of Comparative Legal Research' (2015) Law and Method. DOI: https://doi.org/10.5553/REM/.000010

van Huis A, 'Potential of Insects as Food and Feed in Assuring Food Security' (2013) 58 Annual Review of Entomology 563. DOI: https://doi.org/10.1146/annurev-ento-120811-153704 Vapnek J, Purnhagen K and Hillel B, 'Regulatory and Legislative Framework for Novel Foods', in Shivani Pathania and Brijesh Tiwari (eds), *Food Formulation* (John Wiley & Sons, Ltd 2021) pp. 285-308. DOI: https://doi.org/10.1002/9781119614760.ch14

Volpato A, 'Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective' in Lucia Scaffardi and Giulia Fornici (eds), *Novel Foods and Edible Insects in the European Union* (Springer Nature Switzerland, 2022) pp. 15-36. DOI: https://doi.org/10.1007/978-3-031-13494-4\_2

von Thienen J, Meinel C and Nicolai C, 'How Design Thinking Tools Help To Solve Wicked Problems' in Larry Leifer, Hasso Plattner and Christoph Meinel (eds), *Design Thinking Research: Building Innovation Eco-Systems* (Springer International Publishing, 2014) pp. 97-102. DOI: https://doi.org/10.1007/978-3-319-01303-9\_7

Watson R and others, 'Policy for Sustainable Entrepreneurship: A Crowdsourced Framework'(2023)383JournalofCleanerProduction135234.DOI: https://doi.org/10.1016/j.jclepro.2022.135234

Welch S, *The Theory of Political Culture* (OUP Oxford, 2013) DOI: https://doi.org/10.1093/acprof:oso/9780199553334.001.0001

Wesseler J and Kalaitzandonakes N, 'Present and Future EU GMO Policy' in Liesbeth Dries and others (eds), EU Bioeconomy Economics and Policies: Volume II (Springer International Publishing, 2019) pp. 245-256. DOI: https://doi.org/10.1007/978-3-030-28642-2\_13

Wesseler J and others, '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 839. DOI: https://doi.org/10.1002/aepp.13259

Whelan AI, Gutti P and Lema MA, 'Gene Editing Regulation and Innovation Economics' (2020) 8 Frontiers in Bioengineering and Biotechnology 303. DOI: https://doi.org/10.3389/fbioe.2020.00303

Winter SR, Rice S and Lamb TL, 'A Prediction Model of Consumer's Willingness to Fly in Autonomous Air Taxis' (2020) 89 Journal of Air Transport Management 101926. DOI: https://doi.org/10.1016/j.jairtraman.2020.101926

Woźniak E, Zimny T and Twardowski T, 'Agri-Biotechnology: Legal and Economic Aspects of Using GMOs in EU' in Chetan Keswani (ed), *Bioeconomy for Sustainable Development* (Springer, 2020) pp. 21-41. DOI: https://doi.org/10.1007/978-981-13-9431-7\_2

Xu X and others, 'Global Greenhouse Gas Emissions from Animal-Based Foods Are Twice Those of Plant-Based Foods' (2021) 2 Nature Food 724. DOI: https://doi.org/10.1038/s43016-021-00358-x

Zamir E and Sulitzeanu-Kenan R, 'Explaining Self-Interested Behavior of Public-Spirited Policy Makers' (2018) 78 Public Administration Review 579. DOI: https://doi.org/10.1111/puar.12825

Zhang K and others, 'Development of Meat Analogs: Focus on the Current Status and Challenges of Regulatory Legislation' (2023) 22 Comprehensive Reviews in Food Science and Food Safety. 1006. DOI: https://doi.org/10.1111/1541-4337.13098

Zhou G and others, 'Be Regulated before Be Innovative? How Environmental Regulation Makes Enterprises Technological Innovation Do Better for Public Health' (2021) 303 Journal of Cleaner Production 126965. DOI: https://doi.org/10.1016/j.jclepro.2021.126965

Zimberoff L, *Technically Food: Inside Silicon Valley's Mission to Change What We Eat* (Abrams Press, 2021). ISBN: 9781419747090

Zimny T and Eriksson D, 'Exclusion or Exemption from Risk Regulation?: A Comparative Analysis of Proposals to Amend the EU GMO Legislation' (2020) 21 EMBO reports e51061. DOI: https://doi.org/10.15252/embr.202051061

## **Online resources**

Almagro A and Gosálbez L, 'Novel Foods: Half of New Applications Terminated for the Same Reason' (*Nutraingridients*, 8 June 2023) https://www.nutraingredients.com/Article/2023/06/08/Novel-Foods-Half-of-newapplications-terminated-for-the-same-reason accessed 19 September 2024

Begum S, 'More Companies Entering the Novel Food Space Offering Alternative Protein' (*The Straits Times*, 26 April 2021) <a href="https://www.straitstimes.com/singapore/environment/more-companies-entering-the-novel-food-space">https://www.straitstimes.com/singapore/environment/more-companies-entering-the-novel-food-space</a>> accessed 19 September 2024

