

Lucia Scaffardi
Giulia Formici *Editors*

Novel Foods and Edible Insects in the European Union

An Interdisciplinary Analysis

OPEN ACCESS

 Springer

Novel Foods and Edible Insects in the European Union

Lucia Scaffardi • Giulia Formici
Editors

Novel Foods and Edible Insects in the European Union

An Interdisciplinary Analysis

 Springer

Editors

Lucia Scaffardi
Department of Law, Politics and
International Studies
University of Parma
Parma, Italy

Giulia Formici
Department of Italian and Supranational Public
Law
University of Milan
Milan, Italy



University of Parma

ISBN 978-3-031-13493-7

ISBN 978-3-031-13494-4 (eBook)

<https://doi.org/10.1007/978-3-031-13494-4>

© The Editor(s) (if applicable) and The Author(s) 2022, corrected publication 2022. This book is an open access publication.

Open Access This book is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this book are included in the book's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the book's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.

The use of general descriptive names, registered names, trademarks, service marks, etc. in this publication does not imply, even in the absence of a specific statement, that such names are exempt from the relevant protective laws and regulations and therefore free for general use.

The publisher, the authors, and the editors are safe to assume that the advice and information in this book are believed to be true and accurate at the date of publication. Neither the publisher nor the authors or the editors give a warranty, expressed or implied, with respect to the material contained herein or for any errors or omissions that may have been made. The publisher remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Preface

This volume represents one of the main outputs of the research project “Food Sustainability and Technological Innovation: From Cultured Meat to Edible Insects. The EU Law and Its Implementation at the Regional Level, Between Consumers’ Perception and Clear Rules for Food Producers”, funded by the Emilia-Romagna Region and coordinated between 2020 and 2021 by Professor Lucia Scaffardi (University of Parma) with the cooperation of Giulia Formici, who was awarded a post-doc grant specifically aimed at the implementation of the project.

In particular, the present book stems from the Conference “Novel Foods and Edible Insects, Between Food Safety and Sustainability” held online on 27th May 2021 and organised as one of the above-mentioned research activities. This event took a strongly interdisciplinary approach aimed at investigating all the strictly intertwined legal, scientific, and economic aspects related to Novel Foods and, in particular, edible insects. The widespread and active participation of students, the scientific community, consumers, and public institutions, as well as the growing general interest in this cutting-edge topic inspired the publication of the Conference proceedings.

The present work is thus intended as a valuable resource for academics and anyone else interested in a comprehensive analysis of the potentialities and challenges Novel Foods and edible insects pose in the complex context of the European Union today.

The Editors would like to express their gratitude to all the authors for their precious collaboration and contributions toward the realisation of this volume, to Melisa Liana Vazquez for the linguistic revision, and to Springer for accepting the book proposal.

The Editors also offer sincere thanks to the Department of Law, Politics and International Studies of the University of Parma for its institutional support, the Center for Studies in European and International Affairs of the University of Parma for its financial support, and finally the School of Advanced Studies on Food and

Nutrition of the University of Parma and the Emilia-Romagna Region who generously contributed—through the research project, “*Sostenibilità alimentare: da problema globale a opportunità di sviluppo socio-economico regionale*”—to make open access possible for this publication.

Parma, Italy
Milan, Italy

Lucia Scaffardi
Giulia Formici

Contents

Introduction: Feeding the Future Sustainably—What Role for Novel Foods and Edible Insects?	1
Lucia Scaffardi and Giulia Formici	
Part I Novel Foods: A Necessary Premise	
Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective	15
Annalisa Volpato	
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	37
Lucia Scaffardi	
Food (In)Security: The Role of Novel Foods on Sustainability	59
Stefano Sforza	
Why ‘New’ Foods Are Safe and How They Can Be Assessed	81
Chiara Dall’Asta	
Part II Edible Insects	
Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU	99
Giulia Formici	

The Safety Assessment of Insects and Products Thereof As Novel Foods in the European Union 123
Gabriela Precup, Ermolaos Ververis, Domenico Azzollini,
Fernando Rivero-Pino, Panagiota Zakidou, and Andrea Germini

Consumer Perceptions and Acceptance of Insects As Feed and Food: Current Findings and Future Outlook 147
Giovanni Sogari, Hans Dagevos, Mario Amato, and Danny Taufik

Correction to: The Safety Assessment of Insects and Products Thereof As Novel Foods in the European Union C1
Gabriela Precup, Ermolaos Ververis, Domenico Azzollini,
Fernando Rivero-Pino, Panagiota Zakidou, and Andrea Germini

Editors and Contributors

About the Editors

Lucia Scaffardi Full Professor of Public Comparative Law at the Department of Law, Politics and International Studies, University of Parma (Italy).

Giulia Formici Research Fellow (RTD/A) in Public Comparative Law at the Department of Italian and Supranational Public Law, University of Milan (Italy).

List of Contributors

Mario Amato Department of Political Science, University of Naples Federico II, Naples, Italy

Domenico Azzollini EFSA, Nutrition and Food Innovation Unit, Novel Foods Team, Parma, Italy

Hans Dagevos Wageningen Economic Research, Wageningen University and Research, Wageningen, The Netherlands

Chiara Dall'Asta Department of Food and Drug, University of Parma, Parma, Italy

Andrea Germini EFSA, Nutrition and Food Innovation Unit, Novel Foods Team, Parma, Italy

Gabriela Precup University of Agricultural Sciences and Veterinary Medicine (USAMVCN), Faculty of Food Science and Technology, Cluj-Napoca, Romania

Fernando Rivero-Pino Department of Chemical Engineering, University of Granada, Granada, Spain

Stefano Sforza Department of Food and Drug, University of Parma, Parma, Italy

Giovanni Sogari Department of Food and Drug, University of Parma, Parma, Italy

Danny Taufik Wageningen Economic Research, Wageningen University and Research, Wageningen, The Netherlands

Ermolaos Ververis National and Kapodistrian University of Athens (NKUA), Department of Hygiene, Epidemiology and Medical Statistics, School of Medicine, Athens, Greece

EFSA, Nutrition and Food Innovation Unit, Novel Foods Team, Parma, Italy

Annalisa Volpato Department of Public Law, Maastricht University, Maastricht, The Netherlands

Panagiota Zakidou EFSA, Nutrition and Food Innovation Unit, Novel Foods Team, Parma, Italy

Abbreviations

ADME	Adsorption Distribution Metabolism Excretion
ANFs	Antinutritional Factors
CE	Circular Economy
CJEU	Court of Justice of the European Union
DG	Directorate General
DIAAS	Digestible Indispensable Amino Acid Score
DietEx	Dietary-Exposure
EAQ	Entomophagy Attitude Questionnaire
EC	European Community
EFSA NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
EFSA	European Food Safety Authority
EU	European Union
F2F	EU “Farm to Fork” Strategy
FAIM	Food Additives Intake Model
FAO	Food and Agriculture Organization of the United Nations
FASFC	Belgian Federal Agency for the Safety of the Food Chain
FBO	Food Business Operator
FDA	USA Food and Drug Administration
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FSA	UK Food Standards Agency
FSANZ	Food Standards Australia New Zealand
GDP	Gross Domestic Product
GMOs	Genetically Modified Organisms
GMP	Good Manufacturing Practices
GRAS	Generally Recognized as Safe
HACCP	Hazard Analysis Critical Control Points
IFAD	International Fund for Agricultural Development
iFBOs	Insect European Food Business Operators
IgE	Immunoglobulin E

IPIFF	International Platform of Insects for Food and Feed
IPS	Insect Phobia Scale
ISO	International Organization for Standardization
NGOs	Non-Governmental Organisations
OECD	Organisation for Economic Cooperation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PAH	Polycyclic Aromatic Hydrocarbons
PAPs	Processed Animal Proteins
PBTK	Physiologically Based Toxicokinetic Modelling
PDCAAS	Protein Digestibility-Corrected Amino Acid Score
QPS	Qualified Presumption of Safety
QSAR	Quantitative Structure–Activity Relationship
R&D	Research and Development
ROQ	Register of Questions
SDGs	Sustainable Development Goals
SMEs	Small- and Medium-sized Enterprises
SPS	Sanitary and Phytosanitary Agreement
TBT	Technical Barriers to Trade Agreement
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TTC	Threshold of Toxicological Concern
UK	United Kingdom
ULs	Tolerable Upper Intake Levels
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children’s Fund
USA	United States of America
WFP	United Nations World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
WTP	Willingness to Pay

Introduction: Feeding the Future Sustainably—What Role for Novel Foods and Edible Insects?



Lucia Scaffardi and Giulia Formici

Abstract Food systems all over the world are increasingly under pressure: according to the United Nations, in 2020, 2.37 billion people suffered hunger or were unable to eat a healthy balanced diet on a regular basis. This worrying scenario, mainly affecting developing countries in the Global South, has been exacerbated by different phenomena such as climate change, the global spread of Covid-19, and recent geopolitical tensions. In this context, innovation and technological progress have been considered important allies to promote environmental, social and economic sustainability in the food sector and provide solid answers to the urgent demand of accessible and safe food for present and future generations. So-called Novel Foods represent an interesting and relevant example of the potential role of innovation for the guaranteeing of food security. This introductory chapter aims to present the main issues affecting the food sector globally and offer some first insights on this Volume's main topics: Novel Foods in the European Union and a particular category of 'new' foods, namely insects for human consumption. The structure of the book and the reasons behind the content selection are explored, highlighting the importance of an interdisciplinary approach to such a complex topic.

Keywords Food security · Food sustainability · Novel foods · Edible insects · Innovation

L. Scaffardi

Department of Law, Politics and International Studies, University of Parma, Parma, Italy
e-mail: lucia.scaffardi@unipr.it

G. Formici (✉)

Department of Italian and Supranational Public Law, University of Milan, Milan, Italy
e-mail: giulia.formici@unimi.it

© The Author(s) 2022

L. Scaffardi, G. Formici (eds.), *Novel Foods and Edible Insects in the European Union*, https://doi.org/10.1007/978-3-031-13494-4_1

1 Food Systems Under Pressure: The Need to Find Safe and Sustainable Solutions to Multiple Challenges

Food systems all over the world are increasingly under pressure: according to the United Nations (UN), in 2020, 2.37 billion people suffered hunger or were unable to eat a healthy balanced diet on a regular basis. This disturbing scenario, mainly affecting developing countries in the Global South, has been exacerbated by the global spread of Covid-19. The Food and Agriculture Organisation of the UN (FAO) estimated that while 607 million people worldwide in 2014 were undernourished, in 2020 these numbers grew tragically to between 720 and 811 million. The devastating impact the pandemic produced on national economies also showed its effects on food systems, causing a parallel pandemic of hunger. Virus containment strategies were responsible for severe economic slowdowns, affecting the most vulnerable segments of the population and impairing their access to adequate, nutritious, safe, and sufficient food. Inflated prices, unemployment, and in some cases scarcity of food—resulting from elevated raw material costs or nationalist policies blocking exports—have revealed both the fragility of existent food systems and their major interdependence in a profoundly globalised world.

In this context characterized by serious food insecurity issues and a constantly growing population, estimated to reach 9.3 billion in 2050, the FAO underscored the need to increase global food production by 70%. Feeding the world became an ever more pressing objective but, at the same, an ever more formidable goal to achieve.

In fact, anthropogenic climate change, land degradation, extreme weather events such as droughts, wildfires, and flooding are making it extremely difficult to meet envisaged future food needs. Empirical studies—including those elaborated by the World Food Programme—have demonstrated that a global temperature rise of 2 °C from pre-industrial levels could increase the number of people struck by hunger to 189 million. Moreover, higher temperatures and decreasing precipitation levels translate into a reduction of crop productivity, also affecting livestock, and strongly impacting the guarantee of food safety: climate change affects “the occurrence and intensity of some foodborne diseases,” as affirmed by the European Food Safety Authority in the 2020 report on the repercussions of climate change on food and feed safety. The complexity and consequences of environmental issues are also linked to another relevant criticality: in the above-mentioned scenario, food systems are affected and, at the same time, contribute to this alarming situation. Despite being difficult to quantify, the greenhouse gases produced by the food system are evaluated as being responsible for between 21% and 37% of annual global emissions, thus demonstrating a significant impact on the environment. The exploitation, and in several cases the waste of exhaustible natural resources—particularly soil and water—necessary to keep food systems functioning, together with deforestation, loss of biodiversity, and the pollution produced by the entire food supply chain, are severely compromising the environmental sustainability of food production.

Climate change and pandemics, however, are not the only factors capable of putting pressure on the global food system and of negatively impacting food

security: wars, such as the one currently taking place in Ukraine, endanger agricultural markets. As the European Union Commission and the World Food Programme underlined in the Communication “Safeguarding food security and reinforcing the resilience of food systems” (COM(2022)133 final) of 23 March 2022 and in the document “Food security implications of the Ukraine conflict,” dated March 2022, global grain markets are in turmoil, with immediate and worrying repercussions on food prices and availability of wheat and maize as both food and feed. These consequences, alongside fertilizer shortages and energy insufficiencies, are at the basis of serious global food security concerns. In cereal import-dependent countries especially in the Middle East, Northern and Sub-Saharan Africa and in South Asia, food prices are destined to rise dramatically, severely challenging the ability of low-income consumers to access basic foods. Conflicts, social unrest, and political instability could accompany these phenomena, primarily affecting already vulnerable people.

In the face of these complex and multi-faceted but interrelated challenges, we note once again how food systems today are required to simultaneously increase food production and ensure food security while safeguarding the environment, guaranteeing sustainability, and protecting food safety and consumer health. Recognising these urgent necessities, what clearly emerges from the evaluations here presented is that we cannot reach this objective without a real and pervasive paradigm shift in the current food systems. The negative impact of present practices on the preservation of natural resources and the growing need to contain climate change impel a transition towards a more equitable and healthier food production and distribution system. At the same time, such a system must be more sustainable and resilient, and capable not only of meeting local specificities and needs but also of confronting the wider and strictly interconnected global challenges. Thus, the paradigm shift requires a twofold change: it must account for food security and for the sustainability of food chains. Both are, in the present scenario, urgent and of paramount importance if we are to afford food security for present and future generations. It bears repeating: food security without sustainable food chains is impossible. It is not by chance that the ambitious Agenda 2030, adopted in 2015 by the United Nations General Assembly, dedicated the second Sustainable Development Goal to “End hunger, achieve food security and improved nutrition and promote sustainable agriculture,” thus underlining the importance of guaranteeing access to safe and nutritious food and diets while also insisting upon sustainable practices that safeguard the environment, natural resources, and biodiversity.

In the complex context here described, innovation is considered a precious ally. Solutions coming from technical, technological, and scientific progress are exceedingly useful to countering the drastic challenges food systems are facing, contributing in important ways to the realisation of necessary transitions. In this sense, innovation in the food sector delivers intelligent products, processes, services, and technologies that can help shape our way of eating, both now and tomorrow.

An interesting and relevant example of the potential role of innovation in guaranteeing food security is represented by the so-called Novel Foods. In the European Union, ‘new’ foods are currently disciplined by Regulation (EU) 2015/

2283, which defines as ‘novel’ a food “that was not used for human consumption to a significant degree within the Union before 15 May 1997 [date of the entry into force of the first European Union Novel Foods legislation, Regulation (EC) 258/97], irrespective of the dates of accession of Member States to the Union” and that falls under at least one of the ten categories indicated in Art. 3, para. 2, lett. a). This long and detailed list ranges from food with a new or intentionally modified molecular structure; food consisting of, isolated from or produced from microorganisms, fungi or algae or material of mineral origin; food consisting of engineered nanomaterials; food consisting of, isolated from or produced from animals or their parts, and so on. As is apparent, these categories significantly differ from one another, including not only innovative foods produced by scientifically advanced processes or technologies, but also foods that are already part of the traditional diets of populations living in countries outside the European Union (the so-called traditional foods coming from Third Countries).

Despite their differences, all these ‘new’ foods offer solutions for health issues related to the consumption of certain foods, thus responding to the necessity of ensuring healthy and safe foods. New foods also effectively address food security challenges by delivering more sustainable products and methods of production, and by providing diets with more energy, protein, and micronutrients. Indeed, the European legislator’s awareness of the value of Novel Foods and their potentially positive role in fighting against famine, malnutrition, and unsustainable food production practices clearly emerges from Recital 29: “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.”

Driven precisely by these considerations, a peculiar type of Novel Foods has recently been gaining momentum: edible insects. While insects have long been consumed in several Latin American, Asian, and African countries, the consumption of insects as food and feed in Western Countries is quite recent and brings with it benefits and challenges. In 2013, the FAO published a pioneering and much discussed study, significantly titled “Edible insects. Future prospects for food and feed security.” The examined data demonstrated how on the one hand, meat demand was predicted to have doubled by 2020, in part due to the fact that the consumption of meat in developing countries had grown three times faster than in developed states, with China and Brazil representing two major contributors of this increasing meat demand. On the other hand, the report highlighted how livestock and livestock production processes significantly contribute to global greenhouse gases emissions and deforestation, also requiring considerable amounts of water, soil, and other exhaustible natural resources. Given these data and facing the need to provide the world population with sufficient protein rich foods while limiting the environmental impact of intensive farming, the FAO reflected on the contribution that the consumption of insects could secure. The high feed conversion efficiency, the substantially fewer greenhouse gases emissions, as well as the limited use of land and water required for rearing insects, combined with the high nutritional value of insects, are all beneficial qualities that have attracted the attention of researchers and food

business operators alike. Edible insects and insect-based products have consequently been studied in recent years as possible alternative protein sources and as one of the possible solutions to food insecurity, malnutrition, hunger and unsustainable food practices and food systems. Falling under the definition of Novel Foods in the European Union context, these ‘new’ foods have been at the centre of a lively regulatory and political debate. Food security and environmental considerations have been complemented by food safety concerns and legislative uncertainties related to the applicable provisions regarding rearing and production phases, but also consumer aversion and misconceptions due to misinformation and prejudice.

Edible insects consequently represent a clear example of how, notwithstanding their significant potential, since the end of the twentieth century Novel Foods have raised concerns related to the existence of potential risks for human health deriving from the consumption of unknown food products, foods with a new molecular composition, and foods that are not part of the habitual diets of European Union populations. For these reasons, the supranational legislator introduced a precise preventive risk assessment procedure: the obtainment of a prior authorisation, based on a food safety evaluation of the ‘new’ food, has become a mandatory precondition for placing on the European Union market a food falling within the scope of application of the Novel Foods Regulation.

The regulatory choices made by the European legislator significantly impacted food business operators in the marketing and strategizing of innovative products and production processes. The need to correctly balance the safeguarding of high food safety standards with the promotion of innovation and progress that nevertheless engage resilient food systems with positive impacts on food security and sustainability, has become a complex challenge for European Union institutions and Member States.

In light of the vigorous—and still open—regulatory, scientific, and economic debate over Novel Foods and edible insects, and with careful consideration for this discussion within the broader framework of the urgent challenges currently affecting food systems all over the world, in May 2021 the Conference “Novel Foods and Edible Insects Between Food Safety and Sustainability” was organized at the University of Parma, as part of the project “Food Sustainability and Technological Innovation: From Cultured Meat to Edible Insects. The EU Law and Its Implementation at the Regional Level, between Consumers’ Perception and Clear Rules for Food Producers,” coordinated between 2020 and 2021 by Professor Lucia Scaffardi (University of Parma) and funded by the Emilia-Romagna Region. The purpose of this event, gathering scholars and experts from several different fields, was to shed light on this relatively unexplored topic, in the belief that it should, and hopefully will be further studied in the years to come.

Collecting the proceedings of that Conference, the present Volume intends to offer an in-depth study of the multiple issues connected to Novel Foods and edible insects marketing in the European Union territory, using an interdisciplinary approach that can provide a comprehensive view of this multi-faceted topic. By allowing the reader to appreciate the strong links among legislative choices, food security, food safety, innovation, market needs, and sustainable development, the

book aims to contribute not only to a more informed and aware knowledge of the impact of Novel Foods on the current urgent issues concerning global food systems, but also to a comprehensive understanding of the complex efforts regulators and legislators must face in order to promote an appropriate and efficient balance among different—and, in certain aspects, also conflicting—scientific, economic, cultural, social, and environmental factors.

2 The Structure of This Volume: An Interdisciplinary Approach to Novel Foods and Edible Insects

Reflecting the focus of the papers presented at the Conference that inspired this Volume, the first part of the book is dedicated to Novel Foods, while the second is devoted more specifically to a peculiar yet interesting category of Novel Foods: insects for human consumption. The chapters from 2 to 5, therefore, provide an in-depth investigation of the legal as well as scientific challenges related to the Novel Foods legislation in the European Union scenario, thus representing the broader framework into which the edible insects' focus must be inserted. The last three chapters, from 6 to 8, subsequently assess the specific regulatory issues concerning the marketing of edible insects, as well as the role of the European Food Safety Authority and its food safety evaluations. Insight is also offered on consumer perception and acceptance of insects as food and feed. As clearly emerges from the outlined structure, the book takes an actively interdisciplinary approach. Various contributions touch on different aspects of the same topics, thus allowing for a representation of diverse perspectives and sensibilities. This choice also reflects the importance of fostering an enriching and fruitful dialogue among jurists, economists, and scientists, especially in highly controversial and complex areas where an understanding of scientific and economic aspects is of paramount importance to the implementation of clear and effective legislative rules.

2.1 *Novel Foods*

Since 1997, the EU legislator has been confronted with the need to discipline Novel Foods. In the second chapter, Volpato investigates the European legal framework for the placing on the market of 'new' foods, starting from the definition of Novel Foods, first provided by Regulation (EC) 258/97 and then updated by the currently in force Regulation (EU) 2015/2283. The evolution of the legislative framework, also significantly impacting the authorisation procedure, elicits profound reflection on the roles of the diverse actors involved, and the collocation of Novel Food legislation in the broader context of EU Food Law and an integrated European administration. The author does not fail to highlight how regulating new technologies represents a

“daunting challenge” for policymakers and legislators. Though cognizant of the potential of innovation as an instrument to achieve prosperity and sustainability, Volpato affirms the need to define regulatory solutions that can foster progress and offer new solutions to urgent challenges, while addressing potential unintended effects on consumer health, the functioning of the internal market, and the environment. According to the author, the legislative reform finalised in the 2015 Regulation demonstrates how a new procedure can facilitate a clear distinction not only between Member State and European Union responsibilities and functions but also between scientific and non-scientific factors, by clearly distinguishing the actors devoted to the delicate risk assessment phase from those who deal with the—more politically influenced—risk management decisions.