Bertero A and others, 'We Need an Informed Discussion on Cultivated Meat' (2023) Nature Italy <a href="https://www.nature.com/articles/d43978-023-00056-1">https://www.nature.com/articles/d43978-023-00056-1</a> accessed 19 September 2024

Brookes G and Downes C, 'Can the EU regulatory environment help deliver food innovation?' (2017) Scientific Poster available at: https://www.pgeconomics.co.uk/pdf/BrookesandDownesNUT%20119%2017%20-att%20-%20ESFI%20article%20on%20innovation.pdf accessed 19 September 2024

Cervera M, 'Mosa Meat Eyes Regulatory Clearance in Europe While Beefing up Partnership in Singapore' (*Food Ingredients 1st,* 2 November 2022) <a href="https://fif.cnsmedia.com/a/nwXOILdQNEU=">https://fif.cnsmedia.com/a/nwXOILdQNEU=</a>

Confédération paysanne, 'Viande in Vitro : Pour La Confédération Paysanne c'est Non !' (Press release, 2 February 2023) <a href="https://www.confederationpaysanne.fr/actu.php?id=13176">https://www.confederationpaysanne.fr/actu.php?id=13176</a>> accessed 19 September 2024

Critical Appraisal Skills Programme (CASP), 'Checklist for Qualitative Researches' https://casp-uk.net/casp-tools-checklists/ accessed 19 September 2024

de Lorenzo D, 'Italy Gets One Step Closer To Ban Cultivated Meat Production And Imports' (*Forbes*, 19 July 2023) <a href="https://www.forbes.com/sites/danieladelorenzo/2023/07/19/italy-gets-one-step-closer-to-ban-cultivated-meat-production-and-imports/">https://www.forbes.com/sites/danieladelorenzo/2023/07/19/italy-gets-one-step-closer-to-ban-cultivated-meat-production-and-imports/</a> accessed 19 September 2024

European Risk Forum, 'The Innovation Principle, Stimulating Economic Recovery - Open Letter to Barroso, Van Rompuy and Schultz' (24 October 2013) https://corporateeurope.org/sites/default/files/corporation\_letter\_on\_innovation\_principle.pdf accessed 19 September 2024

FAO and WHO, Food Safety Aspects of Cell-Based Food (FAO, WHO 2023) <a href="https://www.fao.org/documents/card/en/c/cc4855en">https://www.fao.org/documents/card/en/c/cc4855en</a>> accessed 19 September 2024

Freitag J, 'Producing Food Through Precision Fermentation - The Opportunity For Australia' (*Cellular Agriculture Australia*, 2024)

https://www.cellularagricultureaustralia.org/publications/producing-food-through-precision-fermentation---the-opportunity-for-australia accessed 19 September 2024

FRESH, 'Future Ready Food Safety Hub' <a href="https://www.ntu.edu.sg/fresh/about">https://www.ntu.edu.sg/fresh/about</a>> accessed 19 September 2024

Good Food Institute, 'Cultivated Meat Backed by UK Government's New National Vision for Engineering Biology' (2023) https://gfieurope.org/blog/cultivated-meat-backed-by-ukgovernments-new-national-vision-for-engineering-biology/ accessed 19 September 2024

Good Food Institute, 'Defining Alternative Protein' https://gfi.org/defining-alternative-protein/ accessed 19 September 2024

Hoffmann S, 'Grillenmehl in Lebensmitteln: EU Erlaubt Beimischung von Insektenpulver' (*GEO*, 19 January 2023) <https://www.geo.de/wissen/ernaehrung/insekten-in-lebensmitteln-jetzt-in-der-eu-zugelassen-33115156.html> accessed 19 September 2024

IPIFF, 'Contribution Paper: Application of the Novel Food Transitional Measure' (2020) https://ipiff.org/wp-content/uploads/2020/12/10-12-2020-IPIFF-Contribution-paper-novelfood-transitional-measure.pdf accessed 19 September 2024

IPIFF, 'Regulation (EU) 2015/2283 on Novel Foods - Briefing Paper on the Provisions Relevant to the Commercialisation of Insect-Based Products Intended for Human Consumption in the EU' (2021) https://ipiff.org/wp-content/uploads/2019/08/ipiff\_briefing\_update\_03.pdf accessed 19 September 2024

Ives M, 'Singapore Approves a Lab-Grown Meat Product, a Global First' (*The New York Times*, 2 December 2020) <a href="https://www.nytimes.com/2020/12/02/business/singapore-lab-meat.html">https://www.nytimes.com/2020/12/02/business/singapore-lab-meat.html</a> accessed 19 September 2024

Johanna Briggs Institute, 'Checklist for Analytical Cross Sectional Studies' (2020) https://jbi.global/critical-appraisal-tools accessed 19 September 2024

Khor S, 'How Novel Foods Are Bolstering Singapore's Food Security' (*GovInsider*, 14 April 2023) <a href="https://govinsider.asia/intl-en/article/how-novel-foods-are-bolstering-singapores-food-security">https://govinsider.asia/intl-en/article/how-novel-foods-are-bolstering-singapores-food-security</a>> accessed 19 September 2024

Leardi M, 'Gli insetti arrivano al supermercato. Un attacco alla dieta mediterranea' (*Il Giornale*, 24 January 2023) <https://www.ilgiornale.it/news/europa/attacco-dieta-mediterranea-insetti-tavola-ora-sono-commercio-2108431.html> accessed 19 September 2024

Leonard P, 'The Innovation Principle' Encompass (2016) <a href="https://encompass-europe.com/comment/the-innovation-principle">https://encompass-europe.com/comment/the-innovation-principle</a> accessed 19 September 2024

Mridul A, 'Cultivated Meat in Your Freezer? Available, Lah! In Singapore' (*Green Queen*, 16 May 2024) <a href="https://www.greenqueen.com.hk/eat-just-good-meat-cultivated-chicken-retail-hubers-butchery-singapore/">https://www.greenqueen.com.hk/eat-just-good-meat-cultivated-chicken-retail-hubers-butchery-singapore/</a>> accessed 19 September 2024

Neslen A, 'Europe Lags behind in Lab-Grown Meat Race' (*Politico*, 27 December 2020) https://www.politico.eu/article/as-cultured-nuggets-go-on-sale-in-singapore-industry-fears-that-eu-will-chicken-out-of-global-tech-race/ accessed 19 September 2024

OECD, Better Regulation Practices across the European Union (OECD Publishing, 2019) https://doi.org/10.1787/9789264311732-en

Paoloni M, 'Il Cibo Artificiale è Fuorilegge, Ha Vinto Coldiretti' (*Il Punto Coldiretti*, 17 November 2023) <a href="https://www.ilpuntocoldiretti.it/attualita/economia/il-cibo-artificiale-e-fuorilegge-ha-vinto-coldiretti/">https://www.ilpuntocoldiretti.it/attualita/economia/il-cibo-artificiale-e-fuorilegge-ha-vinto-coldiretti/</a> accessed 19 September 2024

Reinhardt T, Monaco A and Purnhagen K, 'Cultivated Foie Gras Flies into Europe – Prepare for Legal Disruption' (*European Law Blog*, 05 September 2024) https://doi.org/10.21428/9885764c.cff9f420> accessed 19 September 2024

Remilk, 'Remilk Racking up Regulatory Approvals' (*Press release*, 23 February 2023) <https://www.prnewswire.com/news-releases/remilk-racking-up-regulatory-approvals-301753694.html> accessed 19 September 2024

Roberts H, 'Lab-Grown Meat Threatens Italian Culture — Meloni Minister' (*Politico*, 16 November 2023) Politico <a href="https://www.politico.eu/article/italy-environment-lab-grown-meat-threatens-culture-meloni-minister/">https://www.politico.eu/article/italy-environment-lab-grown-meat-threatens-culture-meloni-minister/</a>> accessed 19 September 2024

Solar Foods 'Solar Foods Receives Novel Food Regulatory Approval for a Protein Grown with CO2 and Electricity' (*Press Release*, 26 October 2022) <a href="https://solarfoods.com/solar-foods-receives-novel-food-regulatory-approval/">https://solarfoods.com/solar-foods-receives-novel-food-regulatory-approval/</a>> accessed 19 September 2024.

Southey F, "'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-veggieburger-still-on-the-table-votes-European-Parliament> accessed 19 September 2024

Southey F, 'Dissecting Cultivated Meat Regulation Part 1: What's Working in Europe and Israel, and What's Not?' (*Food Navigator*, 8 February 2023) <a href="https://www.foodnavigator.com/Article/2023/02/08/Dissecting-cultivated-meat-regulation-part-1-What-s-working-in-Europe-and-Israel-and-what-s-not">https://www.foodnavigator.com/Article/2023/02/08/Dissecting-cultivated-meat-regulation-part-1-What-s-working-in-Europe-and-Israel-and-what-s-not</a>> accessed 19 September 2024

Southey F, 'Dissecting Cultivated Meat Regulation Part 2: What's Working in the US and Singapore, and What's Not?' (*Food Navigator*, 16 February 2023) <a href="https://www.foodnavigator.com/Article/2023/02/16/dissecting-cultivated-meat-regulation-part-2-what-s-working-in-the-us-and-singapore-and-what-s-not">https://www.foodnavigator.com/Article/2023/02/16/dissecting-cultivated-meat-regulation-part-2-what-s-working-in-the-us-and-singapore-and-what-s-not</a>> accessed 19 September 2024

Southey F, 'GMO "Overregulation" Hinders Tech Development, Market Diversity, and Food Security, Says Researcher' (*Food Navigator*, 8 April 2019) foodnavigator.com <https://www.foodnavigator.com/Article/2019/04/08/GMO-overregulation-hinders-techdevelopment-market-diversity-and-food-security-says-researcher> accessed 19 September 2024

Statista, 'Gross Domestic Product of the European Union from 2011 to 2022' (*Statista*, 2023) <https://www.statista.com/statistics/279447/gross-domestic-product-gdp-in-the-european-union-

eu/#:~:text=In%202022%20the%20gross%20domestic,economic%20strength%20of%20a%2 0country> accessed 19 September 2024.