In keeping with the legal reflections explored in the second chapter, Scaffardi proposes an examination of a peculiar category of Novel Foods, whose inclusion in the scope of application of the 1997 Regulation raised serious concerns not only in Europe but also at the international level: traditional foods coming from Third Countries. These foods, characterised by a history of safe use outside EU borders, thus part of Third Country population diets, are considered ‘new’ foods from the European perspective. Not habitually consumed in the EU before 15 May 1997, these foods were subjected to a long and expensive authorisation process established by the first Novel Foods Regulation. This procedure resulted, in the past, in a serious ‘barrier’ to the marketing of traditional foods coming from Third Countries and was considered by several Governments of developing countries as illegitimate and disproportionate. The author analyses the problematic effects produced by Regulation (EC) 258/97, paying great attention to the strong interconnection between the marketing of this peculiar category of Novel Foods in the EU and the promotion of sustainable development in Global South countries, where the trade of local products such as exotic fruits or tea leaves represents an important source of income that can boost environmentally sustainable production practices and enhance the social and economic sustainability of rural communities. The author also discusses the positive effects produced by the 2015 Regulation, while also delineating persistent issues and challenges.

In the fourth chapter, Sforza explains why Novel Foods could—and partly, already do—play a pivotal role in the concrete realisation of sustainable and resilient food systems. Focusing on dramatic food insecurity data that depict an unbearable and unsustainable situation, the author examines the need to redesign food production systems in a more circular way, namely through the minimisation of food waste, the exploitation of novel biomasses for food production, as well as the promotion of innovative technological solutions. The presentation of such an articulated context allows Sforza to show the potentialities of Novel Foods by providing useful cutting-edge examples covering novel healthy and nutritious foods from sustainable sources, new foods or ingredients deriving from sources not traditionally consumed in the EU, and also new foods or ingredients produced with new technologies, including chemical synthesis. The examination of these relevant examples contributes to demonstrating how Novel Foods can support not only circular economy models

and more sustainable food systems, but importantly new health benefits to the human diet, which are a critical driver for European industry and consumers alike.

In the final chapter of the first part, Dall'Asta examines a fundamental aspect related to the consumption of Novel Foods: food safety. After having explored the legal issues concerning the marketing of Novel Foods in the EU as well as the intertwining of innovation and sustainability as possible solutions to food insecurity, fifth chapter presents an overview of the safety assessment provided by the European Food Safety Authority according to the Novel Food Regulation, with the ultimate purpose of demonstrating why approved Novel Foods can be considered safe. The author elucidates the rigorous procedure and high standards requested for marketing in the EU territory, noting how the information required helps to identify potential knowledge gaps and any need for additional toxicological or nutritional studies. The contribution also reflects on the assessment of the allergenic potential of Novel Foods, which represents a serious constraint. Though the current European safety evaluation process is affected by limitations and bottlenecks and given the impossibility of guaranteeing in absolute and fixed terms that a food will never pose risks to consumers' health, the assessment established by the European legislation represents a structured and serious process upon which consumer trust in Novel Foods can and should be properly based.

2.2 *Edible Insects*

The second part of the Volume explores the main issues and challenges concerning insects for human consumption. Among all the diverse and relevant categories of Novel Foods, edible insects certainly represent an interesting and complex case study. While studies and research on whole insects and by-products derived or isolated from insects have multiplied in recent years, underlining the possibility of relying on this alternative protein source in the near future, the marketing of these foods in the EU still proves to be controversial; the lively political, economic, scientific, and cultural debate surrounding edible insect consumption is destined to persist, especially now that the first EU Commission insect authorisations have begun (in 2021).

The complex legal issues related to the commercialisation of insects-as-food in the EU territory are examined in the sixth chapter. Formici begins with an investigation of the confused regulatory landscape that emerged from the 1997 Novel Foods Regulation, whose scope of application in relation to edible insects was interpreted in various ways by the public authorities of Member States. This fragmented scenario mirrored contrasting national political and cultural approaches to insects and profoundly affected the correct functioning of the internal market by causing significant operative difficulties for food business operators. The author analyses these impacts and pays particular attention to the relevant intervention of the Court of Justice of the European Union in the so-called *Entoma* case (CJ Judgement 1 October 2020, Case C-526, *Entoma SAS v Ministre de l'Économie*

et des Finances, Ministre de l'Agriculture et de l'Alimentation). Even if the interpretative doubts related to the previous Regulation have been addressed by the 2015 Regulation, which explicitly includes whole insects and by-products in the Novel Foods definition, some uncertainties remain. The contribution examines open issues and possible future developments, by scrutinising the impact of the simplified notification procedure as well as the data protection provision disciplined by Art. 26 Regulation (EU) 2015/2283.

Complementing the regulatory perspective, particular relevance is attributed to food safety evaluation specifically devoted to insects-as-food. In their contribution, Precup, Ververis, Azzollini, Rivero-Pino, Zakidou and Germini provide a comprehensive picture of the principles guiding the risk assessment process conducted by the European Food Safety Authority. Close attention is paid to the main challenges that may arise during the safety evaluation of insects and products thereof concerning, specifically, the production process, the compositional and nutritional analysis of the product but also aspects related to toxicological information and allergenicity potential. Carefully examining the scientific opinions adopted up until March 2022, the authors show the multiple and complex profiles the European Food Safety Authority is called to take into proper consideration, by focusing, for example, on the intended and proposed uses indicated by the application or the nutritional profile. The chapter offers insight on the European Food Safety Authority's work and the relevance of its scientific opinions not only for risk managers' decisions but also for food business producers and consumers, by raising awareness on safety aspects that must be considered during the production process and considerations that can contribute to informed dietary choices.

This last aspect related to consumer perception and the acceptance of insects is broadly analysed by Sogari, Dagevos, Amato and Taufik in the eighth chapter. Although in recent years multiple small companies, start-ups, and entrepreneurs have demonstrated growing interest and investment in insect-product sectors, the EU market for insects as food and feed is still restricted by various factors. Among these, consumer unwillingness to eat insects and insect-based foods undoubtedly looms large. Following an examination of the main characteristics of the emerging insect farming industry in the European Union, the state of the art in terms of consumer acceptance of both animals fed with insects and insects for human consumption is then explored. What appears evident from numerous studies, carefully reported in the chapter, is that neophobia together with disgust significantly impact the probability of accepting entomophagy. Starting from this premise and considering the promising potentialities represented by the consumption of insects as food and feed, the authors discuss possible future developments. Although according to recent studies consumers appear to be more open to accepting insects as feed than consuming them directly in their diet, the possible growth of food products containing hidden insects ('entomophagy by stealth') should be properly investigated. Accurate consumer information that also highlights the merits of insect consumption, the rigorous safety assessment established by European Union legislation, and the positive impact on the creation of a circular economy and a more sustainable food system is crucial.

3 Conclusions: Prompting a Fruitful Debate on the ‘Food for the Future’

As has been foregrounded in this Introduction, food systems are now more than ever facing dramatic challenges: emergencies such as war, energy insufficiency, drought, and global pandemic are impacting an already compromised state of affairs, risking to obscure old and unsolved issues. The desperate call for a paradigm shift impels us to re-think the way we produce food. While it is of utmost importance to produce more, thus ensuring food security, at the same time we must produce better, namely in a more sustainable way. This means, *inter alia*, promoting social, economic, and environmentally sustainable development, without compromising consumer health (food safety). Ignoring the acute need to redesign today’s fragile food systems will certainly result in detrimental effects for present and future generations.

If keeping food security and sustainable food systems at the centre of the political, scientific, economic, and regulatory debate is paramount, Governments at all levels, together with private actors and the entirety of stakeholders involved, are asked to urgently develop and implement feasible solutions and strategies. The European Union has made significant efforts in this direction: the European Green Deal, the ‘From Farm to Fork Strategy,’ the Common Agricultural Policy, as well as the significant investment package ‘Next Generation EU,’ adopted recently as a resolute answer to the disruptive effects of the Covid-19 pandemic, show the commitment of the European Union institutions and Member States to designing policies aimed at ensuring a resilient and sustainable food system, that also guarantees the attainment of the United Nations’ Sustainable Development Goals, and other goals established by international agreements such as the Paris Agreement on Climate Change or the Glasgow Climate Pact adopted by the Conference of the Parties (COP) of the United Nations Framework Convention on Climate Change (UNFCCC). Notwithstanding these efforts, more still needs to be done. Concrete implementations of ambitious yet necessary projects often struggle to be included in national or subnational political agendas, while already adopted measures frequently result in timid attempts to encourage environmentally and socially sustainable food systems and agricultural strategies.

In this complex and worrying scenario, Novel Foods play an important role in combating food insecurity and unequal access to healthy, safe, and sustainably produced foods. As Sforza affirms in the fourth chapter, “every Novel Food is a small but essential step towards [the] Sustainable Development Goals.” Starting from the premise that food and food systems are essential for dignified human life, we must give full recognition to the reality that ending hunger, achieving food security, improving nutrition and promoting sustainable agriculture (Goal 2) can significantly contribute to achieving all the other Sustainable Development Goals.

The European Union legislation on Novel Foods, therefore, is a pivotal instrument that can foster innovative solutions in the agri-food sector. The promotion of new foods and their positive impact on sustainable development and practices require careful regulatory choices. Food safety and consumer protection must also

be ensured. At the same time, investment in innovation and technical progress towards sustainable products and resilient, efficient production methods must be encouraged, while not losing sight of investors' economic gain. The long and highly debated legislative reform that led to the adoption of Regulation (EU) 2015/2283 demonstrates the difficulty of finding a clear and appropriate balance among the many diverse needs and interests at stake.

By providing a wide-ranging analysis of this complex and multi-faceted topic including recent, and in some ways revolutionary developments—such as the first authorisations of insects and insect-products as Novel Foods—as well as describing possible future evolutions, the book is intended as a useful resource for students, academics, food business operators, institutional officials, and public authorities interested in better understanding the numerous challenges related to Novel Foods and edible insects. An informed and comprehensive view—to the extent possible—provides the foundation for a thorough and fruitful debate aimed at finding innovative solutions and scientific, economic, and regulatory answers to the urgent questions posed now and in the future. Inexpert readers approaching this fascinating subject for the first time could find in the chapters of this volume useful information for navigating not only the legislative regime adopted in the European Union—alongside its difficulties and criticalities—but also the main scientific and economic aspects concerning the food safety and marketing of Novel Foods. An interdisciplinary and 'integrated' approach to innovative foods could ultimately contribute to promoting transparency by dismantling fake news, misinformation, and bias.

These reflections on the purpose of this work stem from a clear premise: the scientific community is called, especially in difficult and challenging times, to foster knowledge and to ease an enriching dialogue among diverse but strictly interrelated research areas and expertise. This dialogue is key to promoting awareness and informed decision throughout civil society: from consumers to business operators, from public authorities to policymakers. Moving from this key idea, the present Volume strives to offer food for thought, able to inspire and encourage regulatory, economic, and scientific evolutions towards the guarantee of safe, adequate, sustainable, and sufficient food for present and future generations.

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



Part I
Novel Foods: A Necessary Premise

Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective



Annalisa Volpato

Abstract Paying particular attention to the institutional dimension of the EU legal framework for the placing on the market of Novel Foods, this chapter examines the main elements of Regulation 2015/2283, including the definition of Novel Food, the objectives of the legislative measure, and the procedure for the authorisation of Novel Foods. The analysis focuses especially on the roles of the diverse actors involved, and on the Regulation's collocation in the broader context of EU food law and European integrated administration.

Keywords Novel foods · European Administration · Comitology · EFSA · Risk regulation

1 Introduction

The regulation of new technologies constitutes a daunting challenge for policymakers and regulators. The changes brought by innovation hold great potential to enhance prosperity and sustainability for society, but they may also entail significant risks and potential adverse effects for citizens.¹ Regulatory approaches in this context, thus, require a sensible balance between fostering innovation, protecting consumers, and addressing the potential unintended consequences of disruption. This balance is particularly delicate in the field of Novel Food technologies where a vast array of conflicting values, including scientific, economic, traditional, ethical and environmental instances, are inherently interlinked with cultural sensibilities and consumer perceptions on what is safe to be consumed.

Defining a regulatory framework which can unlock the potential of food technology and innovation while safeguarding high food safety standards may prove to be a complex legislative endeavour. Arguably, the success of the regulatory approach

¹Neuwirth (2014), p. 44.

A. Volpato (✉)

Department of Public Law, Maastricht University, Maastricht, The Netherlands

e-mail: annalisa.volpato@maastrichtuniversity.nl

requires not only the adoption of substantive provisions which enshrine a careful consideration of all the legitimate interests in question, but also procedural mechanisms able to include and reconcile divergent instances within the actual decision-making. Therefore, especially in the EU multi-layered institutional landscape, governance design and its articulation across different levels is of particular importance. It should accommodate and prevent the potential tensions between the EU institutions and the Member States, thus touching upon crucial issues of institutional balance in the EU legal system.² At the same time, a successful structure entails clear definition of the role of science and of expertise in the adoption of decisions which will have social, environmental and moral implications.

Paying particular attention to this institutional dimension of the regulatory framework, this chapter will describe the main elements of the regulation of Novel Foods in the EU, including the definition of Novel Food, the objective of the legislative measures (Sect. 2) and the procedure for the authorisation of Novel Foods (Sect. 3). The analysis will focus especially on the evolution of this procedure, reflecting on the role of the diverse actors involved and in its collocation in the broader context of the European space of integrated administration (Sect. 4). More substantive regulatory issues,³ and in particular the specific issue of the authorisation of edible insects as Novel Foods,⁴ will be addressed more in detail in other chapters of this volume.

2 Regulating Novel Foods in the Internal Market

2.1 *The Definition of Novel Foods*

The EU legislator has undertaken the challenge of regulating Novel Food technologies for the first time in the adoption of Regulation (EC) 258/97, which subjected the marketing of ‘Novel Foods’ in the EU territory to the granting of a specific authorisation by the competent authorities.⁵ Novel Foods were defined as “foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community” and which belonged to one of the ten categories listed in Article 1.⁶ These categories included foods and food ingredients

²For a Member-State oriented understanding of institutional balance, see Vos (1997), p. 223. See also Gormley (2004), pp. 40–41.

³In particular, see *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* by L. Scaffardi in this volume.

⁴See *Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU* by G. Formici in this volume.

⁵Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

⁶The categories were specifically: (a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC; (b) foods and food

containing or consisting of genetically modified organisms (GMOs), which were later regulated in a separate legislative act.⁷ The two components of the definition were cumulative and were to be assessed by the Member States' authorities.⁸ The wording of the definition, however, presented relevant ambiguities which gave rise to significant litigation before the Court of Justice of the EU (CJEU).⁹ The interpretation of the concepts determining the scope of application and effects of the different procedures required several interventions by the CJEU, and not only. The rapid developments in food technologies¹⁰ and international trade¹¹ soon called for the reform of a regulatory framework which increasingly appeared fragmented and outdated.¹²

After the failure in the adoption of the legislative proposal presented by the European Commission in 2008,¹³ the EU legislator enacted Regulation (EU) 2015/2283 which represents the legislative framework currently in force.¹⁴ This Regulation maintains a definition of Novel Food composed of two elements. On the one

ingredients produced from, but not containing, genetically modified organisms; (c) foods and food ingredients with a new or intentionally modified primary molecular structure; (d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (f) foods and food ingredients to which a production process not currently used has been applied, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

⁷Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Also, enzymes are now separately regulated Regulation (EC) 1332/2008 of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) 258/97.

⁸CJ Judgment (14 April 2011) Case C-327/09 *Mensch und Natur AG v. Freistaat Bayern*, para. 31. See also Klaus (2011), p. 190.

⁹For instance, on the notion of significant degree, see CJ Judgement (15 January 2009) Case C-383/07 *M-K Europa GmbH & Co. KG v. Stadt Regensburg*, para. 26; on substantial equivalence, CJ Judgement (9 September 2003) Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v. Italy*, para.77; on the scope of the authorisation, CJ Judgment (14 April 2011) Case C-327/09 *Mensch und Natur AG v. Freistaat Bayern*.

¹⁰See Salmon (2009), pp. 97–115; Van Der Meulen (2009), pp. 37–57.

¹¹On the tension between Regulation 1997 and the WTO framework, see Marine (2013), p. 104; Downes (2013), p. 307; Streinz (1998), pp. 265–289; Bronckers and Soopramanien (2008), pp. 361–375.

¹²European Commission, Evaluation Report on the Novel Food Regulation 258/97 Concerning Novel Foods and Food Ingredients, 22 January 2004.

¹³Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure], COM(2007) 872 final.

¹⁴Regulation (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) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

hand, Novel Food is “any food that was not used for human consumption to a significant degree within the Union before 15 May 1997”, thus keeping the day of the entry into force of Regulation (EC) 258/97 as a chronological reference in the new legislative framework.¹⁵ On the other hand, the scope of the regime includes only those Novel Foods which fall into one of the ten updated categories.¹⁶ They include not only products derived from the deployment of innovative food technologies, such as nanotechnologies, cell culture or tissue culture, but also products from animals obtained by non-traditional breeding practices. The latter comprises insects¹⁷ and, in the absence of a specific regulation, cloned animals.¹⁸

¹⁵See CJ Judgement (9 June 2005) Joined Cases C-211/03, C-299/03, C-316/03, C-317/03 and C-318/03 *HLH Warenvertriebs GmbH et Orthica BV v. Bundesrepublik Deutschland*, para. 87.

¹⁶Art. 3 (2) of Regulation (EU) 2015/2283: “(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; (ii) food consisting of, isolated from or produced from microorganisms, fungi or algae; (iii) food consisting of, isolated from or produced from material of mineral origin; (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by: traditional propagating practices which have been used for food production within the Union before 15 May 1997; or non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances; (v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union; (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae; (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 as defined in point (f) of this paragraph; (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”. See also CJ Judgement (9 November 2016) Case C-448/14 *Davitas GmbH v. Stadt Aschaffenburg*.

¹⁷See, *inter alia*, Formici (2020) and Bonora (2016).

¹⁸In 2013, the European Commission presented two proposals on cloned animals: Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, COM/2013/0892 final, and Proposal for a Council Directive on the placing on the market of food from animal clones, COM (2013) 893. Both were withdrawn in 2020. See also Scaffardi (2020), pp. 59–63.

2.2 *The Objectives of the Regulation of Novel Foods*

Since 1997, the marketing of Novel Foods within the EU has been subject to specific rules established by the EU legislator to harmonise the differences between national laws relating to Novel Foods or food ingredients. These differences could hinder the free movement of foodstuffs and create conditions of unfair competition, thereby directly affecting the smooth functioning of the internal market.¹⁹ At the same time, the rules adopted aimed to protect public health and safety, guaranteeing the “high level of protection” of human health required by its legal basis in primary law.²⁰ As effectively recognised by the CJEU in *Monsanto v Italy*, the objective of the Novel Food regime is thus twofold: on the one hand, “to ensure the functioning of the internal market in new foodstuffs” and, on the other hand, “to protect public health against the risks to which they may give rise”.²¹

Strictly related to these objectives, Regulation (EU) 2015/2283 added the further dimension of consumer protection, thus aligning it to the fundamental objectives of EU general food law: guaranteeing the safety of food products which reach the table of the European consumer, while preserving their free movement within the EU internal market.²² As has clearly emerged from the parliamentary debates during the approval of Regulation (EU) 2015/2283, however, concerns related to animal health and welfare, the environment, transparency and innovation within the agri-food industry are also relevant in relation to this regulatory framework.²³

In line with these objectives, the placing on the market of new food products is subject to a specific authorisation. In particular, the marketing of Novel Food is allowed only where the food does not pose a safety risk to human health on the basis of the scientific evidence available.²⁴ The assessment of the safety of the Novel Food is clearly based on scientific grounds and, where scientific information is insufficient, inconclusive, or uncertain, the precautionary principle is applied.²⁵ Moreover, when the Novel Food is intended to replace another food and there is a significant change in the nutritional value, the Novel Food’s intended use must not mislead the

¹⁹Regulation (EC) 258/97, esp. Recital 1.

²⁰Art. 114 (3) and 168 (1) TFEU. See also Art. 35 EU Charter of fundamental rights.

²¹CJ Judgement (9 September 2003) Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v. Italy*, para.74.

²²See Art. 1 of 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.

²³See European Parliament, Legislative Resolution of 25 March 2009 on the proposal for a regulation of the European Parliament and of the Council on novel foods, (COM(2007)0872—C6-0027/2008—2008/0002(COD)). Part of the amendments were retained in Recital 2 of Regulation 2015.

²⁴Art. 7 (1) (a) Regulation (EU) 2015/2283. See also Art. 3 Regulation (EC) 258/97.

²⁵See Recital 20 Regulation (EU) 2015/2283. On the notion and application of the precautionary principle, the literature is abundant. See, *inter alia*, de Sadeleer (2006), pp. 139–172; Scott (2005), pp. 50–74; Weimer (2019); Donati (2021); Zander (2010).

consumer nor differ from that other food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.²⁶ Thus, consumers' interests are safeguarded.

3 The Procedure for the Authorisation of Novel Foods

3.1 *The Historical Development of the Authorisation Procedure*

While the requirements for safety and consumer protection and the first component of the definition of Novel Food have remained a constant in EU law, the procedure for their authorisation underwent a radical reform in 2015.²⁷ Regulation (EC) 258/97, which first introduced the authorisation procedures in the regulation of Novel Foods, distinguished between foods or food ingredients “substantially equivalent to existing foods or food ingredients”,²⁸ whose placing on the EU market simply required a notification procedure to the European Commission,²⁹ and other Novel Foods, which were subject to a more articulated authorisation procedure.³⁰ The latter procedure (the so-called ‘ordinary’ procedure)³¹ generally consisted in two phases situated at different levels of governance.³² Pursuant to Article 4 of Regulation (EC) 258/97, the person responsible for placing on the EU market had to submit a request to the Member State in which the product was to be placed on the market for the first time, contextually forwarding a copy of the request to the Commission. Within 3 months, the competent authority of the Member State had to carry out an initial assessment, which was communicated to the European Commission and then forwarded to the other Member States in order to give them the possibility to object to the assessment.³³ Where an additional assessment was deemed necessary or an

²⁶ Article 7 (1) (b) and (c) Regulation 2015. See also Art. 3 Regulation 1997.

²⁷ Santini (2017), p. 640.

²⁸ Article 3 (4) Regulation (EC) 258/97. On the concept of “substantial equivalence”, see Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council, point 3.3.; CJ Judgement (9 September 2003) Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v. Italy*, para.77.

²⁹ Art. 5 Regulation (EC) 258/97.

³⁰ Art. 4 Regulation (EC) 258/97.

³¹ Scaffardi (2020), p. 48.

³² Santini (2017), p. 641. *Contra* Scaffardi who identifies three procedures: the notification procedure, the authorisation procedure before the national authorities and the authorisation procedure before the European Commission, see Scaffardi (2020), p. 48.

³³ For a detailed analysis of the procedure, see *inter alia* Marine (2013), p. 99; Long and Cardonnel (1998), p. 14.

objection was raised, the procedure moved to the European level through the involvement of the Standing Committee for Foodstuffs and the final decision of the Commission.³⁴ As such, the initial procedure represented a typical example of composite administrative procedure³⁵ with remarkably decentralised characteristics.