The Economist, 'Singapore Is the World Leader in Selling Cultivated Meat' (*The Economist*, 20 July 2023) <a href="https://www.economist.com/asia/2023/07/20/singapore-is-the-world-leader-in-selling-cultivated-meat">https://www.economist.com/asia/2023/07/20/singapore-is-the-world-leader-in-selling-cultivated-meat</a>> accessed 19 September 2024.

United Nations, 'Resolution adopted by the General Assembly on Work of the Statistical Commission pertaining to the 2030 Agenda for Sustainable Development', A/RES/71/31 (2017) https://ggim.un.org/documents/a\_res\_71\_313.pdf accessed 19 September 2024

Varacca A and others 'Relationship between regulations and firm investment decisions: the case of novel foods in the European Union' (*Preprint*, 2023) https://www.realoptions.org/programAbstracts2023/1/33.pdf accessed 19 September 2024.

235

Vranckaert BB Thomas Gils, Koen, 'Design Thinking in the Legislative Process: The Key toUseableLegislation?'(CITIPblog,1April2021)<https://www.law.kuleuven.be/citip/blog/design-thinking-in-the-legislative-process/>accessed 19 September 2024

World Economics, 'Singapore's Gross Domestic Product (GDP)' (2023) <https://www.worldeconomics.com/Country-Size/Singapore.aspx> accessed 19 September 2024

# Legislation, policy documents and scientific guidances

# **European Union legislation**

## Regulations and directives

Consolidated version of the Treaty on the Functioning of the European Union, OJ C 202, 7.6.2016, p. 1–388.

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. OJ L 106, 17.4.2001, p. 1–39

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, p. 1–23

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

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p.1 1997

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, p. 1– 22

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, PE/41/2019/REV/1, OJ L 231, 6.9.2019, p. 1–28

Commission Implementing Regulation (EU) 2021/882 of 1 June 2021 authorising the placing on the market of dried Tenebrio molitor larva as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470, OJ L 194, 2.6.2021, p. 16–20

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, C/2017/8878, OJ L 351, 30.12.2017, p. 72–201

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, C/2017/8878, OJ L 351, 30.12.2017, p. 72–201

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, C/2017/8878, OJ L 351, 30.12.2017, p. 72–201

# Court cases

Court of Justice of the European Union, Case C-162/97, Criminal Proceedings against Nilsson, Hagelgren & Arrborn [1998] ECLI:EU:C:1998:554

Court of Justice of the European Union, Case C-244/95 - P Moskof AE v Ethnikos Organismos Kapnou [1997] ECLI:EU:C:1997:551.

Court of Justice of the European Union, Case C-288/97 - Consorzio fra i Caseifici dell'Altopiano di Asiago v Regione Veneto [1999] ECLI:EU:C:1999:214

Court of Justice of the European Union, Case *C-526/19 - Entoma SAS v Ministre de l'Économie et des Finances, Ministre de l'Agriculture et de l'Alimentation,* [2020] ECLI:EU:C:2020:769

Court of Justice of the European Union, Case C-528/16 - Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt [2018] ECLI:EU:C:2018:583

Court of Justice of the European Union, Case C-438/23, Protéines France and Others [2023] ECLI:EU:C:2024:826

#### Official communications and guidance documents from EU authorities

'Council of the European Union, "Opening Remarks by Commissioner Stella Kyriakides at the Agrifish Council Meeting - Highquality and Primary Farm-Based Food Production" (2024) https://ec.europa.eu/commission/presscorner/detail/en/SPEECH\_24\_384, accessed 19 September 2024

European Commission, 'Approval of First Insect as Novel Food' (2021) <a href="https://ec.europa.eu/food/food/novel-food/authorisations/approval-first-insect-novel-food\_en">https://ec.europa.eu/food/food/novel-food/authorisations/approval-first-insect-novel-food\_en</a>> accessed May 2021.

EuropeanCommission,'BetterRegulationToolbox'(2021)<https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-</td>regulation/better-regulation-guidelines-and-toolbox\_en> accessed 19 September 2024.

European Commission, 'Commission Launches European Regulatory Sandbox for Blockchain Shaping Europe's Digital Future' (2023) <a href="https://digital-strategy.ec.europa.eu/en/news/commission-launches-european-regulatory-sandbox-blockchain">https://digital-strategy.ec.europa.eu/en/news/commission-launches-european-regulatory-sandbox-blockchain</a>> accessed 19 September 2024

European Commission, 'Decisions Terminating the Procedure' https://food.ec.europa.eu/safety/novel-food/decisions-terminating-procedure\_en accessed 19 September 2024

European Commission, 'Ensuring EU Legislation Supports Innovation' (2016) <a href="https://research-and-innovation.ec.europa.eu/law-and-regulations/ensuring-eu-legislation-supports-innovation\_en">https://research-and-innovation.ec.europa.eu/law-and-regulations/ensuring-eu-legislation-supports-innovation\_en</a>> accessed 19 September 2024.

European Commission, 'Identifying Barriers to Innovation' (2016) <a href="https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers\_en">https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation/identifying-barriers\_en</a>> accessed 19 September 2024.

European Commission, 'Q&A on the Novel Food Regulation' (2018) https://food.ec.europa.eu/system/files/2018-01/fs\_novel-food\_leg\_q-n-a-new-regulationnf\_en.pdf accessed 19 September 2024

European Commission, 'Regulatory Sandboxes in the Energy Sector - European Commission' (2023) <a href="https://energy.ec.europa.eu/publications/regulatory-sandboxes-energy-sector\_en">https://energy.ec.europa.eu/publications/regulatory-sandboxes-energy-sector\_en</a> accessed 19 September 2024

European Commission, 'Research and Innovation - The Innovation Principle Factsheet' (2022) <https://research-and-innovation.ec.europa.eu/document/download/294b40e0-ad5a-448e-9612-ea87b5b9e48e\_en?filename=ec\_rtd\_factsheet-innovation-principle.pdf> accessed 19 September 2024

European Commission, 'Summary of Applications and Notifications' https://food.ec.europa.eu/safety/novel-food/authorisations/summary-applications-and-notifications\_en accessed 19 September 2024

European Commission, 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 (2020) COM/2020/381.

European Commission, Communication on Europe 2020, a Strategy for Smart, Sustainable and Inclusive Growth (2010) COM/2010/2020

European Commission, Communication on the European Green Deal (2019) COM/2019/640.

European Commission. Directorate General for Research and Innovation, 'Food 2030 Pathways for Action: Research and Innovation Policy as a Driver for Sustainable, Healthy and Inclusive Food Systems' (Publications Office, 2020) https://data.europa.eu/doi/10.2777/104372 accessed 19 September 2024

European Commission, Proposal for a Regulation of the European Parliament and of the Council on Novel Foods /\* COM/2013/0894 final - 2013/0435 (COD) \*/ 2013

European Commission. Proposal for a Regulation of the European Parliament and of the Council on novel foods /\* COM/2007/0872 final - COD 2008/0002.

European Commission. Directorate General for Research and Innovation., Innovation Union: A Pocket Guide on a Europe 2020 Initiative. (Publications Office, 2013) <https://op.europa.eu/en/publication-detail/-/publication/6f270d5f-8086-4b70-82b2c4353d253720> accessed 19 September 2024

European Food Safety Authority, Panel on Nutrition, Novel Foods and Food Allergens and others, 'Safety of Pea and Rice Protein Fermented by Shiitake (Lentinula Edodes) Mycelia as a Novel Food Pursuant to Regulation (EU) 2015/2283' (2022) 20 EFSA Journal e7205. DOI: https://doi.org/10.2903/j.efsa.2022.7205

European Food Safety Authority, Panel on Nutrition, Novel Foods and Food Allergens and others, 'Guidance on the Scientific Requirements for an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283' (2024) 22 EFSA Journal e8961. DOI: https://doi.org/10.2903/j.efsa.2024.8961

European Food Safety Authority, 'Administrative Guidance for the Preparation of Applications on Novel Foods Pursuant to Article 10 of Regulation (EU) 2015/2283' (2021) 18 EFSA Supporting Publications e6488. DOI: https://doi.org/10.2903/sp.efsa.2021.EN-6488

European Food Safety Authority, 'EFSA's Catalogue of Support Initiatives during the Life-Cycle of Applications for Regulated Products' (2021) 18 EFSA Supporting Publications e6472. DOI: https://doi.org/10.2903/sp.efsa.2021.EN-6472

European Food Safety Authority, 'Guidance on the Review, Revision and Development of EFSA's Cross-Cutting Guidance Documents' (2015) 13 EFSA Journal 4080. DOI: https://doi.org/10.2903/j.efsa.2015.4080

European Parliament, 'Debates - Novel Foods - Wednesday, 28 October 2015' <https://www.europarl.europa.eu/doceo/document/CRE-8-2015-10-28-ITM-005\_EN.html> accessed 19 September 2024 European Parliament, 'Resolution of 19 October 2023 European protein strategy' (2023/2015(INI)).

Liguori B and others, 'Novel Foods: Allergenicity Assessment of Insect Proteins' (2022) 20 EFSA Journal e200910. https://doi.org/10.2903/j.efsa.2022.e200910

General Secretariat of the Council 'Note to Council: The CAP's role on safeguarding highquality and primary farm-based food production' (2024), 5469/1/24 REV 1.

#### National legislations and guidance documents from EU member states

LEGGE 1° dicembre 2023, n. 172. Disposizioni in materia di divieto di produzione e di immissione sul mercato di alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o di tessuti derivanti da animali vertebrati nonché di divieto della denominazione di carne per prodotti trasformati contenenti proteine vegetali.