The application of the regime established in Regulation (EC) 258/97 raised significant conceptual and practical issues.³⁶ Among these shortcomings, the authorisation procedure itself was considered inadequate - being too long, expensive, and non-transparent.³⁷ The financial burden of the application constituted an obstacle to the placing on the market of Novel Foods, especially for small- and medium-size enterprises which could not afford the (often unpredictable) costs of the procedure.³⁸ The procedure generally took more than 3 years³⁹—a duration which discouraged companies from investing in research and innovation.⁴⁰ The reasons behind this situation were probably linked to the lack of binding deadlines for the competent authorities, especially at the European level, and to the multi-level structure of the procedure. In fact, it was often the case that in their initial assessments the national authorities were not able to reach a conclusion on the safety of the Novel Food, and an additional assessment by the European authorities was required.⁴¹ Therefore, the assessment of the product was essentially conducted twice (at the national and then at the European level), consequently doubling the time for the decision.⁴²

With a view to addressing these shortcomings and simplifying the authorisation procedure, as well as taking account of the significant developments in EU law and food technologies, Regulation (EU) 2015/2283 promoted a substantial overhaul of the legislative framework. In particular, it introduced a revised ordinary procedure, meant to be more “efficient, time-limited and transparent” than the previous one,⁴³ together with a new, simplified procedure for the recognition of traditional foods coming from third countries and having a history of safe food use.⁴⁴ Both procedures were put firmly in the hands of the European Commission and the European Food

³⁴ Art. 13 Regulation (EC) 258/97.

³⁵ On the concept of composite procedures, see *inter alia* Hofman (2009).

³⁶ For an overview of the difficulties in the application of the 1997 Regulation and the tortuous path towards the adoption of Regulation (EU) 2015/2283, see Volpato (2015).

³⁷ Marine (2013), p. 104.

³⁸ European Commission, Evaluation Report, p. 6.

³⁹ European Commission, Press memo: Commission Tables Proposals on Animal Cloning and Novel Food, 18/12/2013.

⁴⁰ Van Der Meulen (2009), p. 50.

⁴¹ European Commission, Evaluation Report, p.16.

⁴² Marine (2013), p. 105.

⁴³ Recital 22 Regulation (EU) 2015/2283.

⁴⁴ The procedure for notifying the placing on the market within the Union of a traditional food from a third country is specifically regulated in Article 15 Regulation (EU) 2015/2283. For a detailed analysis of this procedure, see see *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* by L. Scaffardi in this volume.

Safety Authority (EFSA), centralising the powers for assessment and decision on the new applications for Novel Food at the European level.

3.2 *The Procedure for the Authorisation of Novel Foods: The Role of the Commission and EFSA*

The new ‘ordinary’ authorisation procedure can be launched either on the Commission’s initiative or following an application to the Commission by a Member State, a third country, or a natural or legal person who has an interest in placing a new item on the Novel Food market. The application shall contain the administrative and scientific information listed in Article 10 (2) of the Regulation, including scientific evidence demonstrating that the Novel Food does not pose a safety risk to human health.⁴⁵ The application is made available to the Member States without delay and a summary of it (containing in particular the name of the applicant, the name of the Novel Food and the abovementioned scientific evidence) is published on the Commission’s website.⁴⁶ The transparency of the studies on the safety of Novel Foods was recently further enhanced by the specific guarantees established by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain,⁴⁷ which applies also to this procedure as of 27 March 2021.

On receipt of the application, the Commission verifies whether the application falls within the scope of Regulation (EU) 2015/2283 and whether the application fulfils all the requirements.⁴⁸ In the positive case, it can request an opinion from the European Food Safety Authority (EFSA) within 1 month.⁴⁹ Established in 2002 and

⁴⁵ Further application requirements are specified in Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

⁴⁶ See European Commission (2022) Summary of applications and notifications. https://ec.europa.eu/food/safety/novel-food/authorisations/summary-applications-and-notifications_en, last accessed 15 February 2022.

⁴⁷ 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.

⁴⁸ Art. 6 Commission Implementing Regulation (EU) 2017/2469.

⁴⁹ Art. 11 Regulation (EU) 2015/2283. For a detailed analysis of the role of EFSA in the procedure, see *inter alia* Martini *et al.* (2020); Canfora (2016). See also *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza, *Why “New” Foods Are Safe and How They Can Be Assessed* by C. Dall’Asta and *The Safety Assessment of Insects and Products Thereof as Novel Foods in the European Union* by G. Precup, E. Ververis, D. Azzollini, F. Rivero-Pino, P. Zakidou, A. Germini, all in this volume.

located in Parma,⁵⁰ EFSA is one of the most important EU decentralised agencies which support the EU institutions and Member States with the performance of highly specialised tasks of a scientific and technical nature.⁵¹ Although the Commission has discretion on the decision to consult this agency, its involvement in the assessment of a Novel Food complies with the fundamental tenets of EU food policy which, since the White Paper on food safety of 2000, is based on scientific evidence and risk analysis.⁵² According to these principles, the analysis of the risk posed by food products is divided in three phases: risk assessment, risk management, and risk communication.⁵³ While risk management and risk communication are mainly entrusted within the political institutions (*in primis*, the European Commission), the specialised activities related to risk assessment are generally carried out by EFSA and its scientific panels, whose technical and scientific expertise make them adequately equipped for dealing with these issues. The new procedure for the authorisation of Novel Food, hence, reflects more clearly this separation between risk assessment and risk regulation which characterises the fundamental architecture of food policy at the supranational level as it has developed in the last decades.⁵⁴

EFSA shall adopt its opinion within 9 months, which can be extended where additional information is needed from the applicant.⁵⁵ The opinion is forwarded to the Commission, to the Member States and, where applicable, to the applicant. It provides an essential input for the decision of the Commission, which should be based on this opinion, on any relevant provision of Union law (including the precautionary principle), and on ‘any other legitimate factors relevant to the application under consideration.’⁵⁶ The concept of ‘other legitimate factors’ is of particular interest. While irrational fears or other purely emotional reactions (such as the “yuck factor” or “the wisdom of repugnance”)⁵⁷ cannot be considered legitimate factors since they lack the legitimacy generally associated with this notion,⁵⁸ certain non-scientific considerations may be relevant in the risk management phase of the decision. Other legitimate factors can include, for example, societal, economic, traditional, ethical and environmental factors.⁵⁹ Especially in situations where

⁵⁰Regulation (EC) 178/2002.

⁵¹On EU agencies and the phenomenon of agentification of EU administration, see, *inter alia*, Everson et al. (2014), Chamon (2016), Chiti (2002), Tovo (2016) and Alberti (2018).

⁵²See, *inter alia*, Recital 16 of Regulation (EC) 178/2002; Communication from the Commission on the precautionary principle, COM/2000/0001 final. See also Alemanno (2007); Santini (2017), p. 642.

⁵³Art. 3 Regulation (EC) 178/2002.

⁵⁴Santini (2017), p. 642. It is noteworthy that this separation is present also at the international level, see Codex Alimentarius.

⁵⁵Art. 11 Regulation (EU) 2015/2283.

⁵⁶Art. 12 (1) Regulation (EU) 2015/2283.

⁵⁷Kass (1997), p. 217; Jasanoff (2011), p. 634.

⁵⁸Petetin (2019), p. 246.

⁵⁹See, by analogy, Recital 19 of Regulation (EC) 178/2002.

scientific evidence is inconclusive, insufficient or uncertain,⁶⁰ this arguably creates “some real space for the incorporation into decision of values and concerns which go beyond technical and scientific reasons”.⁶¹

In any event, within 7 months from the date of publication of the Authority’s opinion, the Commission drafts an implementing act to be presented to the Standing Committee on Plants, Animals, Food and Feed (PAFF).⁶² This draft implementing act contains the specification of the Novel Food and, where appropriate, the conditions under which the Novel Food may be used. It also includes any additional specific labelling requirements which may be imposed upon its sale in the EU market.⁶³

3.3 *The Procedure for the Authorisation of Novel Foods: The Role of Comitology*

The Standing Committee on Plants, Animals, Food and Feed is part of a highly idiosyncratic system of committees (the so-called comitology system) established under EU law for the adoption of implementing acts according to Article 291 TFEU.⁶⁴ The committees are composed of representatives of Member States and are chaired by the Commission.⁶⁵ The powers and the functioning of the committees depend on the procedure they follow as established by Regulation 182/2011 in relation to the type and relevance of the act to be adopted.⁶⁶

For the adoption of implementing acts concerning Novel Foods the most intrusive and complex procedure is applicable, namely, the examination procedure, which aims to ensure that these implementing acts cannot be adopted by the Commission if they are not in accordance with the opinion of the committee.⁶⁷ According to this procedure, the committee discusses the Commission’s draft and delivers its vote by qualified majority, determined according to the ponderation set forth in the Treaties

⁶⁰ Szajkowska (2010), p. 191.

⁶¹ Lee (2008), p. 83. See also Szajkowska (2012).

⁶² This committee is established by Article 58(1) of Regulation (EC) No 178/2002. The competent section for the adoption of novel food authorisations is the Novel Food and Toxicological Safety section (Comitology register code: C20408).

⁶³ Art. 9 (3) Regulation (EU) 2015/2283.

⁶⁴ Article 291 TFEU. On the historical evolution of comitology, see, *inter alia*, Bergström (2005) and Bianchi (2012).

⁶⁵ The representative of the Commission, however, does not take part in the vote. See Regulation (EU) 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.

⁶⁶ See Art. 2 Regulation (EU) 182/2011.

⁶⁷ Art. 12 (1) Regulation (EU) 2015/2283.

for the adoption of legislative acts by the Council.⁶⁸ The outcome of this vote determines the following steps in the procedure, depending on whether the committee delivers a positive opinion, a negative opinion, or a ‘no opinion’. Where the outcome is a positive opinion, i.e., the qualified majority of Member States’ representatives has approved the draft measure, the Commission is under an obligation to adopt it.⁶⁹ However, as specified in an interinstitutional statement on the adoption of the Comitology Regulation, “this provision does not preclude that the Commission may, as is the current practice, in very exceptional cases, take into consideration new circumstances that have arisen after the vote and decide not to adopt a draft implementing act, after having duly informed the committee and the legislator.”⁷⁰ Therefore, although obliged to adopt the draft implementing act, the Commission exceptionally enjoys a certain margin of discretion where new circumstances arise after the vote.

Where the outcome is a negative opinion, i.e., the qualified majority of Member States’ representatives has opposed the draft text, the Commission is precluded from adopting the implementing act.⁷¹ In this case, the Commission is confronted with three alternatives: either to drop the act, to amend it, or to refer it to the Appeal committee. In the procedure for the authorisation of a Novel Food, where an applicant is expecting a decision on its application, the option of letting the draft implementing act simply drop is not viable. Therefore, in the procedure for the authorisation of a Novel Food the Commission can submit an amended version of the draft implementing act to the same committee within 2 months, hoping for a different outcome to overcome the veto. Otherwise, it can decide to submit the same draft implementing act to the Appeal committee within one month from the negative opinion.

When the outcome is ‘no opinion’, i.e., the committee did not reach a qualified majority either in favour or against the draft implementing measure, the Commission generally “may adopt the draft implementing act.”⁷² This outcome, hence, generally guarantees some discretion to the Commission. However, in the authorisation procedure for Novel Foods, the possibility to adopt the act is expressly precluded to the Commission by Article 30 (3) of Regulation (EU) 2015/2283. The Commission is thus left with the same options applicable in the case of a negative opinion: it can either submit an amended version of that act to the same committee within

⁶⁸ A qualified majority is attained where at least 55% of the members of the Council, comprising at least fifteen of them and representing Member States comprising at least 65% of the population of the Union are in favour. See Art. 16 (4) TEU, referred to in Art. 5(1) Regulation (EU) 182/2011.

⁶⁹ Art. 5(2) Regulation (EU) 182/2011.

⁷⁰ Statement by the European Parliament, the Council, and the Commission on the adoption of the Comitology Regulation, OJ L 55, 28.2.2011, 19.

⁷¹ Art. 5(3) Regulation (EU) 182/2011.

⁷² Art. 5(4) Regulation (EU) 182/2011.

2 months of the vote or submit the draft implementing act within 1 month of the vote to the Appeal committee for further deliberation.⁷³

The submission to the Appeal committee initiates a new phase in the procedure, governed by specific rules. The Appeal committee, which actually represents one of the major innovations of the Regulation 182/2011,⁷⁴ is composed of Member States' representatives who meet "at the appropriate level" of representation.⁷⁵ The underlying idea is that the representatives in the Appeal committee should have "the necessary authority to decide on highly sensitive issues", taking a clear stance on the matter and not leaving discretion to the Commission to decide in case of disagreements in the first phase of the comitology procedure.⁷⁶ In the prevailing practice, the appeal committee is generally composed of members of the Permanent Representation,⁷⁷ who were initially the deputy permanent representatives (thus mirroring the composition of Coreper I) and, more recently, attachés at a lower level.⁷⁸

The voting rules in the Appeal committee follow those established for the examination procedure.⁷⁹ Therefore, also in the case of the appeal committee, the possible outcomes of the vote are threefold, as are their consequences. Firstly, when the Appeal committee delivers a positive opinion, the Commission must adopt the draft implementing measure. Secondly, when the appeal committee delivers a negative opinion, the Commission cannot adopt the measure.⁸⁰ Thirdly, when no opinion is delivered, the Commission has discretion as to whether to adopt or not adopt the draft implementing measure.⁸¹ Considering that the discretion of the Commission in this phase of the procedure is not limited by Article 30 of the Regulation (EU) 2015/2283,⁸² in case of no opinion at the examination committee phase it may be strategically useful for the Commission to refer the matter to the Appeal committee when it expects the same outcome at the higher level.

⁷³ Art. 5 (4) third subparagraph Regulation (EU) 182/2011.

⁷⁴ Christiansen and Dobbels (2013), p. 48.

⁷⁵ Recital 7 and Art. 3 (7) last subparagraph Regulation (EU) 182/2011.

⁷⁶ Corona (2014), p. 100.

⁷⁷ European Commission, Report to the European Parliament and the Council on the Implementation of Regulation (EU) 182/2011, COM(2016) 92 final, p. 5.

⁷⁸ Christiansen and Dobbels (2013), p. 49.

⁷⁹ Art. 6 Regulation (EU) 182/2011.

⁸⁰ This provision is considered problematic since, differently from the previous regime, it entails a definitive stop of the procedure without a clear decision on the matter. See Blumann (2011), p. 18; Bianchi (2013), p. 204.

⁸¹ Art. 6 (3) Regulation (EU) 182/2011.

⁸² The only derogation to the flexibility of this article is the prohibition against adopting the implementing act when definitive multilateral safeguard measures are at stake, see Art. 6-(4) Regulation (EU) 182/2011.

3.4 *The Union List of Authorised Novel Foods and Data Protection*

Once approved through the comitology procedures, the implementing act is adopted by the European Commission and published in the Official Journal. The placing on the EU market of the Novel Food is thus authorised under the specifications, conditions of use, additional specific labelling requirements, or post-market monitoring requirements associated with the authorisation.⁸³ Different from the previous practice, the authorisation is not in the form of a decision with an individual addressee, namely the applicant, but it has general effects. It consists in the inclusion of the relevant Novel Food in the Union List of Authorised Novel Foods.⁸⁴ This list, established by the Commission on 30 December 2017,⁸⁵ contains the 125 Novel Foods authorised under the previous Regulation and the new entries added through the implementing acts resulting from the described procedure.⁸⁶

The establishment of the Union List and the demise of individual authorisations represented an important shift in the regulation of Novel Foods, paving the way for a less burdensome and more extensive production of these products.⁸⁷ Aiming at the simplification and transparency of the system, this major change is intended to favour in particular the small- and medium-sized enterprises since it reduces the unnecessary administrative expenditure and avoids superfluous studies and experiments.⁸⁸ At the same time, however, this system risks penalising the applicant which invested in the development of new food technologies by allowing an undue exploitation of the results by other producers and competitors.⁸⁹ Therefore, in order to stimulate research and development, and consequently innovation within the agri-food industry, Regulation (EU) 2015/2283 sets forth a balanced form of protection of the investment made by the applicants in gathering the information and data provided in support of an application for a Novel Food.⁹⁰

According to Articles 26 and 27, the applicant can request the protection of newly developed scientific evidence and proprietary data provided in support of an application under certain conditions. Where granted, these data cannot be used for the

⁸³ Art. 9 Regulation (EU) 2015/2283.

⁸⁴ Art. 9 Regulation (EU) 2015/2283.

⁸⁵ Commission 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, OJ L 351, 30.12.2017, p. 72–201. The initial list has been repeatedly corrected, most recently by Commission Implementing Regulation (EU) 2022/202 of 14 February 2022 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.

⁸⁶ For a detailed analysis of the Union List, see Haber and Aurich (2018), p. 404.

⁸⁷ *Ibidem*.

⁸⁸ Especially animal testing, see Recital 32 of Regulation (EU) 2015/2283.

⁸⁹ Santini (2017), p. 645.

⁹⁰ Recital 30 Regulation (EU) 2015/2283.

benefit of a subsequent application during a period of five years from the date of the authorisation of the Novel Food without the agreement of the initial applicant.⁹¹ Although on paper this represents a reasonable compromise between the individual protection of the applicant's investment and the general promotion of Novel Foods at larger scale, the current application of these provisions has been strongly criticised as *de facto* impeding effective competition in the market for a significant period of time.⁹²

4 The Centralisation of the Procedure and the Role of the Member States

4.1 *Novel Food Governance in the European Space of Integrated Administration*

From an institutional perspective, the evolution of the legal framework for Novel Foods authorisation—with the described shift from a decentralised to a centralised procedure and with the systematic involvement of EFSA—epitomises significant trends which can be recognised in the overall development of the governance structure of EU law implementation in the last decades. At the same time, it puts into sharp relief the tensions underlying the regulation of controversial policy areas such as those related to risk regulation, where scientific complexities, value judgments, and consumer sensibilities need to be accommodated in the design of the decision-making procedure.

With regard to the centralisation of the procedure, it is important to recognise that its evolution reflects the broader trend towards the progressive emergence of a European space of integrated administration.⁹³ While the EU original governance model was essentially based on the harmonisation of divergent national legislation through the adoption of directives and regulations whose implementation was essentially demanded from national authorities separately (the so-called indirect administration),⁹⁴ the EU integration process led to the increasing development of forms of horizontal recognition of transnational acts, and of mutual cooperation

⁹¹ Art. 26 (1) Regulation (EU) 2015/2283.

⁹² See, *inter alia*, La Porta (2021), esp. p. 47. See also Holle (2014), pp. 280–284. But also, with specific reference to insects-as-food, *Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU* by G. Formici in this volume.

⁹³ *Inter alia*, Hofmann (2009), pp. 24–38; Hofmann *et al.* (2011), pp. 5–11.

⁹⁴ With the exception of certain specific policies, such as competition law, which was already attributed at the European level by the Treaty of Rome. Indirect administration is still the rule, see Article 291 (1) TFEU.

between national authorities.⁹⁵ With the deepening of the internal market, and the consolidation of EU policies towards “an ever closer Union”,⁹⁶ cooperation mechanisms were established not only horizontally between Member States, but also vertically between the European Commission and national authorities, often in the form of procedural linkages between diverse actors and across different levels.⁹⁷ The decentralised composite procedure of Regulation (EC) 258/97 was thus the expression of this particular phase of the EU integration process, characterised by multi-level procedural cooperation among the different actors.

This model of governance has, however, been increasingly dismissed in cases in which the application of EU legislation by national authorities led to persistent inconsistencies and divergences,⁹⁸ also in light of the unsolved issues of effective judicial protection that composite procedures may raise.⁹⁹ As in the case of Novel Foods, the tendency is hence towards the centralisation of the implementing tasks, resulting in forms of direct administration by the European Commission and/or EU agencies.¹⁰⁰ Only recently has this trend perhaps slowed down its pace, with the re-nationalisation of the implementation of certain policies in the name of a more ‘active subsidiarity’.¹⁰¹

With specific regard to the Novel Food authorisation procedure, it was argued that such centralisation of the governance model resulted in the expansion of the powers of EU institutions which, hence, manage to maximise their competences to the detriment of the national authorities.¹⁰² Regulation (EU) 2015/2283 has certainly affected the role of the national authorities which were previously responsible for the assessment of the safety of Novel Foods. The demise of their role and the consequent loss of the expertise acquired in the two decades in which the decentralised procedure was in place was indeed an object of debate during the approval of the Regulation.¹⁰³

Against this backdrop, Article 4 of the Regulation provides for a specific procedure for determination of Novel Food status before the national authorities. Any business operator who is unsure whether or not a food which they intend to place on the market falls within the scope of this Regulation can consult the competent authorities of the Member State where they first intend to place the Novel Food, providing the necessary information for this assessment.¹⁰⁴ The decision on the

⁹⁵ Hofmann (2017), p. 6; De Lucia (2016), p. 245. See also Weiler (1991).

⁹⁶ Art. 1 TEU. See also Petetin (2019), p. 236.

⁹⁷ Hofmann (2017), p. 15.

⁹⁸ De Lucia (2016), pp. 104–105.

⁹⁹ Eliantonio (2015) and Brito Bastos (2018).

¹⁰⁰ De Lucia (2016), pp. 90–114.

¹⁰¹ See, for instance, European Commission, Communication—The Principles of subsidiarity and proportionality: Strengthening their role in EU policymaking, COM(2018) 703 final.

¹⁰² Petetin (2019), p. 236. See also Randour et al. (2014).

¹⁰³ ENVI Committee, First exchange of views on novel foods, 19 March 2014, <http://www.europarl.europa.eu/ep-live/fr/committees/video>, last accessed 20 June 2014.

¹⁰⁴ Art. 4 Regulation (EU) 2015/2283.

Novel Food status of a food is taken by the Member State and communicated to the business, the other Member States, and the Commission.¹⁰⁵ The Commission then makes the information on the Novel Food status publicly available on the Commission's website.¹⁰⁶ Forms of cooperation and information sharing across different levels are thus retained in the new legal framework, blurring the lines of a strict distinction between direct and indirect administration.¹⁰⁷

4.2 *The (Lack of) Tensions Within the Comitology System*

A significant role is maintained by the Member States also within the described comitology procedure which allows them, by qualified majority voting, to oppose the adoption of the Commission's decision. In such a system of intensive interaction between national and supranational representatives, the complex operational rules described ensure the control of the Member States over the exercise of the implementing powers by the Commission, while providing the Commission with the expertise and technical information of experts and national officials working in this field in the Member States.¹⁰⁸

Interestingly, in the approval of Novel Foods Member States have never made use of their veto power against the Commission: all 392 relevant votes of the Standing Committee on Plants, Animals, Food and Feed have resulted in a positive opinion.¹⁰⁹ This is in line with the practice of most comitology committees where positive opinions represent the most common outcome of the procedure, confirming that the comitology system is, also in the field of Novel Foods, a highly consensual

¹⁰⁵ Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

¹⁰⁶ *Ibidem*, Art. 7 (2).

¹⁰⁷ See, *inter alia*, Cassese (2004), pp. 21–36; Della Cananea (2004), pp. 197–218.

¹⁰⁸ In the EU political science literature, there are actually two opposite views of comitology. On the one hand, the idea of “interinstitutional bargaining” according to which comitology is a mechanism of Member State control over the Commission and Member States negotiate in an intergovernmental manner (see, *inter alia*, Steunenberg *et al.* (1994), pp. 329–344; Pollack (2003); Franchino (2000), pp. 155–181; Ballmann *et al.* (2002), pp. 551–574). On the other hand, the idea of “deliberative supranationalism” according to which committees have evolved into forums of discussion among experts, based on persuasion and dialogue (see, *inter alia*, Joerges and Neyer (1997), pp. 273–299; Dehousse (2003), pp. 798–813). See Blom-Hansen and Brandsma (2009), pp. 719–740.

¹⁰⁹ Voting sheet data on the Standing Committee on Plants, Animals, Food and Feed - Novel Food and Toxicological Safety section (Comitology register code: C20408) retrieved from the Comitology Register. <https://ec.europa.eu/transparency/comitology-register/screen/datasets?lang=en>, last accessed 18 February 2022.

exercise.¹¹⁰ However, these data contrast sharply with the ones available on the procedure for authorising a GMO for food or feed, where similar economic, scientific, and societal issues are at stake.

In the authorisation of GMO food and feed, a significant number of comitology procedures result in a ‘no opinion’ scenario before the examination committee and, subsequently, before the Appeal committee.¹¹¹ In fact, the majority of cases tackled by the Appeal committee relate to this controversial area or to the authorisation of plant protection products.¹¹² In these areas, the discretion granted to the Commission in case of a ‘no opinion’ scenario at appeal level is increasingly perceived as problematic since it pushes the Commission to act on politically sensitive matters which have a direct impact on citizens and business, and where the public opinion is strongly polarised, without clear backing from the Member States.¹¹³ Arguably, in recent years the Member States appear to have used this mechanism strategically to abstain from assuming responsibility for controversial decisions before the electorate. For these reasons, in 2017 significant amendments to the comitology system were proposed by the Commission to tackle this issue.¹¹⁴ Should these amendments be adopted by the Parliament and the Council, the rules applicable in the case of no opinion and the correlated balance between the Commission and the Member States would be altered significantly.¹¹⁵

It is thus remarkable that, while in relation to GMO the adoption of decisions through a centralised procedure was perceived to be so controversial that unprecedented amendments to the comitology system were proposed,¹¹⁶ the approval of

¹¹⁰European Commission, Report to the European Parliament and the Council on the Implementation of Regulation (EU) 182/2011, COM(2016) 92 final, p. 2.

¹¹¹See Comitology Register, available at <https://ec.europa.eu/transparency/comitology-register/screen/datasets?lang=en>, last accessed on 18 February 2022.

¹¹²European Commission, Report to the European Parliament and the Council on the Implementation of Regulation (EU) 182/2011, COM(2016) 92 final, p. 6.

¹¹³Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No. 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, COM (2017) 85, p. 3.

¹¹⁴See Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No. 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, COM (2017) 85. In relation to GMO, see also Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM (2015) 177; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Reviewing the decision-making process on genetically modified organisms (GMOs), COM(2015) 176 final.

¹¹⁵For a discussion of the possible implications of the reform, see Volpato (2022), pp. 186–187.

¹¹⁶In relation to GMO cultivation, the trend towards decentralisation is even more clear, as it can be recognised in the introduction of ‘opt out’ clauses by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC regarding the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. See Petetin (2019), p. 242.

Novel Foods did not raise similar tensions between levels of governance. On the one hand, this may be partially explained by the authority enjoyed by EFSA's opinion in the authorisation procedure which, different from the case of plant protection products for instance, has never been called into question.¹¹⁷ In fact, decisions on Novel Food authorisations are systematically aligned to the outcome of the risk assessment, leaving limited room for debate on the non-scientific legitimate factors in risk management.¹¹⁸ On the other hand, the Novel Foods authorised so far have not polarised the public debate to the same extent as GMOs or plant protection products (especially, glyphosate), thus shielding the representatives of the Member States from the pressure of national politics. From the *travaux préparatoires* of the Regulation it could be expected that strong opposition may be raised in relation to edible insects and cloned animals.¹¹⁹ Although Regulation 2015/2283 entered into force in 2018, the first authorisations for edible insects were issued only starting from summer 2021. Apart from this and the authorisation of *stevia*,¹²⁰ it is arguable that the institutional design of the centralised authorisation procedure has thus not yet been put to the test of a significant tension between different governance levels.

5 Conclusions

The regulation of Novel Foods in the internal market inevitably touches a vast array of delicate and conflicting issues, such as innovation and safety in the agri-food sector, sustainability concerns and ethical values, as well as cultural sensibilities and consumer perceptions.¹²¹ Certainly, the growing global population and the consequent food needs urgently require new sustainable solutions for the future of food production, which innovative food technologies and non-traditional breeding techniques may provide. Nevertheless, food safety concerns and societal values need to be taken into account to guarantee a high level of consumer protection and to endow the regulatory approach with legitimacy and transparency. A careful weighing of the divergent interests and values is, therefore, crucial in the design of the substantive and procedural rules applicable in this field.

The EU legislator strove to find this delicate balance, initially with the Regulation (EC) 258/97 which laid down detailed provisions on the definition and the placing into the EU market of Novel Foods, and subsequently with Regulation (EU) 2015/

¹¹⁷ On the glyphosate saga, see *inter alia* Morvillo (2020) and Leonelli (2018).

¹¹⁸ Petetin (2019), pp. 246–249.

¹¹⁹ *Inter alia*, European Parliament, Report on the proposal for a regulation of the European Parliament and of the Council on novel foods (COM(2013)0894 - C7-0487/2013 - 2013/0435 (COD)).

¹²⁰ As reported by Marine (2013), p. 108.

¹²¹ On this point see *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook*, by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

2283 which updated, strengthened and simplified the applicable regulatory framework. This legislative reform purposefully maintained continuity in the main elements of the definition of Novel Food, the regulatory objectives, and the level of food safety to be guaranteed to European consumers. Conversely, it realised a paradigm shift in the structure of the authorisation procedure and in the legal effects of this authorisation, centralising decision-making powers in the hands of the European Commission and establishing the Union list.

While this change from a form of decentralised composite procedure to a clearer expression of direct administration is in line with the general development of EU food law and of the European space of integrated administration, the reform of the procedure entailed a fundamental re-shaping of the reciprocal roles, both of the Member States and their national authorities, and of the European Commission and EFSA. Despite these changes, the practice of Novel Foods authorisation has proven to be less problematic and controversial than what one could have expected in light of the tensions underlying the field, and given the reality of the parallel system of GMO authorisations. This may show that the new procedure has successfully accommodated the tensions between scientific and non-scientific factors (through the clearer distinction between risk assessment and risk management), and between national and European levels. It is, however, undeniable that the new procedure has yet to be tested against truly controversial matters. Considering the importance of the interests at stake for the future of food and feed in Europe, and for the future of our planet, it remains to be seen whether the institutional structure and the governance model adopted in Regulation (EU) 2015/2283 will manage to reconcile differing values and uphold the fundamental tenets of EU food policy.

References

- Alberti J (2018) *Le agenzie dell'Unione Europea*. Giuffrè, Milano
- Alemanno A (2007) The Shaping of the precautionary principle by European Courts: from scientific uncertainty to legal certainty. In: Cuocolo L, Luparia L (eds) *Valori costituzionali e nuove politiche del diritto*. Cahiers Européens, Halley, pp 11–24
- Ballmann A, Epstein A, O'Halloran S (2002) Delegation, comitology and the separation of powers in the European Union. *Int Organ* 56(3):551–574
- Bergström CF (2005) *Comitology. Delegation of powers in the European Union and the comitology system*. Oxford University Press, Oxford
- Bianchi D (2012) *De Comitatus. L'origine et le rôle de la comitologie dans la politique agricole commune*. L'Harmattan, Paris
- Bianchi D (2013) La comitologie dans le droit agroalimentaire: Une procédure complexe au service d'impératifs de participation démocratique et de contrôle étatique. In: Merten-Lentz K, Mahieu S (eds) *Sécurité alimentaire. Nouveaux enjeux et perspectives*. Larcier, Leuven, pp 175–211
- Blom-Hansen J, Brandsma GJ (2009) The EU comitology system: Intergovernmental bargaining and deliberative supranationalism? *J Common Mark Stud* 47:719–740
- Blumann C (2011) Un nouveau départ pour la comitologie. Le règlement n° 182/2011 du 16 février 2011. *Cahiers de Droit Européen* 19:23–52
- Bonora G (2016) I Novel Foods nel Reg. (UE) n. 2015/2283 e gli insetti: una possibile evoluzione dei costumi alimentari? *Rivista di diritto alimentare* 1:42–54

- Brito Bastos F (2018) Derivative illegality in European composite administrative procedures. *Common Mark Law Rev* 55(1):101–134
- Bronckers M, Soopramanien R (2008) The impact of WTO law on European food regulation. *Eur Food Feed Law Rev* 3(6):361–375
- Canfora I (2016) Alimenti, nuovi alimenti e alimenti tradizionali nel mercato dell'Unione europea dopo il regolamento 2015/2283. *Diritto agroalimentare* 1:29–47
- Cassese S (2004) European administrative proceedings. *Law Contemp Prob* 68:21–36
- Chamon M (2016) EU agencies. Legal and political limits to the transformation of the EU administration. Oxford University Press, Oxford
- Chiti E (2002) Le agenzie europee. Unità e decentramento nelle amministrazioni comunitarie. Cedam, Padova
- Christiansen T, Dobbels M (2013) Non-legislative rule making after the Lisbon Treaty: implementing the new system of comitology and delegated acts. *Eur Law J* 19(1):42–56
- Corona D (2014) The adoption of secondary legislation through comitology in the EU: some reflections on the regulation (EU) 182/2011 in comparison with the Pre-Lisbon reform. *Theory Pract Legis* 2:85–107
- De Lucia L (2016) From mutual recognition to EU authorization: a decline of transnational administrative acts. *Italian J Public Law* 8(1):90–114
- De Sadeleer N (2006) The precautionary principle in EC health and environmental law. *Eur Law J* 12(2):139–172
- Dehousse R (2003) Comitology: who watches the watchmen? *J Eur Public Policy* 10:798–813
- Della Cananea G (2004) The European Union's mixed administrative proceedings. *Law Contemp Prob* 68:197–218
- Donati A (2021) Le principe de précaution en droit de l'Union européenne. Bruylant, Brussels
- Downes C (2013) The rise and fall of the new EU novel food regulation: the complex influence of the WTO SPS agreement. *Asian J WTO Int Health Law Policy* 8(1):249–300
- Eliantonio M (2015) Judicial review in an integrated administration: the case of 'composite procedures'. *Rev Eur Admin Law* 7(2):65–102
- Everson M, Monda C, Vos E (2014) European agencies in between institutions and member states. Wolters Kluwer, Alphen aan den Rijn
- Formici G (2020) Novel Food e insetti per il consumo umano tra interventi legislativi e Corte di giustizia: alla ricerca di un difficile equilibrio. *Rivista di Diritto alimentare* 4:48–68
- Franchino F (2000) The Commission's executive discretion. Information and comitology. *J Theor Polit* 12:155–181
- Gormley L (2004) Disturbing or rebalancing powers within the European Union? In: De Zwaan J, Jans J, Nelissen F (eds) *The European Union. An ongoing process of integration*. TMC Asser Press, The Hague, pp 35–52
- Haber B, Aurich S (2018) The Union list of authorised novel foods. *Eur Food Feed Law Rev* 13(5):403–410
- Hofman HCH (2009) Composite procedures in the EU Administrative Law. In: Hofmann HCH, Türk A (eds) *Legal challenges in EU Administrative Law: the move to an integrated administration*. Edward Elgar, Cheltenham, pp 136–167
- Hofmann HCH (2009) Mapping the European Administrative Space. In: Egeberg M, Curtin D (eds) *Towards a new executive order in Europe*. Routledge, Abingdon-on-Thames, pp 24–38
- Hofmann HCH (2017) European Administration: nature and developments of a legal and political space. In: Harlow C, Leino P, della Cananea G (eds) *Research handbook on EU administrative law*. Edward Elgar, Cheltenham, pp 21–43
- Hofmann HCH, Rowe GC, Türk A (2011) *Administrative law and policy of the European Union*. Oxford University Press, Oxford
- Holle M (2014) The protection of proprietary data in novel foods – how to make it work. *Eur Food Feed Law Rev* 9(5):280–284
- Jasanoff S (2011) Constitutional moments in governing science and technology. *Sci Eng Ethics* 17:621–638

- Joerges C, Neyer J (1997) From intergovernmental bargaining to deliberative political processes: the constitutionalisation of comitology. *Eur Law J* 3(3):273–299
- Kass L (1997) The wisdom of repugnance. *The New Republic*, pp. 17–26
- Klaus B (2011) Another attempt at interpretation of the novel food legislation. *Eur Food Feed Law Rev* 6(3):187–192
- La Porta B (2021) Gli insetti edibili alla prova del mercato. Il regolamento di esecuzione (UE) 2021/882 relativo all'immissione in commercio della larva di *Tenebrio molitor* essiccata: criticità. *Rivista di Diritto Alimentare* 15(2):35–51
- Lee M (2008) EU regulation of GMOs: laws and decision-making for new technology. Edward Elgar, Chaltenham
- Leonelli GC (2018) The glyphosate saga and the fading democratic legitimacy of European Union risk regulation. *Maastricht J Eur Comp Law* 25(5):582–606
- Long A, Cardonnel P (1998) Practical implications of the novel foods regulation. *Eur Food Law Rev* 11(1):11–25
- Marine F-P (2013) Les nouveaux aliments. In: Mathieu S, Merten-Lentz K (eds) *Sécurité alimentaire. Nouveaux enjeux et perspectives*. Bruylant, Bruxelles, pp 89–114
- Martini D, Del Bò C, Riso P (2020) Legislazione europea e ruolo di EFSA nella valutazione della sicurezza d'uso dei Novel Foods: principi e prospettive. *BioLaw J* 2:9–23
- Morvillo M (2020) Glyphosate effect: has the glyphosate controversy affected the EU's regulatory epistemology? *Eur J Risk Regul* 11(3):422–435
- Neuwirth RJ (2014) Novel food for thought on law and policymaking in the global creative economy. *Eur J Law Econ* 38:13–50
- Petetin L (2019) Managing novel food technologies and member states' interests. In: Varju M (ed) *Between compliance and particularism*. Springer, Berlin, pp 233–253
- Pollack M (2003) *The engines of European integration*. Oxford University Press, Oxford
- Randour F, Janssens C, Delreux T (2014) The cultivation of genetically modified organisms in the European Union: a necessary trade-off? *J Common Mark Stud* 52:1307–1323
- Salmon N (2009) What's cooking? From GM food to nanofood: regulating risk and trade in Europe. *Environ Law Rev* 11(2):97–115
- Santini A (2017) La revisione della disciplina dei novel foods tra tutela di interessi generali e obiettivi economici. *Il Diritto dell'Unione europea* 3:625–650
- Scaffardi L (2020) I novel food, un futuro ancora da definire. *BioLaw J* 2:43–66
- Scott J (2005) The precautionary principle before the European Courts. In: Macrory R (ed) *Principles in European Environmental Law*. Europa Law Publishing, Zutphen, pp 50–74
- Steunenberg B, Koboldt C, Schmidtchen D (1994) Policymaking, comitology and the balance of power in the European Union. *Int Rev Law Econ* 16:329–344
- Streinz R (1998) The novel foods regulation - a barrier to trade in the international movement of goods? *Eur Food Law Rev* 3:265–289
- Szajkowska A (2010) The impact of the definition of the precautionary principle in EU food law. *Common Mark Law Rev* 47:173–196
- Szajkowska A (2012) *Regulating food law: risk analysis and the precautionary principle as general principles of EU food law*. Wageningen Academic Publishers, Wageningen
- Tovo C (2016) *Le agenzie decentrate dell'Unione Europea*. Editoriale Scientifica, Napoli
- Van Der Meulen B (2009) *Reconciling food law to competitiveness*. Wageningen Academic Publishers, Wageningen
- Volpato A (2015) La riforma del regolamento sui Novel Food: alla ricerca di un impossibile equilibrio? *Rivista di Diritto Alimentare* 4:26–43
- Volpato A (2022) *Delegation of powers in the EU legal system*. Routledge, Abingdon-on-Thames

- Vos E (1997) The rise of committees. *Eur Law J* 3(3):210–229
- Weiler JHH (1991) The transformation of Europe. *Yale Law J* 100:2403–2483
- Weimer M (2019) Risk regulation in the internal market – lessons from agricultural biotechnology. Oxford University Press, Oxford
- Zander J (2010) The application of the precautionary principle in practice. Comparative dimensions. Cambridge University Press, New York

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



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



Lucia Scaffardi

Abstract Since 1997, traditional foods coming from Third Countries and not regularly consumed in the European territory before 1997 are included in the definition of Novel Foods provided by the EC Legislator. This peculiar category of ‘new’ foods has raised significant issues, also at the international level, due to the important and strict link between the marketing of such foods and the promotion of sustainable development. The chapter aims at deeply analysing the legislative debate, as well as the regulatory solutions finally approved by the EU legislator, by highlighting the persistent challenges, paying particular attention to the difficult balance-point determined—or still to be determined—among the free circulation of goods, food safety, food security and sustainability.

Keywords Traditional foods coming from Third Countries · Novel foods · Food security · Sustainable development

1 Introduction

‘New’ and previously unknown foods, deriving from scientific and technological progress or as a direct consequence of an expanding globalisation of trade and markets, are gaining increasing momentum in the European Union (EU). If it is undoubtedly true that food circulation and ‘hybridisation’ of diets and food habits are recurrent in world history—e.g., tomatoes, potatoes, and cocoa, which were not originally part of the European diet and were initially received with diffidence—, it is similarly true that the quantity of ‘Novel Foods’ entering the EU market has greatly increased in recent decades. Fast-paced innovation and the global dimension of

L. Scaffardi (✉)

Department of Law, Politics and International Studies, University of Parma, Parma, Italy

e-mail: lucia.scaffardi@unipr.it

© The Author(s) 2022

L. Scaffardi, G. Formici (eds.), *Novel Foods and Edible Insects in the European Union*, https://doi.org/10.1007/978-3-031-13494-4_3

commercial exchanges, together with a renewed attention for sustainable and healthy products, have had a significant impact on the marketing of new foods,¹ especially in high-income countries.

Notwithstanding the potentialities linked to an expansion of the agri-food market towards innovative products,² the EU legislation concerning new foods remains particularly cautious, paying great attention to the protection of consumer health and the guarantee of a high level of food safety. This ‘precautionary’³ approach, characterising the Novel Food regime since the Regulation dated 1997, takes the form of a stringent prior risk assessment and a long preventive authorisation procedure.⁴ The approach taken with this first legislation thus negatively affected the marketing of Novel Foods in the EU territory, also significantly impacting the commercialisation of traditional foods coming from Third Countries, which represent a peculiar category of Novel Foods according to the definition provided by Reg. (EC) 258/97.⁵

Considered a novelty from the European perspective, but also at the same time part of the ‘food heritage’ of populations outside EU borders, traditional foods have been at the centre of an intense and complex political and regulatory debate at both the international and the EU levels. More specifically, representatives of national food business operators in developing countries interested in exporting their products to the EU accused the European legislator of establishing restrictive rules and barriers to trade, placing a disproportionate and unnecessary burden on business.

The lively debate, present also within the World Trade Organization (WTO), had serious repercussions. The EU legislator was forced to re-think the established balance between the free circulation of goods on the one hand, and food safety on the other, also with regard to the effects and proportionality of the European ‘preventive’ approach impacting Third Country food producers. The legislative reform process of the Novel Foods Regulation consequently represented an opportunity for EU regulators to evaluate the strict links among the circulation of goods, sustainable development, and food (in)security. Indeed, the marketing of traditional foods has been an important source of income for poor and middle-income communities in Latin America, Asia or Africa, representing a way to prompt environmentally but also socially sustainable methods of production through the valorisation of traditions and the promotion of social inclusion in rural areas. This complex relationship therefore reveals the paramount importance of correctly understanding the

¹Hermann (2009) and Meybeck and Gitz (2017).

²See, on this point, *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume.

³Van der Meulen et al. (2010), p. 1.

⁴These characteristics will be better explained in the next sections of this chapter. For an in-depth analysis of the current EU Novel Foods Regulation, see *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, by A. Volpato in this volume.

⁵Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

difficulties faced during the long legislative debate that led to the approval, in 2015, of Reg. (EU) 2015/2283.⁶

With the aim of shedding light on the persistent issues and shortcomings of the European Novel Foods legislation that regulates traditional food marketing today, the present chapter intends to provide a brief overview of two key concepts, recurrent in the whole Volume, and crucial for an informed understanding of the challenges at stake: sustainable development and food security (Sect. 2). This will be followed by an analysis of the previously in-force Reg. (CE) 258/97, its effects, and the criticalities that have emerged in the international arena (Sect. 3). The chapter concludes with an examination of the regulatory evolution in the EU context, paying specific attention to the improvements that have been introduced so far, as well as the remaining shortcomings and possibilities for future development (Sect. 4).

2 A Preliminary Analysis of Two Key Concepts: Sustainable Development and Food (In)Security

The world is currently facing crucial challenges destined to produce effects on present and—especially—future generations: the often reckless consumption and waste of non-renewable resources⁷ and the closely related climate changes⁸ are at the very basis of the current dramatic energy crisis,⁹ which is destined to profoundly affect not only the economy of both so-called Developed and Developing Countries, but also many aspects of daily human life, from housing to transport, from work to the food system.¹⁰

In the face of these urgent issues and their detrimental consequences, the call for sustainable solutions has increased in recent years, putting sustainable development at the centre of a lively economic and political debate, at different yet fundamental regulatory levels: international, European, national, and sub-national. But the concept of ‘sustainable development’ remains difficult to define concretely, implement in policies, and manage politically,¹¹ especially when applied to the food sector.¹²

⁶Regulation (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) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

⁷On the strict relationship between exhaustible resources and economic growth, see Dasgupta and Heal (2011).

⁸Siegmann (2021).

⁹Von Homeyer et al. (2021) and Maris and Flouros (2021).