Rijksoverheid, 'Code of Practice Safely Conducting Tastings Cultivated Foods Prior to EU Approval' (2023) https://open.overheid.nl/documenten/39127f7e-b18b-4ddf-95a7-0be5ff660aed/file accessed 19 September 2024

#### Australia-New Zealand legislation and guidance documents

Food Standards Australia New Zealand, 'A1175 - Rapeseed Protein Isolate as a Novel Food'(12November2018)https://mta-sts.foodstandards.govt.nz/food-standards-code/applications/A1175accessed 19 September 2024

Food Standards Australia New Zealand, 'A1263 - Rhodomonas Salina Biomass and Extract as a Novel Food' (4 January 2023) https://mta-sts.foodstandards.govt.nz/food-standardscode/applications/A1263-Rhodomonas-salina-biomass-and-extract-as-a-novel-food accessed 19 September 2024

Food Standards Australia New Zealand, 'A1269 - Cultured Quail as a Novel Food' (2 March 2023) https://www.foodstandards.gov.au/code/applications/Pages/A1269---Cultured-Quail-as-a-Novel-Food.aspx accessed 19 September 2024

Food Standards Australia New Zealand, 'Advisory Committee Novel Foods' https://www.foodstandards.gov.au/industry/novel/novelcommittee/Pages/default.aspx accessed 19 September 2024

Food Standards Australia New Zealand, 'Application A1186 Soy Leghemoglobin in Meat Analogue Products' (12 July 2019) <https://www.foodstandards.gov.au/food-standards-code/applications/A1186> accessed 19 September 2024.

Food Standards Australia New Zealand, 'Application Handbook' (2019) https://www.foodstandards.gov.au/code/changes/Documents/Application%20Handbook%20at %201%20July%202019.pdf accessed 19 September 2024

Food Standards Australia New Zealand, 'Exclusivity of Use for Novel Foods and Nutritive Substances' https://www.foodstandards.gov.au/industry/novel/Pages/Exclusivity-of-use-for-novel-foods-and-nutritive-substances.aspx accessed 19 September 2024

Food Standards Australia New Zealand, 'Pre-Application Assistance' https://www.foodstandards.gov.au/food-standards-code/changing-the-code/pre-applicationassistance accessed 19 September 2024

Food Standards Australia New Zealand, 'Record of Views Formed in Response to Inquiries' https://www.foodstandards.gov.au/industry/novel/novelrecs/Documents/Record-of-Views-updated-July-2023.pdf accessed 19 September 2024

Food Standards Australia New Zealand, 'Australia New Zealand Food Standards Code – Standard 1.1.2 – Definitions used throughout the Code' [F2024C00725].

Food Standards Australia New Zealand, 'Australia New Zealand Food Standards Code – Standard 1.5.1 – Novel foods' [F2017C00324].

Food Standards Australia New Zealand, 'Australia New Zealand Food Standards Code – Schedule 25 – Permitted novel foods' [F2023C00770].

## Singapore legislation and guidance documents

Singapore Food Agency, 'Factsheet on Insect Regulatory Framework' (2023) https://www.sfa.gov.sg/docs/default-source/default-document-library/sfa-insect-regulatoryframework-factsheet.pdf accessed 19 September 2024

Singapore Food Agency, 'Factsheet on Roundtable for Novel Food Regulations 2023' (2023) https://www.sfa.gov.sg/docs/default-source/default-document-library/factsheet-roundtablefor-novel-food-regulations-2023\_31oct23.pdf accessed 19 September 2024

Singapore Food Agency, 'Requirements for the Safety Assessment of Novel Foods and NovelFoodIngredients'(2023)https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-foods-and-novel-food-ingredients.pdf accessed 19 September 2024

Singapore Food Agency, '30 by 30 -Strengthening Our Food Security' (2020) https://www.ourfoodfuture.gov.sg/30by30/ accessed 19 September 2024

Singapore Food Agency, 'Vision, Mission and Values' https://www.sfa.gov.sg/about-sfa/whowe-are accessed 19 September 2024

Singapore Food Agency, 'What We Do' https://www.sfa.gov.sg/about-sfa/what-we-do accessed 19 September 2024

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# About the author

#### **Personal profile**

Alessandro Monaco was born in Biella, Italy, on July 31 1996. Alessandro studied his Bachelor in "Scienze Gastronomiche" at the University of Gastronomic Sciences in Pollenzo (Italy). During his Bachelor, Alessandro had the opportunity to conduct several study trips in Italy and abroad, in Canada, Cuba, Georgia, and Greece. Throughout these experiences, he has come into contact with the modern challenges related to food production, commercialisation, and consumption. Afterwards, Alessandro completed a Master of Science in "Food Safety - Food Law & Regulatory Affairs" at Wageningen University, in the Netherlands. He then pursued his PhD at the Chair of Food Law of the University of Bayreuth, in Germany, as part of the project "Regulating Food Innovation - Technical Innovation requires Regulatory Innovation". The project was funded by the the Deutsche Forschungsgemeinschaft (DFG), grant agreement 465588286, and by the Oberfrankenstiftung, grant agreement No. FP00535.

Alessandro's academic career has been shaped by his passion for food and its political, legislative and cultural implications. In his PhD research, Alessandro explored the influence of risk triggers on the regulation of novel foods and investigated how authorisation procedures affect the innovation process within the EU food sector.