¹⁰Flood et al. (2022).

¹¹For an extensive analysis of sustainable development, see Atkinson et al. (2014) as well as Atapattu et al. (2021) on environmental sustainability.

¹²Banterle et al. (2018).

More generally, sustainable development has been notably described in the 1987 Brundtland Report titled “Our Common Future” as, “development that meets the needs of the present without compromising the ability of future generations to meet their own needs. (...) In essence, sustainable development is a process of change in which the exploitation of resources, the direction of investments, the orientation of technological development and institutional change are all in harmony and enhance both current and future potential to meet human needs and aspirations.”¹³ After more than two decades during which political and academic attention to this principle gained ever more momentum—even if with limited concrete results¹⁴—the United Nations (UN) General Assembly adopted in 2015 the so-called 2030 Agenda for Sustainable Development, also elaborating 17 Sustainable Development Goals (SDGs).¹⁵ This document is considered a milestone, providing a comprehensive, integrated strategy and objectives intended to prompt the international community into “achieving sustainable development in its three dimensions—economic, social and environmental—in a balanced and integrated manner.”¹⁶ This tripartite composition is usually depicted as three intersecting circles with ‘sustainable development’ in the central intersecting area. In this view, ‘sustainability’ is seen as the reconciliation of economic development with social and environmental issues. It includes the promotion of growth that nullifies or limits any possible negative impacts on the environment, such as climate change deriving from human activities.¹⁷ Societal impact, for example the effects of economic growth on respect for human rights, workers’ rights, and access to welfare services, is also considered.¹⁸ This vision has broadly inspired the ‘institutionalisation path’ of the sustainable development concept, which has also been recognised by the European Union legislator: Art. 3, para. 3 of the Treaty on European Union explicitly refers to sustainable development as a common objective, considered as “based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment.”¹⁹

Notwithstanding the critiques levied on such a broad principle, which has often fallen short of having any operative repercussions for regulatory choices and policies,²⁰ sustainable development has been identified, especially in recent decades, as a

¹³Report of the World Commission on Environment and Development “Our Common Future”, available at <https://sustainabledevelopment.un.org/content/documents/5987our-common-future.pdf>, last accessed 15 February 2022.

¹⁴As underlined by many critical studies, among which see Lafferty (2004).

¹⁵United Nations (2015a, b).

¹⁶*Ibidem*.

¹⁷Saija and Salomone (2014). Specifically on the environmental impact of food systems and agriculture with reference to greenhouse gas emissions and other produced effects on natural resources, see Crippa et al. (2021) and FAO (2021).

¹⁸Davico (2004).

¹⁹Humphreys (2017) and Violini (2019).

²⁰Purvis et al. (2019).

key concept to be placed at the centre of current political decisions and strategies which must not ignore the needs of future generations²¹ and should bring to bear the duties of present generations.²²

As a consequence, ‘sustainability’ has assumed paramount importance also in the determination of food strategies and policies, becoming an essential paradigm for facing critical issues and challenges related to the functioning of food systems. It comes as no surprise that the UN SGDs recognized the access to safe, nutritious, and sufficient food for all people as a fundamental target (Target 2.1.), together with the eradication of all forms of malnutrition (Target 2.2.). This document therefore clearly affirms the urgent necessity to defeat hunger and ensure food access for all in order to achieve a real and concrete ‘sustainable development.’²³ The ambitious aim of “peace and prosperity for people and the planet, now and into the future”²⁴ could, consequently, also be reached through the guarantee of food security, which represents a second key concept of this Volume.

Differently from food safety,²⁵ food security is defined as the situation that emerges “when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life.”²⁶ This ambitious concept has lately been specified by the Food and Agriculture Organization of the United Nations (FAO), who identified four dimensions of food security: availability, access, utilization, and the stability of the other three dimensions over time. The document states that, “food availability addresses the ‘the supply side’ of food security and is determined by the level of food production, stock levels and net trade,” utilisation, and “the way the body makes the most of various nutrients in the food.” The concept of stability aims at underlining that “even if your food intake is adequate today, you are still considered to be food insecure if you have inadequate access to food on a periodic basis, risking a deterioration of your nutritional status.”²⁷

²¹ For a vast analysis of the legal concept of ‘future generations’, see D’Aloia (2016) and Bifulco and D’Aloia (2008).

²² Pantalone (2021) and Cerrina Feroni et al. (2016).

²³ As affirmed by the UN, also during the Food Systems Summit of 2021, “sustainable food systems don’t just help to end hunger. They can help the world achieve critical progress on all 17 Sustainable Development Goals”, <https://www.un.org/en/food-systems-summit/sdgs>, last accessed 15 February 2022.

²⁴ United Nations (2015a, b).

²⁵ Food safety guarantees consumer health through all the food system phases, from the handling to the preparation and storage of foods, in order to prevent food-related illnesses and harms to consumer health. For the distinction between food safety and food security and the rising importance of the latter in recent years, see Costato (2011), Bolognini (2013), Ramajoli (2015) and Giuffrida (2015).

²⁶ This widely recognized definition of food security has been provided by the World Food Summit in the 1996 “Plan of Action”.

²⁷ FAO (2008).

The complexity that emerges from such a composite meaning of food security prompts us to think about the comprehensive and articulated actions and guarantees necessary to ensure adequate, sufficient, and nutritious food for all in a stable way. The present situation, characterised by extreme weather events such as drought or floods—but also the pandemic²⁸ and the Ukrainian war²⁹—severely impacts the capability of the current food system to ensure food security all over the world.³⁰ The fight against food insecurity has thus become one of the most urgent challenges present generations are called to face.³¹ In order to do so, food security must be read together with—or better, as part of—the attainment of sustainable development:³² famine, malnutrition and hunger cannot be overcome only by looking at present day necessities but must also consider the needs of future generations. Consequently, the promotion of a sustainable food system assumes paramount importance for the creation of a food-chain that encompasses all the different phases of food production: from agriculture, to transformation, from transport to retailing. Such a system must, at the same time, be resilient to climate changes and able to limit its effects on the environment and on natural resources. It must also promote economic and social sustainability by protecting rural communities' rights, workers' fundamental rights, and by furthering equality and non-discrimination.

The European Union legislator has been called to tackle these issues and to implement a regulatory framework that considers all the intertwined dimensions and profiles of sustainability and food security.³³ In this context, finding a reasonable balance between market needs and adequate food safety and food security has proved difficult, as seen in the challenges presented by the approval of the Novel Food Regulation(s), in recent decades. Facing the need to regulate these unusual foods, which can make important contributions to the enhancement of a more sustainable food system,³⁴ EU Institutions have had to consider all the key concepts here analysed, recognising that a more food safety-oriented legislation could significantly affect the achievement of food security as well as of sustainability goals. This delicate aspect, highlighted in the pages of this Volume, appears with more strength and emphasis with reference to a peculiar category of Novel Foods: traditional foods coming from Third Countries.

²⁸FAO (2020) and Albisinni (2021).

²⁹World Food Programme (2022).

³⁰Elver (2021) and UN Special Rapporteur on the Right to Food (2021).

³¹FAO, IFAD, UNICEF, WFP, WHO (2021).

³²Iannarelli (2015).

³³The 'EU Green Deal' and the 'From Farm to Fork Strategy', already mentioned in the Introduction to this Volume, are clear examples of the attention paid by the EU Institutions to sustainability and food security in the food sector, intended in an integrated way.

³⁴For an in-depth analysis on the relationship between food security and Novel Foods, see *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume.

3 How Novel Foods Regulation (EC) 258/97 Affected the Marketing of Traditional Foods Coming from Third Countries: Criticalities and Concerns Expressed in the International Arena

As already analysed in the previous chapter,³⁵ according to the first Novel Foods legislation adopted by the European Community back in 1997, a food was considered ‘new’ when it met both these conditions: (1) the food has not been used for human consumption to a significant degree within the Community before the entry into force of the Regulation (15 May 1997); (2) it falls under one of the categories expressly listed in Art. 1, para. 2.³⁶ This definition consequently imposes the qualification as Novel Foods (as per Reg. 258/97/EC) of not only ‘innovative’ foods, inexistent before 1997 and resulting from scientific and technological processes—such as intentionally modified foods or foods with new molecular structures or based on engineered nanomaterials—but also ‘traditional foods’ coming from Third Countries. This term refers to food that, despite being habitually eaten outside the EU territory—and therefore part of the traditional diets of Third Country populations—were absent from the EU food market in 1997. This category thus includes, for example, chia seeds, noni fruit juice, exotic fruits, herbs and nuts, some kinds of tea leaf and, in some cases, also insects.³⁷

As a result, traditional foods coming from outside the EU have had to undergo the same authorisation procedure required for ‘new’ foods considered *strictu sensu* because the history of safe use in Third Countries was not sufficient to exclude—or limit—the prior (expensive and complex) approval path. As clearly synthesized by Hyde et al., “if an applicant can demonstrate that food has a history of use within

³⁵See in particular *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, by A. Volpato in this volume.

³⁶“a) Foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC; b) foods and food ingredients produced from, but not containing, genetically modified organisms; c) foods and food ingredients with a new or intentionally modified primary molecular structure; d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances,” Art. 1, para. 2, Reg. 258/97/EC. It is important to stress that foods deriving from or containing genetically modified organisms (GMOs), despite initial inclusion in the definition of ‘Novel Food,’ were subsequently excluded from the scope of application of Reg. 258/97/CE: in 2003 the European legislator decided to specifically discipline this highly debated category of foods by dedicating to them an *ad hoc* legislative provision (Reg. EC/1829/2003).

³⁷On this point, specifically see *Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU* by G. Formici in this volume.

the EU prior to 1997, the food will not require authorisation. However, foods with history of use outside the EU require authorisation and must therefore go through the regulatory process.”³⁸ The EU legislator’s choice to absorb traditional foods coming from Third Countries into the definition of Novel Foods is the direct product of the particularly ‘relativist’ European approach, that considers the ‘novelty’ of a product by adopting a specific—and, in this sense, ‘limited’—European perspective. This regulatory decision appeared consistent with the premarket approval scheme itself, aimed at safeguarding and ensuring a high level of food safety in the EU: “the European legislator seems to work from the presumption that conventional foods, that is to say foods that have a tradition of use in the EU, can be considered safe unless new scientific findings indicate otherwise. (..) For other products, that is products that are in some way artificial or new, the safety must be proven before they may come to the market.”³⁹ Following this approach, the 1997 Regulation therefore did not properly consider the fact that traditional foods were part of a Third Country ‘food heritage’, so that no *ad hoc* authorisation procedures were determined for traditional foods coming from outside the EU: food producers interested in marketing this category of Novel Food were then obliged to follow the unique process established by the Regulation and characterised by a ‘precautionary’ scheme that “structurally shifts the burden of proof from authorities to businesses.”⁴⁰ Moving from this consideration, if the pursued purpose was only to admit in the EU market new products assessed and proven to be safe for consumers, a specific technical and scientific dossier was considered proportionate and necessary to provide useful studies that could demonstrate the lack of danger to human health as well as the safety of the product.

But the expensive studies and documents required to submit an application only represented the first step of a long and articulated procedure,⁴¹ complicated by the lack of a centralised authorisation process. The complexity of the described authorisation process significantly limited the marketing of new foods in the EU territory: according to the ‘Briefing paper – Economic impact assessment of the way in which the EU Novel Food regulatory approval procedures affect the EU food sector,’ published in 2007 by Brookes for the Confederation of the food and drink industries of the EU and the Platform for ingredients in Europe, the estimated time necessary to obtain a Novel Food authorisation was identified as thirty-five months on average, while the costs required to meet all the regulatory requirements—including the

³⁸Hyde et al. (2017), p. 481.

³⁹Van der Meulen and Van der Velde (2008), p. 271.

⁴⁰Van der Meulen et al. (2010), p. 1.

⁴¹The single national authority to which the application has been presented, had 90 days to evaluate the application and analyse the food safety information and studies presented by the food business operator. The results of such initial assessment would be followed by EFSA’s intervention if an additional risk assessment by the European Authority was considered necessary. Other Member States were also allowed to propose reasoned objections to the decision taken by the competent national authority, thus creating a very complex procedure, in which multiple actors were called to intervene, in the absence of a centralised and homogeneous risk assessment.

research and development costs necessary to produce the studies for the application—were estimated between 0.3 and 0.75 million per Novel Food application.⁴² Moreover, as revealed in a study elaborated by the European Parliamentary Research Service, another relevant disincentive to Novel Food marketing in the EU was the limited “predictability of the process. Uncertainty as to the successful outcome of the process was more of a problem for smaller companies who could only rely on a small range of products, as opposed to larger companies that have the capacity to absorb these uncertainties.”⁴³ ‘Grey areas’, legal doubts and opacities were mainly due to the inconsistent approaches and interpretations of the national authorities. These made it so that cost, time, and approval rate—i.e., the probability of success and the seriousness of the evaluation analysis taken by the national authorities—significantly differed according to the Member State in which the application was submitted.⁴⁴ As a consequence, only well established and economically solid food producers were able to afford the long and expensive path imposed by the European legislation. Small and mid-sized enterprises were usually less likely to invest in new foods products, often considering the costs to be unacceptable when compared to the merely uncertain future profits. The European authorisation procedure thus discouraged innovation in the food field, as clearly demonstrated by the minimal number of applications presented until 2008: “around 7-10 applications were submitted per year. It seems impossible to assess the real size of the novel food market because of its diversity (covering many different products) as well as confidentiality policies and intellectual property rights issues. However, given the market potential in Europe and the high level of innovation in the food industry, this number has to be considered very low.”⁴⁵ In other words, “although the regulation still achieves the key goals of protecting public health and protecting the internal market by subjecting novel foods to a single safety assessment, few would disagree that the system is too lengthy and cumbersome and it is outdated because it relies on risk assessments by multiple national authorities rather than a single centralized assessment by the EFSA.”⁴⁶

⁴²Brookes (2007).

⁴³European Parliamentary Research Service (EPRS) (2014), p. 34.

⁴⁴These inconsistent approaches also led to profound differences between Member States’ involvement in the authorisation procedure, with a higher percentage of applications submitted in front of national authorities in the Northern EU Member State—such as UK and The Netherlands—where the administrative costs were usually lower and the application’s results more favourable than in the rest of the EU. On this point, see DG Sanco (European Commission) (2008), Scarpa and Dalfrà (2008) and Verhagen et al. (2009).

⁴⁵Szajkowska (2012), p. 73. One of the most dangerous consequences of such a complex and inefficient procedure is the high number of new products marketed without a prior authorisation, as registered in 2018 (before the entry into force of the current Novel Foods Regulation) by the Rapid Alert System for Food and Feed (RASFF), the European system for urgent notification signalling the presence of non-authorised food and feed in the EU territory. For more information, see RASFF, 2017 annual report, https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2017.pdf, last accessed 15 February 2022.

⁴⁶Jones (2012), p. 82.

All the above analysed criticalities and shortcomings caused by Reg. (EC) 258/97 have strongly affected the marketing of traditional foods coming from Third countries. This particular category of Novel Foods, as described at the beginning of this Section, suffered acutely the weaknesses and failures characterising the European legislation, resulting in a ‘marginalisation’⁴⁷ of Novel Foods’ producers from developing or under-developed Countries. Limited economic resources, lack of technical and scientific expertise, and the need for peer-reviewed studies elaborated by qualified authorities and experts to document the food safety of the product made it almost impossible for small and mid-sized farmers and food business operators in African, Latin American or Asian countries to bear the costs of an authorisation submission compliant with the EU Novel Foods Regulation. Beyond producing a mere economic effect, these concrete obstacles have seriously impacted the promotion and implementation of sustainable food systems in already disadvantaged areas of the world. The production and marketing of traditional foods such as exotic fruits or tea leaves, represented—and still represents—a precious source of ‘sustainable income’ for rural communities in the global South. Traditional foods in this sense can foster social inclusion among small communities and provide fair work and equitable contractual conditions for peasants, thus avoiding exploitation, discrimination, and inequality, and thereby strengthening the support for the guarantee of fundamental rights. Traditional food production systems are typically more respectful of the environment and of biodiversity since the production methods traditionally employed by rural communities are usually more attentive to the preservation of natural resources. In short, the opportunity to commercialise traditional foods in wealthy markets, such as that of the European Union, could be an instrument for the achievement of the SDGs clearly established by the UN, by alleviating poverty without dismantling or exploiting rural communities who are already grounded in more environmentally sustainable practices.

Confirming the close link between the commercialisation in the EU territory of traditional foods coming from Third Countries and the social, economic, and environmental sustainable development of small and mid-size enterprises or communities in Africa, Asia and Latin America, donors and Non-Governmental Organizations (NGOs) as well as governmental authorities have paid particular attention to the promotion in under-developed areas of projects and activities aimed at fostering traditional food production and trade.⁴⁸ In this context, it comes as no surprise that under Novel Foods Regulation (EC) 258/97, governmental and non-governmental organisations have decided in several cases to support small businesses preparing the complex and expensive application dossiers required by the European legislation. Hermann’s study reported, for example, that the authorisation of Baobab fruit pulp as a Novel Food in the EU was possible only because Phytotrade was supported by a fifty-five-member consortium which presented all the complex documents required by the EU provisions. Similarly, “Unilever submitted

⁴⁷Hyde et al. (2017), p. 480.

⁴⁸Hermann (2009).

the application in the context of the Novella Africa Partnership, a ‘textbook’ public-private partnership involving overseas development donors, the World Agroforestry Centre, the World Conservation Union, NGOs, local communities, and the private sector. Motivated by the lesser ecological footprint of allanblackia oil vis-à-vis its substitutes (e.g., palm oil) and recognizing the commercial potential of allanblackia seed oil in the global food market, this partnership seeks to assist allanblackia producers in five Sub-Saharan countries with improving supply and market access.⁴⁹ The application of another traditional food, the noni fruit historically used in Polynesia, was made possible only because of the interest manifested by a big US company, Morinda Inc., which bore the costs of two different submissions: one for the juice deriving from this product and one for the leaves. Thanks to this application, several other smaller companies, based both in the EU and abroad, were able to commercialise this Novel Food by activating the so called ‘substantial equivalence’ simplified procedure established by Reg. (CE) 258/9. Indeed, according to that legislation, the authorisation’s effect was only nominative, meaning that it was referred only to the applicant’s specific product and not to the Novel Food *per se*; once a Novel Food was authorised, it was nonetheless possible for other business operators interested in commercialising the same Novel Food to market it following a faster and more affordable procedure: the dossier to be submitted was only required to contain data and information demonstrating the ‘substantial equivalence’ of the product with another already authorised Novel Food. Although the payment of application costs and the preparation of the scientific dossier proving the equivalence to marketed new foods were mandatory, the simplified ‘equivalence’ procedure surely helped the diffusion of already authorised traditional food products coming from Third Countries.

Even so, these positive results could not be considered a definitive solution to the severe impact the Novel Food Regulation has produced on the marketing of foods already part of Third Countries’ food heritage: on the contrary, with reference to this peculiar category of Novel Foods, the difficulties that have emerged from the European pre-market approval requirement have begun to be strongly opposed by developing countries, who were particularly worried about the economic and also social impacts of the restrictive authorisation procedure imposed by Reg. (CE) 258/97. Specifically, this legislation has been considered an illegitimate ‘non-tariff’ barrier to trade: Government representatives and private stakeholders have denounced how “barring export of traditional foods (..) has negative effects on trade relations between the EU and Developing Countries. It restricts the use of some countries’ comparative advantage—their rich natural biodiversity. It also works against economic development efforts that focus on expanding trade opportunities for local exporters who need these opportunities to improve the socio-economic position of poor and very poor groups. Reducing such opportunities may result in increased illicit activities—for example, production of coca leaves or unsustainable exploitation of forests. Non-tariff trade barriers also appear

⁴⁹The same happened for the allanblackia seeds: Hermann (2009), p. 504.

to contravene World Trade Organization (WTO) trade objectives.”⁵⁰ These accusations were designed to provoke a profound legislative reform of the European regulatory scheme by introducing different procedural requirements for traditional foods coming from Third Countries. More specifically, some developing countries considered it manifestly disproportionate and unreasonable to subject both foods considered ‘innovative’—thus ‘new’ because previously unknown or not used as foods for human consumption—and foods already consumed by different populations outside the EU territory to the same authorisation process. While the former raised concerns related to the guarantee of food safety and consumer protection, the latter did not present the same risk level, given their inclusion in other populations’ diets. Considering these fundamental differences, developing countries have required the EU legislator to diversify the burden of proof imposed on the food producer. From this perspective, the potential dangers the EU sought to avoid by establishing a prior risk assessment procedure seemed to be insufficient to justify undifferentiated processes and requirements for both ‘new’ and ‘traditional’ Novel Foods.

Faced with the inaction of EU Institutions, unable to find a compromise over the approval of a revised Novel Food legislation,⁵¹ Peru and other Latin America Countries expressed their concerns about the legitimacy of Reg. (EC) 258/97 through a communication to the WTO, specifically to the Committee on Sanitary and Phytosanitary measures. The obligations deriving from the so-called Sanitary and Phytosanitary Agreement (SPS Agreement)⁵² established some limits on the States’ discretionary power to adopt measures necessary to protect human, animal or plant life and health. This kind of provision, having a strong impact on the free circulation of goods and free trade, could not be applied “in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.” In other words, measures resulting in a barrier to trade must: (a) be limited to what is strictly necessary to guarantee health and consumer protection; (b) be based on scientific principles and evidence (Art. 2.2); (c) be based on the use of appropriate risk assessment techniques; (d) minimise negative trade effects by imposing only what is proportionate and necessary to the pursued objective (Arts. 5.1, 5.4, 5.6). Considering these rigid requirements, the Peruvian Government—while still recognising the legitimacy of the prior risk assessment scheme established by the EU legislation—contested as excessive and disproportionate the complex procedure and the documents/proofs required of traditional foods. The history of safe use and habitual consumption of traditional foods in non-European diets should not be ignored but rather properly considered in order to lower the level of controls and

⁵⁰UNCTAD (2013).

⁵¹For more information on this point, see the analysis described in the next Paragraph, but also Scaffardi (2020b).

⁵²Agreement on the Application of Sanitary and Phytosanitary Measures entered into force with the establishment of the World Trade Organization on 1 January 1995.

risk assessment evaluations required.⁵³ Moreover, Peru underlined how “implementation of the Regulation also has adverse social effects such as disincentives to the development of promising economic activities, increased cultivation of illicit crops for economic ends, failure to contribute improving the health of the world as a whole through the consumption of traditional foods with a high nutritional value and a decline in the income of poorest sectors of the population.” This serves as confirmation of the above analysed strict link between sustainable development and the promotion, production, and marketing of traditional foods in developing countries characterised by rich biodiversity and natural resources. It also seeks the protection of poor rural communities whose economic growth is mainly dependent upon the export of agricultural and food products. At the end of the examined communication, Peru “reiterates its request to the EU not to include traditional products in the novel foods category, and deems that a distinction needs to be drawn between foods and ingredients that are new in the strict sense and those that are new only to the EU.”⁵⁴ Similar considerations were also shared by scholars, who have begun to underline the importance of a legislative reform able to consider “the proposal’s likely consequences on developing countries and (..) how alternative measures will affect both food safety and the developing countries. And lastly, the European Community should strengthen its provision of development assistance to enable the developing countries to comply with the food safety standards.”⁵⁵

While affirming the need to seriously consider the concerns expressed by several countries before international institutions, the European Commission considered that the compliance of the European regulatory measures needed to be evaluated according to the requirements and conditions established by the Technical Barriers to Trade Agreement (so called TBT Agreement) and not the SPS Agreement, as affirmed by the Peruvian Government. The Novel Food Regulation disciplined the registration, identification, and labelling requirements affecting ‘new’ products, so that it could not be considered to directly respond to food safety purposes specifically regulated by the SPS Agreement.

⁵³ Communication from Peru to the WTO, regarding the Regulation 258/97 of the European Parliament and of the Council on Novel Foods, G/SPS/GEN/1087, 7 June 2011.

⁵⁴ *Ibidem*. Interestingly, “the representatives of Bolivia, Brazil, Colombia, Ecuador, India, Paraguay and the Philippines shared the concerns raised by Peru. The representative of Ecuador indicated that a study on the impact of the novel food regulation was about to be finalised. Preliminary results of this study showed that this regulation could have negative economic and social consequences for Ecuador’s production system by having an effect both on current exports and on products with export potential in the European Communities that were currently marketed in other countries (G/SPS/GEN/714). The representatives of Bolivia and Colombia highlighted that some of the products were currently being promoted inter alia by policies supporting alternatives to narcotic crops, some of which were funded by the European Communities or its member States,” WTO (2006).

⁵⁵ Broberg (2009), p. 2. See also Lahteenmaki-Uutela (2007) and Guzman (2012).

Without lingering on the details of these ‘formal’ and ‘technical’ aspects, mainly pertaining to the international law field,⁵⁶ what seems relevant is the practical and ‘substantial’ result of the debate opened in the international arena and prompted by developing countries. Despite the real opportunity—and possibility or legitimacy—to activate formal charges against the EU based on the SPS Agreement’s provisions, the evident merits of Peru’s intervention, followed by other interested governments, lay in the precipitation of a serious discussion on the proportionality of the risk assessment measures implemented by the European legislation. Indeed, the urgent necessity to reform the 1997 Regulation became even clearer when considering the consequences of a high level of food safety protection and ‘preventive’ approach on the attainment of sustainability goals in those developing countries interested in fostering the commercialisation of traditional foods as an instrument to boost economic, social, and environmentally sustainable development. As we will see in the next paragraph, the concerns raised before the WTO acted as a ‘leverage’ on European Institutions and, specifically, on the revision of Novel Food Regulation, which was begun in 2013 after the first reform proposal failed in 2011. This renewed attempt by the European authorities, intended to confront and solve the denounced shortcomings of the 1997 legislation, made it unnecessary for developing countries to activate a formal complaint against EU: “notwithstanding the tenuous basis of the legal arguments, the number of countries voicing complaints and the frequency of comments created a dynamic for regulatory change to which the European Commission felt compelled to respond.”⁵⁷

4 The EU Legislator’s Recognition of the Specificities of Traditional Foods Coming from Third Countries: Significant Improvements and Persistent Issues

The serious shortcomings and criticalities derived from the 1997 Novel Food Regulation and signalled by food producers, Third Countries, consumers, and scholars, prompted the European Institutions to rediscuss the established balance between food safety, innovation, free circulation of goods, and sustainability. Such a pressing need was considered even more compelling starting from 2003, when foods containing or deriving from Genetically Modified Organisms (GMOs) were removed from the Novel Food definition and regulated in a specific legislation. This decision “led to concerns that the Novel Food Regulation imposed too high a

⁵⁶“Aspects of the Novel Food Regulation’s operation may be found to fall short of the procedural disciplines envisaged in the SPS Agreement; yet more fundamental complaints, raised by third countries challenging the overall subjection of traditional food to pre-market approval, find little textual support,” Downes (2013), p. 265, but also Argese (2016).

⁵⁷Downes (2013), p. 267.

level of scrutiny on foods that were not as risky as the GM foods that the drafters intended to target at the beginning”.⁵⁸

In this complex context, the Commission decided to initiate a public consultation, started in 2002 and finished in 2006, and to finally adopt, in January 2008, a proposal to revise the Novel Foods provisions.⁵⁹ Notwithstanding the highly awaited reform and the importance, highlighted by the stakeholders participating in the consultation, to speed up the legislative procedure,⁶⁰ the Council, the European Parliament and the Commission took, during the reform process, irreconcilable positions that even the Conciliation Committee was unable to resolve. Not surprisingly, the most contentious issues leading to the failure of this first proposal revision involved debated ethical topics, such as the provisions regarding foods derived from cloned animals⁶¹ or engineered nanomaterials. With respect to traditional foods coming from Third Countries, the 2008 revised text represented a first serious attempt to face the charges and drawbacks that had emerged from the 1997 Regulation: in particular, the Commission proposed the introduction of a simplified notification procedure by eliminating the previously required expensive and time-consuming toxicological data and dossiers, so that ‘compositional data’ and ‘evidence of use-data’ were considered sufficient. But, on this specific point, Member States, the Council, as well as EFSA expressed serious doubts, so that the faster and easier procedure for traditional foods coming from outside the EU became one of the most disputed and delicate issues.⁶² The ‘friction’ between different stakeholders and the food safety concerns were put at the centre of the legislative debate, leading to significant modifications of the initial proposal. After the first reading before the European Parliament, the notification process for traditional foods was replaced by a normal authorisation procedure characterised by the introduction of provisions aimed at speeding up the different authorisation phases. Consequently, what emerged from the legislative discussion was a new balance point between different needs: in particular, a faster process was considered a proper solution for traditional foods coming from Third Countries.

As already underlined, this first attempt failed due to the incompatible positions expressed by the multiple legislative actors on delicate aspects of the Novel Foods

⁵⁸Hyde et al. (2017), p. 480.

⁵⁹See European Commission, Proposal for a Regulation of the EU Parliament and of the Council on novel foods, COM (2007)872 final, based on a previous Draft report on impact assessment for a Regulation replacing Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients. For an analysis of this proposal, see Gerstberger (2008) and Jones and Craddock (2009).

⁶⁰The results of the consultation procedure carried out from 2002 to 2006, are available in Directorate General for Health and Consumers, Responses to the online consultation on the revision of Novel Food regulation, EC L258, 2007.

⁶¹“The issue of cloning then achieved a status within the debate that by far exceeded its practical significance. (...) It will not surprise the objective observer that such a discussion influenced strongly by ethical and political arguments cannot be tamed by a legal instrument such as the Novel Food Regulation,” Ballke (2014), p. 286. See also Carreno (2014).

⁶²Downes (2013), p. 269.

legislation; but the importance of reforming the outdated and increasingly inefficient 1997 Regulation, together with the ‘push’ derived from the concerns expressed by developing countries at the international level, led the European institutions to re-discuss their positions and promote a new legislative proposal on ‘new’ foods. Thus, in 2013 the Commission presented a new package of legislative proposals, including the revision of the Novel Food Regulation and two different proposals regarding animal cloning and food deriving from cloned animals. Overcoming all the challenges that had previously brought the reform attempt to fail, the proposal was finally approved in November 2015, so that the Reg. (EC) 258/97 was replaced by the current Reg. (EU) 2015/2283, applied since 1st January 2018.

The new discipline contains many novelties intended to overcome past inefficiencies and criticalities: from the centralised procedure, managed by the European Commission, to the unique and centralised risk assessment evaluation provided by EFSA. The provisions also include the introduction of a clearer definition of the scope of application of the Regulation and a more defined procedure and timeline. The creation of a transparent Union list of authorized Novel Foods is accompanied by a significant reform of the efficacy of the authorisation itself, that is not specifically addressed to the applicant, as it was in the past, but it has general effects.⁶³

In this scenario, the European legislator also introduced a crucial innovation by establishing a new simplified notification procedure expressly dedicated to traditional foods coming from Third Countries. In order to do so, the legislator has provided, for the first time, a specific definition of ‘traditional foods’ considered as a Novel Food, “other than novel food as referred to in points (a) (i), (iii), (vii), (viii), (ix) and (x) thereof which is derived from primary production as defined in point 17 of Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a Third Country” (Art. 3, lett. c). With reference to this particular category of ‘new’ foods, the applicant is asked to demonstrate that the product has been consumed continuously “in at least one third country for at least 25 years as a part of the customary diet of a significant number of people. The history of safe food use should not include non-food uses or uses not related to normal diets,” Recital 15.⁶⁴ This different burden of proof concerning the food safety of the product is to be considered one of the main differences—and a simplification—from the ‘standard’ authorisation procedure: the dossier required of the food business operator should only include “documented data demonstrating the history of safe food use in a third country” (Art. 14) and not the “scientific evidence demonstrating that the novel food does not pose a safety risk to human health,” as demanded for ‘new’ foods, considered *strictu sensu*. As clearly emerges, the costs and the level of complexity of the procedural requirements as well as the necessary documentation and expertise appear to be significantly reduced if compared to the previous 1997 legislation, thus

⁶³Rizzoli (2016) and Canfora (2019).

⁶⁴For a deeper analysis of the term ‘history of safe use’, see Pisanello and Caruso (2018), in particular p. 47. See also EFSA (2016).

addressing the serious requests of reform proposed by different stakeholders in previous years.⁶⁵

In addition, the notification procedure too is now characterised by a relevant time reduction and simplification. The submitted notification is evaluated by the European Commission who is asked to control the validity and the completeness of the dossier; within one month the Commission must forward the notification to Member States and EFSA; these authorities then have four months to present “duly reasoned safety objections” to the marketing of the traditional food. If no objection is submitted, the Commission authorises the Novel Food which will be formally included in the Union List. On the contrary, if objections are presented, the notified product cannot be authorised, and the applicant is required to submit a standard application. In this case, the food business operator does not benefit from the simplified documentation necessary for the notification and is instead obliged to include specific scientific data addressing the objections proposed. In this more complex scenario, the procedure is similar to the ‘standard’ one, even if with some important differences, mainly regarding the timeline: EFSA provides, within six months, a precise risk assessment, evaluating both the safety of the traditional food for human health and the reliability of history-of-safe-use data. Even when a faster EFSA intervention occurs, the Regulation specifies that, in duly justified cases, an extension of the established timing can be allowed if the need for additional information from the applicant emerges. The Opinion, resulting from the EFSA analysis, should then be properly evaluated by the Commission, which must prepare a draft implementing act, authorising—or not—the marketing of the traditional food, to be submitted within three months to the Standing Committee on Plants, Animals, Food and Feed. In the case of a favourable vote of the Committee members, the traditional food can be lawfully placed on the European Union market.

The 2015 Regulation, therefore, clearly recognises the *sui generis* category of traditional food coming from Third Countries by attributing a different and specified risk assessment procedure and admitting that the ‘history of safe food use’ must be properly taken into account. By not excluding this peculiar category of ‘new’ foods from the scope of application of the 2015 Regulation, the legislator decided to confirm the importance of a pre-authorisation procedure; at the same time, the possibility to opt for a faster and simplified notification path allows for a more proportionate burden of proof, reflecting the reduced level of risk these already consumed foods represent, on the one side, but also guaranteeing, on the other side, a proper food safety control, should scientific doubts or objections be proposed.

These improvements had an immediate positive effect on traditional foods coming from Third Countries’ marketing: since 2018, fifteen notifications have been submitted and seven traditional foods have already been authorised (until February 2022). These data represent a significant and evident amelioration if compared to the situation registered before the 2015 Regulation entered into force (from 1997 to

⁶⁵ Formici (2020) and Scaffardi (2020a).

2008, only four traditional foods coming from Third Countries were authorised, with an average duration of the authorisation procedure of more than 2 years).

Despite this encouraging information, a critical analysis of the current legislation cannot ignore some persistent issues related to traditional foods. First of all, by allowing EFSA and Member States to block, in the initial phase, the notification procedure by proposing duly reasoned safety objections, the procedure does not provide the applicant with the opportunity to clarify or answer the questions and doubts raised by national or centralised authorities. This automatic rejection of the notification procedure, without the possibility to promote a moment of dialogue and confrontation between the interested actors could potentially frustrate the specific provisions established for the benefit of traditional foods producers: the interruption of the notification procedure and the obligation to submit a new application, more similar to the ‘standard’ authorisation process, implying longer times and more detailed and expensive documents, increases the cost for food business operators. In addition, the ‘reasonableness’ of the objections proposed represents quite a vague requirement to assess and evaluate.⁶⁶ As a consequence, the effectiveness and efficacy of the simplified procedure promoted by the 2015 Regulation depends on the approach taken by Member States and EFSA: if they submit objections to traditional foods notifications frequently, this will *de facto* compromise the legislators’ choice to offer a different procedure for this category of Novel Foods. For this reason, it will be important to monitor now and in the future the functioning of this simplified procedure and its impact on the marketing of traditional foods coming from outside the EU.

Though the possible evolution and material implementation of the novelties introduced in 2015 are still unfolding, the reform of the traditional foods legislative regime undoubtedly reveals important risks that a generalized prior authorisation scheme could cause to the marketing of ‘new’ foods; these reflect the strict links among trade of food products, sustainable development, adequate income, and access to food. As the previous 1997 Regulation demonstrated, stringent marketing conditions, even when aimed at guaranteeing a high level of food safety, could result in disproportionate costs and procedural burdens,⁶⁷ with negative economic, social, and environmental implications for Third Countries interested in trading goods in the EU.⁶⁸ In the specific case of traditional foods, the exacting requirements imposed by the previous legislation ended up jeopardising the efforts by governmental and non-governmental authorities to promote sustainable methods of production, with

⁶⁶Hyde et al. (2017) talks about the risks of a narrow interpretation of the requirement of ‘history of safe use’: the more precise and detailed the proof of ‘history of safe use’ is demanded to be, the more difficult it is for food producers to benefit from the simplified notification procedure.

⁶⁷As underlined by Holle, “pre-market approval is a high barrier to market entry. Its impact on innovation and competitiveness of food businesses depends to a large extent on the requirements and duration of the authorization process. The higher the number of unknown variables in the equation, the more reluctant businesses are with their decision to invest on innovation,” Holle (2018), p. 291.

⁶⁸Henson and Jaffee (2007).

a detrimental effect on the development of low-income societies in poor rural areas. In this specific case, such a significant restriction—or, at least, disincentive—to traditional foods' access to the EU market did not appear to be entirely motivated by food safety concerns: the lack of proper consideration of the safe use of such foods in Third Country diets made it difficult to accept the complex and expensive scientific data required as proportionate.

The new Regulation, on the contrary, demonstrates that a different legislative solution is possible, by determining—after a protracted and lively legislative debate—a new balance point between food safety and the marketing of new foods; the legislator seems to have taken into proper consideration the impact of its legislative choices on the promotion of sustainable practices even outside the EU, thus considering sustainability and economic, social, and environmental aspects as significant elements to be evaluated in the difficult balancing exercise.

References

- Albisinni F (2021) Rules, responsibilities and governance facing Covid-19 in the agri-food sector. EU and Italian perspectives. *Rivista di Diritto Alimentare* 1:11–24
- Argese F (2016) Verso un'effettiva coerenza tra obiettivi interni di tutela della salute umana e obblighi internazionali in tema di liberalizzazione degli scambi e promozione dello sviluppo? Il caso della disciplina dei nuovi prodotti alimentari nell'Unione europea. *Quaderni del Dipartimento di Scienze Politiche, Università Cattolica del Sacro Cuore* 1:27–60
- Atapattu SA, Gonzalez CG, Seck SL (eds) (2021) *The Cambridge handbook of environmental justice and sustainable development*. Cambridge University Press, Cambridge
- Atkinson G, Dietz S, Neumayer E, Agarwala M (eds) (2014) *Handbook of sustainable development*. Edward Elgar Publishing, London
- Balle C (2014) The new novel food regulation. *Reform 2.0. Eur Food Feed Law Rev* 5:285–292
- Banterle A, Ricci EC, Cavaliere A (2018) Environmental sustainability and the food system. In: Bremmers HJ, Purnhagen K (eds) *Regulating and managing food safety in the EU. A legal-economic perspective*. Springer, Cham, pp 57–88
- Bifulco R, D'Aloia A (eds) (2008) *Un diritto per il futuro. Teorie e modelli della responsabilità intergenerazionale*. Jovene, Napoli
- Bolognini S (2013) Tempi di insicurezza alimentare: un approccio giuridico. In: Serafin S, Brollo M (eds) *Donne, politica e istituzioni*. Forum, Udine, pp 241–255
- Broberg M (2009) European Food Safety regulation and the developing countries: regulatory problems and possibilities. *DIIS Working Paper* 9: 1–44
- Brookes G (2007) Economic impact assessment of the way in which the European Union novel food regulatory approval procedures affect the European Food Sector. Briefing Paper for the Confederation of the Food and Drink Industries of the European Union CIAA and the Platform for Ingredients in Europe (PIE), <https://www.pgeconomics.co.uk/pdf/novelfoods.pdf>. Accessed 15 Feb 2022
- Canfora I (2019) “Products of Innovation” in Agri-food markets. Legal rules for the access of innovating products and paradigms in the agri-food market. In: AIDA (ed) *Innovation in agri-food law between technology and comparison*. Cedam, Padova, pp 61–72
- Carreno I (2014) European Commission proposes to revise the EU's legislative framework on Novel Foods and animal cloning. *Eur J Risk Regul* 5(3):362–365
- Cerrina Feroni G, Frosini TE, Mezzetti L, Petrillo PL (2016) Environment, energy, food. Comparative legal models for sustainable development. Cesifin, Florence

- Costato L (2011) Dalla food security alla food insecurity. *Rivista di Diritto Agrario* 1:3–15
- Crippa M, Solazzo E, Guizzardi D, Monforti-Ferrario F, Tubiello FN, Leip A (2021) Food systems are responsible for a third of global anthropogenic GHG emissions. *Nat Food* 2:198–209
- D'Aloia A (2016) Voce Generazioni future. *Enciclopedia del Diritto Annali IX*. Giuffè, Milano, pp 331–390
- Dasgupta PS, Heal GM (2011) *Economic theory and exhaustible resources*. Cambridge University Press, Cambridge
- Davico L (2004) *Lo sviluppo sostenibile. Le dimensioni sociali*. Carocci, Roma
- DG Sanco (European Commission) (2008) Impact Assessment for a Regulation Replacing Regulation (EC) n. 258/97 on Novel Food and Novel Food Ingredients. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52008SC0012>. Accessed 15 Feb 2022
- Downes C (2013) The rise and fall of the new EU novel food regulation: the complex influence of the WTO SPS agreement. *Asian J WTO Int Health Law Policy* 8:249–300
- EFSA (2016) Guidance on the preparation and presentation of the notification and application for authorization of traditional foods from third countries in the context of regulation (EU) 2015/2283. <https://www.efsa.europa.eu/en/efsajournal/pub/4590>. Accessed 15 Feb 2022
- Elver H (2021) At the blink of famine in conflict and natural disaster zones: human rights approach to extreme hunger and malnutrition. In: Webster E, Gupta A, Ambros R (eds) *Transnational food security*. Routledge, London, pp 15–42
- European Parliamentary Research Service (EPRS) (2014) Novel foods. Complementary impact assessment reviewing and updating the European Commission's 2008 Impact Assessment for a Regulation on Novel Foods. https://ec.europa.eu/food/system/files/2018-07/novel_food_leg_impact-assessment-2013.pdf. Accessed 15 Feb 2022
- FAO (2008) An introduction to the basic concept of food security. <https://www.fao.org/3/al936e/al936e.pdf>. Accessed 15 Feb 2022
- FAO (2020) Agricultural trade and policy responses during the first wave of the Covid-19 pandemic in 2020. <https://www.fao.org/3/cb4553en/cb4553en.pdf>. Accessed 15 Feb 2022
- FAO (2021) Emissions due to agriculture. Global, regional and country trends 2000–2018. <https://www.fao.org/3/cb3808en/cb3808en.pdf>. Accessed 15 Feb 2022
- FAO, IFAD, UNICEF, WFP, WHO (2021) The state of food security and nutrition in the World. Transforming food systems for food security, improved nutrition and affordable healthy diets for all. <https://www.fao.org/documents/card/en/c/cb4474en/>. Accessed 15 Feb 2022
- Flood S, Columbié YJ, Le Tissier M, O'Dwyer B (eds) (2022) *Creating resilient futures. Integrating disaster risk reduction, sustainable development goals and climate change adaptation agendas*. Springer, Cham
- Formici G (2020) Novel Food tra esigenze di mercato, sicurezza alimentare e sviluppo sostenibile: la complessa disciplina degli alimenti tradizionali provenienti da Paesi terzi. *BioLaw J* 2:67–87
- Gerstberger I (2008) The proposal for a revised novel food regulation. An improvement for the worse? *Eur Food Feed Law Rev* 4:213–231
- Giuffrida M (2015) Il diritto fondamentale alla sicurezza alimentare tra esigenze di tutela della salute umana e promozione della libera circolazione delle merci. *Rivista di Diritto Alimentare* 3: 34–44
- Guzman ML (2012) The ambiguous categorization of risk concerning the traditional foreign products. In: Dutilleul F (ed) *De la terre aux aliments, des valeurs au droit*. Instituto de Investigacion en Derecho Alimentario, San José, pp 277–300
- Henson S, Jaffee S (2007) Understanding developing countries strategic responses to the enhancement of food safety standards. *World Econ* 4(31):548–568
- Hermann E (2009) The impact of the European novel food regulation on trade and food innovation based on traditional plant foods from developing countries. *Food Policy* 34:499–507
- Holle M (2018) Pre-market approval and its impact on food innovation: the novel foods example. In: Bremmers HJ, Purnhagen K (eds) *Regulating and managing food safety in the EU. A legal-economic perspective*. Springer, Cham, pp 291–330