During his PhD, Alessandro has been a lecturer in several courses part of the Master's programmes at the Faculty of Life Sciences of the University of Bayreuth: "Introduction to Law and Food Law" (2020-2024), "Food Safety and Risk Management" (2020-2024), "Food Trade Law" (2020-2024), "Food Quality and Food Authenticity Law" (2021-2024), "Alternative Proteins: Policies & Regulation" (2022 and 2024). As part of his PhD, Alessandro has been a visiting researcher at the University of Melbourne and regularly attends and presents his research at reputable scientific conferences.

Alessandro was among the founding members and later President of the "Bayreuth - Kulmbach Alt Protein Project", which aims to increase awareness about alternative proteins and sponsor research in the field as part of a global network of universities promoted by the Good Food Institute.

# List of publications

## 2025

Alessandro Monaco. "Design thinking principles in the regulation of novel foods in the European Union and Singapore: A comparison." *European Business Law Review*, 36(3), 403-422 (2025). <u>https://doi.org/10.54648/eulr2025026</u>

Alessandro Monaco. "The Regulation of Novel Foods in the European Union and in Australia-New Zealand: Barriers and Incentives to Innovation in the Alternative Proteins Sector." *British Food Journal*, 127(13), 171-189 (2025). <u>https://doi.org/10.1108/BFJ-06-2024-0650</u>

Tilman Reinhardt, Alessandro Monaco. "How innovation-friendly is the EU novel food regulation? The case of cellular agriculture." *Future Foods*, 11, 100574 (2025). https://doi.org/10.1016/j.fufo.2025.100574

Alessandro Monaco. "A perspective on the regulation of cultivated meat in the European Union." *npj- Science of Food*, 9, 21 (2025). <u>https://doi.org/10.1038/s41538-025-00384-0</u>

Alessandro Monaco. "The role of heuristics and biases in the choice of risk triggers for novel foods and GMOs in the European Union." *European Journal of Risk Regulation*, 16(1), 217 – 227 (2025). <u>https://doi.org/10.1017/err.2024.48</u>

#### 2024

Alessandro Monaco, Johannes Kotz, Mirna Al Masri, Anila Allmeta, Kai Purnhagen, Laura M. König. "Consumers' perception of novel foods and the impact of heuristics and biases: A systematic review." *Appetite*, *196*, 107285 (2024) <u>https://doi.org/10.1016/j.appet.2024.107285</u>

Tilman Reinhardt, Alessandro Monaco, Kai Purnhagen. "Cultivated Foie Gras flies into Europe: prepare for legal disruption." (*European Law Blog*, 5<sup>th</sup> September 2024) https://doi.org/10.21428/9885764c.cff9f420

#### 2023

Alessandro Monaco. "Data Protection Under the Novel Food Regulation: Valuable Instrument or Barrier to Innovation? Insights from the Insect Sector." *European Food and Feed Law Review*, 18, 172-178 (2023) <u>https://effl.lexxion.eu/article/EFFL/2023/3/7</u> 248
Alexandra Molitorisová, Alessandro Monaco. "Innovating food law with mycelium." In: Markus Möstl, Kai Purnhagen (Hrsg.): *Die Regulierung von Innovationen im Lebensmittelsektor: Produkte, Probleme, Perspektiven.* - Frankfurt am Main: Fachmedien Recht und Wirtschaft, (2023)

Kai Purnhagen, Yasmine Ambrogio, Detlef Bartsch, Dennis Eriksson, Petra Jorasch, Jens Kahrmann, Maximilian Kardung, Alexandra Molitorisová, Alessandro Monaco, Amrit Nanda, Jörg Romeis, Nils Rostoks, Katharina Unkel, Xenia Schneider. "Options for Regulating New Genomic Techniques for Plants in the European Union." *Nature Plants*, 9, 1958–1961 (2023) https://doi.org/10.1038/s41477-023-01570-2

#### 2022

Alessandro Monaco, Kai Purnhagen. "Risk Triggers as Innovation Triggers? Risk analysis and innovation's promotion under the Novel Food Regulation." *European Food and Feed Law Review*, 3, 219-227 (2022) <u>https://effl.lexxion.eu/article/EFFL/2022/3/6</u>

#### 2021

Alexandra Molitorisová, Alessandro Monaco, Kai Purnhagen: *An analysis of the regulatory framework applicable to products obtained from mushroom and mycelium*. (2024) Available in SSRN Electronic Journal: <u>https://doi.org/10.2139/ssrn.3955899</u> and on the website of the Adalbert-Raps-Stiftung: <u>https://www.raps-stiftung.de/projekte/analysis-of-the-regulatory-</u>environment-applicable-to-products-obtained-from-mushrooms-and-fungal-mycelium

# **Attended events**

#### 2024

Attendee at the '18<sup>th</sup> European Food and Feed Law Conference' (Brussels, BE) *17-18 October 2024* 