- Humphreys M (2017) Sustainable development in the European Union. A general principle. Routledge, London
- Hyde R, Hartley S, Millar K (2017) European novel foods policy at a critical juncture: drawing lessons for future novel food governance through a retrospective examination of regulation 258/97. *Food Drug Law J* 72:472–505
- Iannarelli A (2015) *Cibo e diritti*. Per un'agricoltura sostenibile. Giappichelli, Torino
- Jones C (2012) The novel food regulation: revisions required. A view from a regulator. *Eur Food Feed Law Rev* 7(2):81–83
- Jones A, Craddock N (2009) Concerning the proposed amendments to the European Novel Foods Regulation (EC) 258/97 with particular reference to traditional foods from developing countries. Definitions, concepts and history of safe food use assessment. discussion paper for UNCTAD, https://repositorio.promperu.gob.pe/bitstream/handle/123456789/1385/Definitions_concepts_history_safe_food_use_assessment_2009_keyword_principal.pdf?sequence=1&isAllowed=y. Accessed 15 Feb 2022
- Lafferty WM (ed) (2004) Governance for sustainable development. The challenge of adapting form to function. Edward Elgar, Cheltenham
- Lahteenmaki-Uutela A (2007) European novel food legislation as a restriction to trade. Poster for the 106th Seminar of the EAAE, <https://ideas.repec.org/p/ags/eea106/7909.html>. Accessed 15 Feb 2022
- Maris G, Flouros F (2021) The green deal, national energy and climate plans in Europe: Member States' compliance and strategies. *Adm Sci* 11(3):75
- Meybeck A, Gitz V (2017) Sustainable diets with sustainable food systems. *Proc Nutr Soc* 76:1–11
- Pantalone P (ed) (2021) *Doveri intergenerazionali e tutela dell'ambiente*. Il diritto dell'economia, Special Issue
- Pisanello D, Caruso G (2018) Novel foods: the “History” of safe use approach. In: Pisanello D, Caruso G (eds) *Novel foods in the European Union*. Springer, Cham, pp 47–54
- Purvis B, Mao Y, Robison D (2019) Three pillars of sustainability: in search of conceptual origins. *Sustain Sci* 14:681–695
- Ramajoli M (2015) Dalla Food Safety alla Food Security e ritorno. *Amministrare* 2(3):271–292
- Rizzoli S (2016) Novel food. In: Costato L, Albisinni F (eds) *European and global food law*. Wolters Kluwer, Milano, pp 487–504
- Saija G, Salomone R (eds) (2014) *Pathways to environmental sustainability. Methodologies and experiences*. Springer, Cham
- Scaffardi L (2020a) I Novel Food, un futuro ancora da definire. *BioLaw J* 2:43–66
- Scaffardi L (2020b) Novel Food, una sfida ancora aperta. In: Scaffardi L, Zeno-Zencovich V (eds) *Cibo e diritto. Una prospettiva comparata*. Roma TrE-Press, Roma, pp 735–773
- Scarpa B, Dalfrà S (2008) Regulating the novel foods sector: moving forward. *Eur Food Feed Law Rev* 3(5):292–299
- Siegmann A (ed) (2021) *Climate of the middle. Understanding climate change as a common challenge*. Springer, Cham
- Szajkowska A (2012) Regulating food law. Risk analysis and the precautionary principle as a general principle of European Food Law. Wageningen Academic Pub, Wageningen
- UN Special Rapporteur on the Right to Food (2021) Interim Report of the Special Rapporteur on the Right to Food, A/76/237, <https://documents-dds-ny.un.org/doc/UNDOC/GEN/N21/208/03/PDF/N2120803.pdf?OpenElement>. Accessed 15 Feb 2022
- UNCTAD (2013) New EU Commission's Proposal on novel foods regulation (2013). A preliminary overview from the perspective of biodiversity-based and traditional foods, https://unctad.org/system/files/official-document/ditcted2014d2_en.pdf. Accessed 15 Feb 2022
- United Nations (2015a) Resolution Adopted by the General Assembly on 25 September 2015 A/RES/70/1. Transforming Our World: The 2030 Agenda for Sustainable Development, https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_70_1_E.pdf. Accessed 15 Feb 2022

- United Nations (2015b) Transforming Our World: the 2030 agenda for sustainable development, https://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E. Accessed 15 Feb 2022
- Van der Meulen BMJ, Van der Velde M (2008) European food law handbook. Wageningen Academic Press, Wageningen
- Van der Meulen B M J, Bremmers H, Wijnands J H M, Poppe K (2010) Food chain partners and the application of premarket approval schemes in EU food legislation, https://www.researchgate.net/publication/45313471_Food_chain_partners_and_the_application_of_premarket_approval_schemes_in_EU_food_legislation. Accessed 15 Feb 2022
- Verhagen H, te Boekhorst J, Kamps L, van Lieshout MJ, Ploeger H, Verreth D, Salminen S, van Loveren H (2009) Novel foods: an explorative study into their grey area. *Br J Nutr* 101:1270–1277
- Violini L (2019) Scelte europee e sviluppo sostenibile. *Atlantide* 45:1–6
- von Homeyer I, Oberthur S, Jordan AJ (2021) EU climate and energy governance in times of crisis: towards a new agenda. *J Eur Public Policy* 28:959–979
- World Food Programme (2022) Food security implications of the Ukraine conflict, https://docs.wfp.org/api/documents/WFP-0000137463/download/?_ga=2.40757410.1626377593.1648027569-2025779271.1648027569. Accessed 15 Feb 2022
- WTO (2006) Regulation of the European Parliament and of the council on novel foods, G/SPS/R/42, <http://spsims.wto.org/en/SpecificTradeConcerns/View?ImsId=238>. Accessed 15 Feb 2022

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



Food (In)Security: The Role of Novel Foods on Sustainability



Stefano Sforza

Abstract Food production today impacts heavily on the environment and available resources while at the same time failing to provide equal access to food security and healthy diets for everyone. To improve this situation, food production systems need to be redesigned in a more circular way, minimising food waste, developing new technologies, and exploiting novel biomasses for food production. Novel Foods are the consequence of this evolution and can play a pivotal role towards the target of providing sustainably produced, secure, and healthy food for everyone.

Keywords Food security · Food sustainability · Food waste · Healthy diets · Novel ingredients

1 Introduction

What do Novel Foods have to do with Sustainability and Food Security? The relationship suggested by the title might appear odd at a first sight, but the data and the considerations presented in this chapter will hopefully make clear the profound connection existing between these concepts. Indeed, it will be shown how Novel Foods can play a definite role in helping the transition to a world where food security for everyone and sustainable food production everywhere will be cornerstones for a new sustainability paradigm.

Let's start by defining what is meant by sustainability. In 1987, the United Nations Brundtland Commission defined sustainability as “meeting the needs of the present without compromising the ability of future generations to meet their own needs”.¹ Clear as this definition is, it does not indicate how it is possible to meet the present needs without compromising the future generation's needs. As of today, are development and progress not inextricably intertwined with a ceaseless consumption

¹World Commission on Environment and Development (1987), p. 41.

S. Sforza (✉)

Department of Food and Drug, University of Parma, Parma, Italy

e-mail: stefano.sforza@unipr.it

of all our available resources? Is the only possible solution to stop the depletion of our resources to give up on development and progress? Stated in plain words, is Sustainable Development ever possible?

The United Nations (UN), and many with them, believe in the concept of Sustainable Development as the way to meet both sustainability and development goals. In 2015, the UN General Assembly adopted the 2030 Agenda for Sustainable Development.² With its 17 Sustainable Development Goals (SDGs), the 2030 Agenda is a collection of impressive targets ranging from zeroing poverty and hunger, achieving health, wellbeing, peace, justice, and education for all, reducing inequality while at the same time ensuring economic growth, industry and infrastructure innovation as well as responsible consumption and production. In order for such ambitious programs to be met, a combination of many efforts and solutions will be required to achieve development and sustainability at the same time.

Sustainable food production is a core aspect of the SDGs. As we will see in detail in the next sections, food production and consumption are among the most unsustainable and inefficient human activities today. They put an enormous burden on the environment and the available resources, while at the same time spectacularly failing to provide secure access to healthy and nutritional food for all. In addition, enormous amounts of wasted materials are left behind. In short, today our situation is characterized by unsustainable food production together with food insecurity for many of the inhabitants of this planet. This scenario seems to present an insuperable conundrum: to secure food production for everyone in a world where the human population is growing every day, we would need to produce more food. At the same time, the amount of food produced today already exceeds the available resources and the possibility to accommodate the waste produced. In short, we need to produce more, but we cannot afford to produce more.

The solution to this apparent Catch-22 situation lies in a paradigm shift: the transition to sustainable and secure food production for all will require a complete rethinking of today's technological solutions, means of production, food ingredients, and consumption habits. This incredibly difficult challenge will require multiple diverse solutions and profound changes in our current knowledge, habits, and approach. Though it might not be immediately evident, such changes have already begun, and Novel Foods already have, and will continue to have, a clear role in this transition, as I will elucidate.

²United Nations (2015).

2 Food (In)Security and Food Production (Un)Sustainability

The latest Food and Agriculture Organisation (FAO) report on global Food Security depicts a grim landscape as far as food inequality is concerned.³ This report estimates that between 720 and 811 million people in the world experienced hunger in 2020. Of those, more than half were found in Asia (418 million) and more than one-third in Africa (282 million). In addition to hunger, many more people are unable to access diets meeting basic nutritional standards. Healthy diets have high costs which, combined with the high levels of poverty and income inequality in the poorest parts of the world, result in nutritionally inadequate food intake for nearly 2.37 billion people. This means that more than one-fourth of the human population today experiences one form or another of food insecurity, as they do not regularly eat what they need to preserve health and wellbeing.

The same report describes in detail the external and internal factors which drive food insecurity. External factors are there for all to see: conflicts, poverty, climate change. They are all causing food insecurity and are often also interconnected. Conflicts cause poverty, and poverty causes conflicts, and all this exacerbates food insecurity, already compounded in many parts of the world by climate change. Internal factors are somehow less obvious, but equally important, if not more. They point directly to low productivity, inefficient use of raw ingredients, and inefficient food supply chains. These internal factors show that our food production system is entirely unable to face the task of food security for everybody. This inadequacy increases the costs and reduces the availability of healthy and nutritious foods, pushing healthy diets out of reach for many human beings.

This problem does not equally impact all parts of the world, as we have already seen above. Looking at the differing intake of macronutrients in diet, the inequality existing in our world emerges in all its crudeness. Richer countries have a much larger share of high-quality animal proteins in their diet, with an almost perfectly linear correlation between average income and proteins consumed. Countries with an average Gross Domestic Product (GDP) per person below \$5000 have an average prevalence of animal protein in the diet that never exceeds 2–4%, whereas this latter figure rises to 10% and above when the average GDP per person approaches \$50,000.⁴ It is a well-known phenomenon seen in recent decades in developing countries that as soon as the average GDP increases, animal protein consumption immediately increases with it. Lower-income countries rely on a less diversified and mostly cereal-based diet. When the average GDP per person is less than \$5000, the prevalence of cereals in the diet is far above 50%, and up to 80% in the poorest countries. This number drops below 20% in the richest countries. Fruit and vegetable consumption, an important part of a healthy diet, are below guidelines in many

³FAO, IFAD, UNICEF, WFP, WHO (2021).

⁴Ritchie and Roser (2017).

countries of South America, Africa, and the poorest countries of Asia. Summarizing all the above data, simply stated, poor countries eat a large quantity of cereals, and very little animal proteins, fruit, and vegetables, whereas rich countries eat fewer cereals, and have adequate or more than adequate amounts of high-quality proteins, fruits, and vegetables in their diet. Thus, high-income countries (mostly in North America, Europe, and far east Asia) have access to better diets than low-income countries (mostly in Africa, South America, and the rest of Asia).

But the description of a world divided into rich and poor countries, with everyone in the former eating better than everyone in the latter, is not completely accurate. In every country, rich or poor, there are also vertical differences within the population, again driven by the diverse incomes. Thus, even in rich countries, the part of the population with the lowest income faces food insecurity, in percentages ranging from 8% to 20% of the total population.⁵ It is to be noted, and this is particularly true for rich countries, that nutritionally poor diets do not always take the form of hunger or undernutrition. When access to nutritious foods (costly and sometimes unavailable) is restricted, the consumption of less nutritious foods (cheaper and more readily available) can lead to obesity, which is ultimately another form of malnutrition. The reduction in the diet of fresh fruits, vegetables, meat, and dairy products, and the increase in foods high in fat, sugar, and salt (usually much cheaper than the former), leads to overweight and obese children and adults in poor as well as in rich countries. The coexistence in this world of overweight and underweight people is the most striking display of how the target of healthy food security for everyone is badly managed. About 1.9 billion adults worldwide are overweight, while 462 million are underweight. 41 million children under the age of 5 years are overweight or obese, while at the same time more than 200 million children are failing to develop properly.⁶

Thus, the obvious question is: how to tackle this situation and reduce inequality, granting food security and good diets for everyone? One solution would be to secure universal easy access to healthy foods at an affordable price. This obvious solution dictates, however, that we produce more, above all increasing the amount of healthy food produced, ideally at reduced costs. Secondly, we need not only to produce more but also to make sure that healthy food is equally distributed and accessible all over the world. At the same time, we must remember that the world population continues to increase, and this will require more food production. According to some estimates, by 2050 60% more food will be needed to be able to properly feed a world population of 9.3 billion.⁷

As clear as this solution seems, we simply cannot afford it with the food production systems employed today. As a simple example, if we focus only on animal proteins, human nutritionists recommend that about one-third of the daily

⁵Pollard and Booth (2019).

⁶WHO (2020).

⁷Da Silva (2022).

protein requirement originate from proteins of animal origin.⁸ This is much lower than the present average consumption throughout the world, however, and so we should increase animal protein production. But animal protein production has an extreme impact on the environment and on the available resources: about 200 square meters of arable land⁹ and 15,000 L of water¹⁰ are consumed to produce 1 kg of beef meat. This simple example demonstrates a very inconvenient reality: we simply cannot support nine billion people on an animal protein-rich diet in 2050. In the absence of technological changes and mitigation measures, the environmental impact of food production will increase by that time by 50–90%, reaching levels that are beyond the planetary boundaries which define a safe operating space for humanity.¹¹

Adding further impact to environmental resources and also making the inefficiency of our food production systems quite clear, is the huge amount of food waste generated all along the food production chain, at the production, distribution, and household levels. In 2011, a report by the FAO estimated that about one-third of food produced globally was lost or wasted, up to an impressive 1.3 billion tonnes each year,¹² with industrialized and developing countries each wasting roughly the same amount of food. It has been believed for a long time that food waste at the household level took place largely in developed countries, while production, storage, and transportation losses were concentrated in developing countries. However, recent reports indicate that even in low-income countries household food waste is substantial.¹³ Those recent estimates place food waste at levels ranging from 60 to 120 kg/capita/year, with no real differences between high-income and low-income countries, possibly suggesting that the total amount of food waste is even higher than what has been previously estimated. The possibility to reduce food waste or to valorise it as a new source of food would save plenty of soil and water destined for food production and allow for a transition to a more sustainable world.

Thus, the steps towards healthy and affordable diets for everyone necessarily lead to redesigning food production systems in a more ‘circular’ way, minimizing food waste and food loss, rethinking the logistics of food distribution, valorising more local resources in food production, developing new technologies to create more durable and healthy foods, exploiting underused and neglected biomasses as food ingredients, improving the safety of food material, studying new methods for animal and vegetal production, and implementing in the population a shift to more healthy and sustainable diets. Those are certainly a huge tasks, but ones that certainly must be endured if we want to achieve the above targets of food security and food sustainability in a world of nine billion people.

⁸Jackson and Truswell (2007).

⁹Flachowsky et al. (2017).

¹⁰Mekonnen and Hoekstra (2010).

¹¹Springmann et al. (2018).

¹²Gustavsson et al. (2011).

¹³United Nations Environment Programme (2021).

Novel Foods, as we shall see in the following sections, are part of these solutions.

3 Novel Foods: What They Are and How They Can Support Food Security and Sustainable Food Production

Novel Foods are defined in the European Union as foods that do not have a significant history of consumption, or, foods produced by a method that has not previously been used. Specifically, according to EU legislation, the status of a Novel Food, as well as its authorization for commercialization, must be requested for every food that had not been consumed to a significant degree by humans in the EU before 15 May 1997. The protocol for the authorization and the use of Novel Foods, also including Novel Food ingredients, has been harmonized in the European Union through a specific Regulation¹⁴ adopted indeed in 1997. A new regulation, adopted by the EU in 2015, laid down the rules for placing Novel Foods on the market within the Union so as to ensure the effective functioning of the internal market while providing a high level of protection for human health and consumer interests.¹⁵

The procedure for placing a Novel Food on the market, as outlined by the above Regulations, has been elucidated in other chapters in this volume in detail.^{16,17}

An important distinction that exists under the current legislation concerns Novel Foods that are entirely new, in the sense that they do not have a history of consumption anywhere in the world, as compared to foods that are only new to the European Union but do have a history of consumption in other parts of the world. These latter foods, addressed in more depth in the third chapter of this volume, are referred to as traditional food from a third country, and their approval as Novel Foods in the EU follows a slightly different procedure.¹⁸

Since 2017, the European Commission maintains a European Union list of all the approved Novel Foods.¹⁹ The list includes their conditions of use, labelling requirements, and specifications. This Union list serves as a reference for economic operators who wish to place on the market an authorized Novel Food unless data

¹⁴Regulation (EC) 258/97.

¹⁵Regulation (EU) 2015/2283.

¹⁶For a more detailed analysis of this legislation as well as of the specific authorization procedure, see, in particular, *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, by A. Volpato in this volume.

¹⁷With reference to EFSA's role and food safety issues, see *Why "New" Foods Are Safe and How They Can Be Assessed* by C. Dall'Asta and, specifically on insects, *The Safety Assessment of Insects and Products Thereof as Novel Foods in the European Union* by G. Precup, E. Ververis, D. Azzollini, F. Rivero-Pino, P. Zakidou, A. Germini, all in this volume.

¹⁸For an in-depth study of this innovative procedure, see *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* by L. Scaffardi in this volume.

¹⁹Commission Implementing Regulation (EU) 2017/2470.

protection is requested by the applicant. As per the first months of 2022, about 200 Novel Foods and Novel Food ingredients have been authorized in the market of the European Union.

An important first consideration when assessing Novel Foods is to try to understand the reason for their coming into existence. Why should something that has not been consumed before 1997 be consumed now? Or in other words, what are the dietary or other needs that Novel Foods are trying to satisfy that are not properly satisfied by the already existing foods? To understand this point, it might be interesting to have a critical look at the list of Novel Foods approved until now to explore the reasons at the basis of their commercialization. If we look critically at the approximately 200 Novel Foods approved so far, we might categorize them in several subgroups: (a) new foods or ingredients deriving from sources having a low environmental impact; (b) new foods or ingredients deriving from sources not traditionally used in the EU; (c) new foods or ingredients deriving from food by-products; and (d) new foods or ingredients produced with new technologies, including chemical synthesis. The fact that almost every Novel Food approved falls in one (or sometimes simultaneously in more than one) of the above categories already gives some strong indications on the reasons for their existence: Novel Foods are an attempt at using as food ingredients sources never used before, or to apply technologies never used before. This strongly suggests that Novel Foods are the consequence of modifications already happening in our food production system, even if it is not immediately clear why these new sources, or these new technologies, should be included in our food production systems, and why we cannot be content with what we have now.

Looking at the list in an even deeper way, a common point which characterizes almost all approved Novel Foods emerges, a point which is the key core element behind their entrance in our markets: almost all the approved Novel Foods have been characterized as containing compounds that are known to have or are supposed to have a positive impact on the state of health and wellbeing. The list of Novel Foods contains foods that, through specific compounds or specific ingredient composition, are beneficial for our health. Simply stated, Novel Foods are there to improve our health and wellbeing in new ways not guaranteed by the traditional foods already present in our markets. This is the real core reason why Novel Foods have entered and keep entering our lives.

It is important to underline that the authorization of the European Commission (and the EFSA assessment before that) for the commercialization of Novel Foods is not based on their beneficial properties, since this is out of the scope of the Novel Food Regulation. According to that regulation, EFSA performs a risk assessment on the safety of a Novel Food upon request by the European Commission. A candidate Novel Food is not requested to be beneficial, only to be safe, and not nutritionally disadvantageous. Thus, the Novel Foods present in the Union list are not there because of their beneficial content, but simply because they have been demonstrated to be safe. And yet, the beneficial compounds contained in them are, for the most part, the very reason why these Novel Foods came into existence and why they are commercialized today.

Thus, according to the above considerations, and taking into account what has been described at the beginning of this chapter, we can state that Novel Foods are there because they allow us to redesign our food production system (by using food by-products, or new sources with low impact, or new technologies) while at the same time providing high quality foods and food ingredients which help our state of wellbeing and health in ways never before experienced in European Union. Novel Foods, when we see them from this perspective, play a pivotal role in the transition to a system producing more and healthier food that is also more sustainably produced.

To further demonstrate this point, in the following pages some typical examples of Novel Foods will be presented, describing how they fulfil the role of helping the transition to a more sustainable, equal, healthier, and more nutritious food production system. The Novel Foods I will address have been approved for consumption in the European Union, but as the examples will demonstrate, many of them can find applications for improving equal access to sustainable healthy food all over the world.

3.1 Novel Healthy and Nutritious Foods from Sustainable Sources: Insects and Microalgae

Edible insects are probably the most known Novel Foods authorized in the EU, and the fastest developing, even if they entered the list very recently. As of February 2022, there are three Novel Foods in the list belonging to this category: dried *Tenebrio molitor* larva (the common mealworm), frozen, dried, and powder form of *Locusta migratoria* (the migratory locust), both authorized in 2021, and frozen dried, and powder form of *Acheta domesticus* (the house cricket), authorized in 2022. Many more requests for authorization are pending, thus the number of edible insects is expected to increase substantially in the coming years.

Without entering into too much detail,²⁰ insects are a typical example of Novel Foods that play a clear role in improving food security, providing nutritious diets for everyone and lowering environmental impact all at the same time. Indeed, insects are an excellent source of important nutrients, first and foremost highly nutritious proteins, which, as we have seen above, will be in great demand in the next 30 years. The protein content of an insect meal can reach 76% of the dry matter, depending on the insect type and development stage.²¹ At the same time, insects, unlike other sources of highly nutritious animal proteins, are very resource-efficient: the production of 1 kg of insect proteins requires only 1.7 kg of cereals, less than 100 L of water, consumes 15 m² of arable land, and emits in the atmosphere 1 g of CO₂. For

²⁰ A more detailed analysis of legal and scientific aspects related to insects as food, together with an insight on consumer perception can be found in Part II of this Volume.

²¹ Kouřimská and Adámková (2016).

the sake of comparison, the production of the same number of bovine proteins requires 10 kg of cereals, 15,000 L of water, consumes 200 m² of arable land, and emits in the atmosphere 2850 g of CO₂. Moreover, the raising of common livestock produces methane gas, a major contributor to global warming/climate change, and nitrous oxide and ammonia are also released by cattle into our environment. Raising insects produces between 10 to 80 times less methane gas than does the raising of cattle, and 8–12 times less ammonia. Another important point regarding insects as food concerns the reduction of inequalities: farming insects does not require large tracts of land or expensive machinery, thus even the poorest segment of the population can do it profitably. Insect production can therefore strongly contribute to increasing the income of the poorest parts of the world. Last, but certainly not least, insects can thrive on food by-products, thus they can be used to reduce the production of food waste, valorising it and transforming it into insect biomass of high nutritional value while at the same time reducing environmental burden.²²

All the above numbers and considerations demonstrate how insects are Novel Foods that can help to secure a healthy diet for everyone while at the same time reducing inequality and the environmental impact of food production.