Speaker at 'Bioeconomy Economics Workshop on Economics & Governance of The Global Bioeconomy' (University of Passau). Contribution title: "Regulatory Barriers and Incentives for Alternative Proteins in the European Union and Australia-New Zealand". 09-10 October 2024

Speaker at 'Shaping Gastronomy: Regenerating Food Systems and Societies', panel 'Justice, Governance, and Sovereignties' (University of Gastronomic Sciences, Pollenzo, IT). Contribution title: "Regulatory Barriers and Incentives for Alternative Proteins in the European Union and Australia-New Zealand". 26-28 September 2024

Lecturer for the session: "Alternative protein products: Policy and acceptance" at the 'Alternative Proteins - Challenges and Chances BioSC International Summer School 2024' (RWTH Aachen, DE). 2-6 September 2024

Speaker at 'FLAN Conference 2024: Legal issues for a sustainable agrifood chain' (University of Bari, IT). Contribution title: "A perspective on the regulation of cultivated meat in the EU". 15-16 May 2024

Facilitator at 'Citizens' Jury on New Genomic Techniques' (University of Bayreuth, DE) 26-28 January 2024

#### 2023

Attendee at 'Food for Thought: Pioneering the Future of Food' (RMIT University, AUS) 27-28 November 2023

Attendee at '10th International Symposium on Delivery of Functionality in Complex Food Systems' (Monash University, AUS) 25-27 October 2023

Speaker at 'ICABR 2023' (Buenos Aires, ARG). Contribution title: "Innovation Systems Analysis of the EU Novel Food Regulation". With Tilman Reinhardt. *4-7 July 2023* 

Participant at 'UNFCC – Climate Change Conference' (Bonn, DE) 05-15 June 2023

Speaker at 'Future of Food Law - Annual WUR Law Group Conference Series' (Wageningen, NL) Contribution title: "How innovation-friendly is the novel food regulation?" With Tilman Reinhardt".

25-26 May 2023

### 2022

Speaker at 'Design Thinking – Innovation, Law, Politics & Biotechnology '22' (Potsdam, DE). Contribution title: "Innovate Food Law Workshop Methodologies: Effective Deliberative Benefit Assessment and Re-Designing the Novel Food Regulation for Food Innovation".

15 December 2022

Speaker at '4. LGL-Kongress Lebensmittelsicherheit und Tiergesundheit' (Erlangen, DE). Contribution title: "The Novel Food Regulation in the EU". 25-27 November 2022

Speaker, at '21. Bayreuther FLMR-Herbstsymposium Die Regulierung von Innovationen im Lebensmittelsektor' (University of Bayreuth, DE). Contribution title: "Innovating food with mycelium: EU regulations". With Alexandra Molitorisová. *13-14 October 2022* 

# Speaker at 'Design Thinking – Innovation, Law, Politics & Biotechnology '21' (Potsdam, DE). Contribution title: "Risk Triggers for Food Innovation Regulation within the EU Legal Framework".

15 December 2021

Speaker at 'Innovate Food Law' (Kulmbach, DE). Contribution title: "Risk Triggers and the Regulation of Food Innovations in the EU Legal Framework". *16 November 2021* 

Online participant at the 'Parma Summer School Food Safety Aspects of Integrated Food Systems' (Università di Parma, in collaboration with Università Cattolica del Sacro Cuore and European Food Safety Authority) 28-30 September 2021

Keynote speaker, at 'Insecta 2021' (Magdeburg, DE). Contribution title: "Looking for Insects in the Regulatory Forest: Critical Aspects and Challenges Posed by the Regulatory Environment applicable to Insects in the European Union". *8-9 September 2021* 

## 2021

# Eidesstattlichen Erklärungen

Hiermit versichere ich eidesstattlich,

- dass ich die Arbeit selbstständig verfasst und keine anderen als die von mir angegebenen Quellen und Hilfsmittel benutzt habe (vgl. Art. 97 Abs. 1 Satz 8 BayHIG) (§ 8 Satz 6).
- dass ich die Dissertation nicht bereits zur Erlangung eines akademischen Grades eingereicht habe und dass ich nicht bereits diese oder eine gleichartige Doktorprüfung endgültig nicht bestanden habe (§ 8 Satz 6).
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Hiermit erkläre ich mein Einverständnis,

- dass die elektronische Fassung der Dissertation unter Wahrung meiner Urheberrechte und des Datenschutzes einer gesonderten Überprüfung unterzogen werden kann (§ 8 Satz 2 Nr. 10).
- dass bei Verdacht wissenschaftlichen Fehlverhaltens Ermittlungen durch universitätsinterne Organe der wissenschaftlichen Selbstkontrolle stattfinden können (§ 8 Satz 11).

Hiermit bestätige ich, dass alle Informationen und beigefügten Dokumente der Richtigkeit entsprechen und vollständig sind. Mir ist bewusst, dass ich verpflichtet bin, in meiner Dissertation ordnungsgemäß nach den Standards des guten wissenschaftlichen Arbeitens auf vorab veröffentlichte Teiler meiner Dissertation hinzuweisen.

(Ort, Datum)

(Unterschrift)