Microalgal Novel Foods, as opposed to insects, have been present in the Union list since the beginning. As of February 2022, there are five different Novel Foods (with some variants) based on microalgal biomasses. Some of them simply consist in the dried algal biomass (*Odontella aurita* microalgae, dried *Tetraselmis chuii* microalgae), whereas others are food ingredients derived from the microalgal biomass (Oil from the microalgae *Ulkenia sp.*, oil from the microalgae *Schizochytrium sp.*, oleoresin from *Haematococcus pluvialis*). All of the above microalgal Novel Foods have significant amounts of polyunsaturated fatty acids, proteins, or antioxidants, depending on the species. *Odontella aurita* is rich in eicosapentaenoic acid, and it has been demonstrated that a diet rich in this microalga prevents insulin resistance resulting from high-fat diets.²³ *Tetraselmis chuii* has a high protein content rich in essential amino acids, and it has been proposed in the formulation of food to increase the protein nutritional profile, and as a protein supplement.²⁴ The oil from the microalgae belonging to the species *Ulkenia* is also high in omega-3 fatty acids and is used as an ingredient in baked goods. Also, the oil from the microalgae belonging to the species *Schizochytrium* is extremely rich in unsaturated fatty acids and has very high levels of docosahexaenoic and eicosapentaenoic acid. For this reason, it is used as an additive in a wide range of foods, including infant formulas and baby foods, or as a food supplement, particularly for pregnant women. The oleoresin from *Haematococcus pluvialis* is extremely rich in carotenoid antioxidants, and specifically astaxanthin, making it a useful food additive for preparing food with high antioxidant properties.

²²Leni et al. (2021).

²³Amine et al. (2016).

²⁴Toro et al. (2020).

As stated above, the content of the beneficial compounds described has not been considered when approving these products as Novel Foods (only their safety was assessed), but this is undoubtedly the reason why these products entered the market. There are many foods already in the market with high protein content, or that are rich in unsaturated fatty acids or antioxidants. Why, then, introduce microalgae as Novel Foods? The reasons are very similar to what we have already seen for insects: microalgae cultivation is resource-efficient and has low environmental impact. Microalgae need only sunlight, water, and CO₂ to be cultivated, alongside nutrients that can easily be taken from wastewaters, mainly nitrogen and phosphorus. In this way, nutrients can be recovered from wastewaters in the cultivation chain, at the same time saving on fertilizers and helping to prevent nutrient-rich effluents from being released in the environment, causing eutrophication.²⁵ Thus again, as we have seen for insects, not only are microalgae Novel Foods containing healthy beneficial compounds, but they are also foods that can be produced in an environmentally friendly and resource-efficient way. In this sense, they are part of a new food production system aimed at securing healthy food in a sustainable way for everyone on the planet.

3.2 Novel Healthy Food Ingredients and Supplements from Marginal and Exotic Biomasses

A relevant number of Novel Foods present in the Union list are derived from marginal and/or exotic biomasses that are not typically used as food, at least in the European Union. A few examples will be given, trying to assess also in these cases the origin of the interest in these new foods and the true reasons behind their commercialization, which will again be, as will be shown, the content of beneficial compounds.

A typical example is represented by chia oil and chia seeds, two Novel Food ingredients derived from *Salvia hispanica*. Chia seeds are Novel Foods in the European Union, but they have been used as part of traditional diets for thousands of years in Central America. The plant originated from Mexico and Guatemala, and it has been a part of human food for about 5500 years. In pre-historic times in Columbian societies, it was the second main crop after beans.²⁶ Chia oil is used as an additive to fat and oil preparation, whereas the specified use of chia seeds as ingredients includes bread products, baked products, breakfast cereals, nut and seed mixes, fruit juice, and fruit/vegetable blend beverages, fruit spreads, yogurt, ready to eat meals based on cereal grains, pseudocereal grains and/or pulses, and chocolate preparations. The great interest in chia derivatives as food ingredients relies on the benefits, largely reported in the literature, linked to their content of fibre,

²⁵ Chiu et al. (2015).

²⁶ Ullah et al. (2016).

vitamins, minerals, and powerful antioxidants (caffeic acid, chlorogenic acid, kaempferol, quercetin). Thus, the commercialization of chia seeds is mostly driven by their strong health benefit potential, which allows us to expand the base of healthy foods in our diet using a vegetable plant that already has a long and significant tradition outside the EU.

As a further example, an even larger share of Novel Foods and Novel Food ingredients is represented by the Noni plant (*Morinda citrifolia*). Five different entries in the Union list are represented by this plant: Noni fruit juice, Noni fruit juice powder (used as food supplement), Noni fruit puree and concentrate (used for candy/confectionery, cereal bars, powdered nutritional drink mixes, carbonated beverages, ice cream, yoghurt, biscuits, cakes and pastries, breakfast cereals, jams and jellies, sweet spreads, fillings and icings, savoury sauces, pickles, gravies and condiments, and as food supplement), Noni leaves (used for infusions), and Noni fruit powder (used as food supplement). *M. Citrifolia* is a perennial, fruit-bearing plant that grows up to 6 m in height and is native to Southeast Asia. The root, stem, fruits, and leaves are traditionally used by several East Asian cultures for the treatment of numerous diseases such as arthritis, headaches, burns, and even disorders related to tuberculosis, diabetes, and hypertension.²⁷ Indeed, more than 200 compounds with confirmed biological activity have been identified in *M. Citrifolia*, such as anthraquinone, damnacanthal, coumarin, scopoletin, and flavonoids, like rutin and quercetin. These bioactive compounds are promising for therapeutic applications, although the medical and nutritional values of this plant are not yet fully proven. Thus, quite interestingly, a plant mostly used as a source for pharmacological compounds outside the EU, it has been introduced in Europe as a Novel Food, clearly trying to exploit its potential beneficial purposes. Moreover, what makes this plant even more interesting, and a possible contributor for bringing healthy and beneficial foods to the poorest parts of the world, is its ability to grow in very diverse, and sometimes hostile, conditions. *M. citrifolia* can grow and develop in open rocky or sandy coasts, plains and open meadows, ravines, in recent flows of lava, or even in humid forests with low luminosity. It can grow in relatively wet to moderately wet environments, from sea level up to 800 m altitude. It has a resistance to high rainfall levels up to 4000 mm, but it can also survive in arid environments, being able to withstand 6 months or more of extreme drought. It can grow in high solar luminosity or in environments with more than 80% shade. It also has a good regeneration capacity: after being subjected to fire burning, Noni can generate leaves from the root or the stem. Thus, again, the reasons for having this plant in the list of Novel Foods are clear: it is a very flexible plant able to grow under almost any condition (therefore with the potential to be grown in the least productive parts of the world), and potentially able to bring many beneficial compounds into the human diet.

One Novel Food derived from a botanical species which is not exotic in the European Union, but is not usually used as food, is an extract obtained from the

²⁷ Almeida et al. (2019).

leguminous plant lucerne, also called alfalfa (*Medicago sativa*). This plant is commonly used as feed in animal nutrition, due to its high protein content of elevated nutritional value. The lucerne leaf extract, also rich in highly nutritious proteins, has been approved with a proposed use as a food supplement for its range of potential benefits to the human diet. Indeed, many studies have demonstrated that lucerne concentrate can not only help fight malnutrition (because of the high protein content), but can also prevent ischemia, and various digestive tract disorders. It also increases the resistance of the immune system, improves the content of haemoglobin in the blood, and promotes a beneficial intestinal microbial population.²⁸ Again, it became a Novel Food because it can bring health and well-being to consumers.

The last example of Novel Food ingredients belonging to the category of exotic biomasses, but of animal origin, originates from the Antarctic krill (*Euphausia superba*): Antarctic Krill oil and, as a distinct list entry, Antarctic Krill oil rich in phospholipids. The approval of these Novel Food ingredients has been given for use in dairy products, cheese products, non-alcoholic beverages, spreadable fat and dressings, cooking fats, breakfast cereals, bakery products, nutrition bars/cereal bars, food supplements for the general population, and pregnant and lactating women. Again, the reason for the presence of these Novel Foods in the market is strongly linked to their beneficial properties. Krill oil is characterized by a high concentration (39.29–80.69%) of phospholipids (PLs), associated with the essential lipids eicosapentaenoic acid and docosahexaenoic acid. It also contains considerable amounts of bioactive minor components such as astaxanthin, sterols, tocopherols, vitamin A, flavonoids, and minerals. Krill oil has been documented to have various health benefits, including anti-inflammatory effects, cardiovascular disease (CVD) prevention, women's health enhancement, neuroprotection, and anticancer properties.²⁹

All the above examples, which are only representative of the many diverse Novel Foods obtained from marginal and exotic biomasses present in the Union list, demonstrate how the driving force for a Novel Food creation from these biomasses are the benefits (or supposed benefits) that this Novel Food can bring to the human diet by improving health and wellbeing. The use of these marginal or exotic biomasses, often originating from difficult environments, has the purpose of making these benefits available in the European market, but also in the poorest countries, where other healthy foods that are more 'standard' in rich countries are not readily available due to adverse economic, social, or environmental causes.

²⁸Gawel et al. (2017).

²⁹Xie et al. (2019).

3.3 *Novel Healthy Food Ingredients and Supplements from Food Byproducts*

If there is a category of Novel Food ingredients that puts in clear evidence the important role played by them in the transition towards a circular economy, and with it towards sustainable food production, it is the one including ingredients obtained by food by-products. The possibility of obtaining a food ingredient, and even a healthy food ingredient (rich in protein, fibre, or antioxidants) from residual biomass meant for waste, gives the twofold advantage of reducing the amount of food waste to be treated and of saving the traditional sources for these ingredients, eventually increasing their availability in the market, and possibly lowering their costs. Some typical examples are reported below.

Lycopene, the main carotenoid of tomato, is present in the Union list of Novel Foods with four different entries. Of these, two of them concern the obtainment of lycopene from tomatoes (lycopene from tomatoes and lycopene oleoresin from tomatoes). Tomato skins, which are the leftovers from pulp, puree, and paste production, are a rich source of lycopene. The fact that lycopene extracted from these sources is to be considered a Novel Food might appear strange considering that the compound is common in tomatoes, which are part of the diet of billions of people around the world. But pure lycopene is certainly a Novel Food ingredient since it is never purposely added to our food preparations as such, but only as part of the tomato. Pure lycopene has been proposed for use in fruit/vegetable juice-based drinks, drinks targeted for athletes, diet replacements for weight control, breakfast cereals, fats and dressings, soups other than tomato soups, and bread, all foods usually completely devoid of lycopene. Lycopene is also present in the Novel Foods list as extracted from *Blakeslea trispora*, a mould that produces large amounts of carotenoids, and even as synthetic lycopene. The fact that lycopene has been authorized as a Novel Food ingredient from four different sources, including synthesis, demonstrates that there is a great deal of interest in commercializing this compound as a food additive. Interest is due to the celebrated antioxidant properties of lycopene, which in the literature have been associated with positive effects in the control of serum lipid levels, of endothelial dysfunction, of inflammation, of blood pressure, as well as for its strong antioxidative potential.³⁰ Certainly, lycopene has big market potential, and is well known among the general public as a ‘good’ antioxidant molecule, which may well have triggered the requests for its recognition as a Novel Food ingredient. As stated above, health benefits are the driving force for companies for making applications for lycopene as a Novel Food, but again those benefits are not the criteria by which a Novel Food is approved or not, which regard only its safety.

A further example concerns plum kernel oil, a Novel Food which has been approved to be used for frying or seasoning, in line with other vegetable oils. The

³⁰Khan et al. (2021).

Novel Food status comes from the fact that usually plum kernels are discarded as food process waste. Plum kernel oil is usually used in cosmetic products, but lately, it has been marketed as a virgin oil with a delicate almond-like flavour. In this case, the driving force for its commercialization and its application as a Novel Food came from being a supposed food specialty, more than from its health benefits, and mostly for the possibility to valorise and give added value to a discard of the plum industry. Nevertheless, it has also been branded as a source of Vitamin E and oleic acid (70% of the lipid fraction).

If the previous Novel Foods extracted from by-products are a source of lipids and antioxidants, wheat bran extracts are a Novel Food to be used as a source of fibre. Wheat bran, a by-product of the industrial roller milling of wheat, is added to food products because of its favourable nutritional profile and physiological effects.³¹ The bran fraction approved as a Novel Food is rich in arabinoxylan oligosaccharides, and its proposed use is for addition to beer and beer substitutes, ready-to-eat cereals, dairy products, fruit and vegetable juices, soft drinks, and meat preparations. Here once again health benefits are the driving force leading to the approval of this Novel Food, together with the intention to valorise a by-product of the wheat industry which still has much potential as a food additive.

The last example of Novel Food obtained by a food by-product concerns a product of animal origin. The Union list reports among Novel Foods a protein extract from pig kidneys meant as a food supplement. Pig kidneys are by-products of the slaughter process, and as such are usually discarded. Still, the protein extract contains a relevant amount of the enzyme diaminoxidase. Diamine oxidase supplements are products that restore the diamine oxidase enzyme in the human body. This enzyme degrades histamine in histamine-rich foods and reduces symptoms of histamine intolerance. These supplements might offer relief from headaches, digestive issues, and skin reactions provoked by an excessive consumption of histamine-rich food (like cheese). Thus, once more the driving force for bringing to the market as Novel Food this product is the health benefit that can be obtained from it, as well as the obvious economic advantage of valorising a product that is usually simply discarded as waste.

All the above examples demonstrate how Novel Foods can contribute towards the creation of a truly circular economy both by bringing sustainability to the food production system through the valorisation of food by-products and food discards, as well as the added value of introducing new health benefits to the human diet.

³¹ Hemdane et al. (2016).

3.4 Novel Ingredients for Healthier Baby Foods Also Extended to Foods for Adults

A significant number of Novel Foods are specifically dedicated to the well-being of children and toddlers and are commercialized as ingredients in infant formula, follow-up formula, and baby foods, but interestingly also as food ingredients for adults. This category of Novel Food makes extremely clear how health benefits are the true driving force for a Novel Food application. The most relevant ingredients belonging to this class are mono- and oligosaccharides present in human breast milk and recognized to be important for child development, such as *N*-acetyl-D-neuraminic acid, 2'-fucosyllactose, galactooligosaccharides, and Lacto-*N*-neotetraose. The status of Novel Foods for those compounds is compelled by the fact that, although present in human breast milk, they had never been used as supplements in infant formula before 1997, and thus in a sense they are 'new' as food ingredients (although obviously, every breastfed baby experienced them in his/her diet), and they are obtained by chemical or enzymatical synthesis. What is particularly interesting is that the above Novel Foods, although developed mostly for infant formula and baby food supplementation, and inspired by the composition of human breast milk, have also been proposed as Novel Food ingredients in foods meant for adults (milk and dairy products, cereal bars, fruit, and vegetable-based drinks, coffee, tea, and herbal infusions, food supplements for adults, etc.), clearly aiming at extending the supposed benefits of these compounds to an adult population.

N-acetyl-D-neuraminic acid is a major component of sialic acid in the human body, and sialyloligosaccharides represent a significant fraction of human breast milk oligosaccharides. They have been described as essential nutrients in the development of the infant brain, since their highest concentration in milk during early lactation concurs with a rapid increase of brain gangliosides. Furthermore, the content of gangliosides and protein-bound sialic acid is higher in the brains of breast-fed infants in comparison to formula-fed infants.³² In any case, in stark contrast with human breast milk composition, infant formulas are usually very poor in *N*-acetyl-D-neuraminic acid and, consequently, of sialic acid. Thus, the supplementation of this compound, obtained by chemical synthesis, has been suggested to improve brain development in infants. 2'-fucosyllactose is a trisaccharide, also present in human breast milk but generally not in infant formula, that modulates the gut microbiota in formula-fed infants when added as a supplement.³³ 2'-fucosyllactose from chemical synthesis can therefore be added to infant formula to improve the health of the gut microbiota. Analogously, galactooligosaccharides have been associated with many health-promoting effects in newborn children, such as growth promotion of beneficial bacteria, inhibition of pathogen adhesion, and

³²Oliveros et al. (2018).

³³Van den Abbeele et al. (2019).

improvement of gut barrier function. For these reasons, as a Novel Food ingredient, they are now used as prebiotics for the gut microbiota in infant formulations. Galacto-oligosaccharides are produced through an enzymatic reaction controlled by β -galactosidases of bacterial or fungal origin.³⁴ Lacto-*N*-tetraose is also a prebiotic present in human breast milk, and it has been demonstrated to selectively support the growth of desirable bifidobacteria and therefore to contribute significantly to the development of a natural microbiome in newborns.³⁵ As a Novel Food ingredient, it is produced by fermentation using a genetically modified strain of *Escherichia coli* and added as an additive to infant formula, baby foods, cereal bars, milk and dairy products, herbal and tea infusions, etc.

Bovine lactoferrin, a common milk protein, is also a Novel Food ingredient authorized as an additive for infant formula and foods for young children, but also for a wide range of other foods meant for adult consumption, such as processed cereal food, milk, and dairy products, non-alcoholic drinks, cakes and pastries, candies, and chewing gums. As a dietary supplement, bovine lactoferrin has been repeatedly demonstrated in the literature to enhance and support the immune system response through its antioxidant, antibacterial, and antiviral properties.³⁶ As for some of the previously described Novel Foods, it might appear strange that a protein that is commonly present in milk is to be considered a Novel Food: after all, drinking milk always means drinking a certain amount of lactoferrin. Pure bovine lactoferrin is indeed produced on an industrial scale from cheese whey or skimmed milk. What makes bovine lactoferrin a Novel Food is that, when used as an additive, it is added in concentrations that are not commonly found in milk and dairy products: what is new in this case is the amount of lactoferrin entering our diet all at once from a single source.

Arachidonic acid-rich oil from the fungus *Mortierella alpina* is a Novel Food ingredient exclusively developed for infant formula and as a food supplement for children, and today commonly used in baby food formulations. Arachidonic acid has multiple physiological functions and is an important nutrient for infants and the elderly. However, most of the arachidonic acid in humans is usually taken from dietary animal sources such as meat and eggs, which are not usually part of the infant diet. Also, extraction of arachidonic acid from the above sources to be used as an additive is not practical for large-scale production. Instead, fungi such as *M. alpina*, which in some strains is a strong arachidonic acid producer, can be used to supplement infant formula efficiently.³⁷ Since *M. alpina* arachidonic-rich strain has never been consumed in the past, it needed approval as Novel Food. In this case, the intended application was restricted to infant formula and baby foods, since the adult population is supposed to have sufficient intake of arachidonic acid from animal

³⁴ Ambrogi et al. (2021).

³⁵ Gotoh et al. (2018).

³⁶ Mulder et al. (2008).

³⁷ Kikukawa et al. (2018).

sources, but certainly, this has the potentiality to be extended to the segment of the world population unable to access sufficient amounts of foods of animal origin.

Through the few examples presented above, it appears clear that this group of Novel Foods is mostly aimed at tackling first and foremost baby diet insufficiencies by producing Novel Food ingredients that mimic compounds naturally present in human breast milk, or compounds that are well known to be beneficial for children at many different levels (brain development, health microbiota, immune system, etc.). As mentioned previously, however, the extension of these Novel Foods to adults could extend those benefits to a much larger part of the population, producing significant positive effects. The maximum benefits of these Novel Food ingredients, once equal access is granted globally, will be felt most strongly among the populations where children and their mothers, but also the rest of the adult population, do not have access to complete and nutritious diets. As seen previously, the real purpose and promise of these Novel Foods is once again the possibility to access diets that are healthier and more nutritious, thus increasing food security for everybody and reducing food access inequality.

3.5 Novel UV-Treated Foods for Tackling Vitamin D Deficiency

As the last example of how Novel Foods are primarily intended to improve health and wellbeing, I refer to a special category of Novel Foods that includes commonly consumed foods that have been treated by UV irradiation. In this case, although the foods in this category are very common ones, approval as Novel Foods was needed because the UV treatment was a technology never before applied to them. Thus, those foods after treatment are indeed Novel Foods, in the sense of never having been consumed before in the European Union. There are four UV-treated Novel Foods in the Union list: UV-treated mushrooms (*Agaricus bisporus*), UV-treated baker's yeast (*Saccharomyces cerevisiae*), UV-treated bread, and UV-treated milk. In all cases, the treatment was done to increase the content of vitamin D. When mushrooms, yeast, or bread are treated with ultraviolet light, a conversion of ergosterol to ergocalciferol (Vitamin D₂) is induced. The treatment of the pasteurized milk with UV radiation results in an increase in the conversion of 7-dehydrocholesterol to vitamin D₃ (cholecalciferol). The relevance of stimulating vitamin D production in food is paramount in a healthy diet. The percentage of the world's population with vitamin D deficiency is continuously increasing, and this problem is mostly felt in the poorest parts of the world. Vitamin D deficiency can lead to a loss of bone density, which can contribute to osteoporosis and bone fractures. Very few foods contain vitamin D, and therefore dietary guidelines recommend supplementation of vitamin D.³⁸ In this sense, these UV-treated Novel

³⁸Nair and Maseeh (2012).

Foods might make a difference: they are traditional common foods (bread, milk), usually poor in vitamin D content, but widely consumed. The UV-induced increase in their vitamin D content could be an easily applied solution that is accessible to all as part of efforts to reduce malnutrition in many parts of the world.

4 Conclusions

The considerations and illustrations expounded upon in this chapter show how the main driving force for a company to develop, validate, test, and ask for approval for a Novel Food is the possibility to brand this new food as a healthy ingredient, capable of bringing in our diets new compounds with nutritional advantages that were not present before its introduction. This is even clearer if we observe how many times the terms ‘Food Supplement’ or ‘Food for Special Medical Purposes’ appear in the list of the intended use of the Novel Foods. ‘Food Supplements’ are intended to correct nutritional deficiencies, maintain an adequate intake of certain nutrients, or to support specific physiological functions, whereas ‘Food for Special Medical Purposes’ are foods designed for patients who, due to a particular disease, disorder, or medical condition, have nutritional needs that cannot be met by consuming standard foodstuffs; these patients they have a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foods, or certain nutrients or metabolites. Both categories aim at improving the health of consumers with dietary challenges caused by a special condition or illness. Those terms are over-represented in the European Union list of Novel Foods: within approximately 200 entries, the use of Novel Foods as ‘Food Supplement’ appears more than 100 times and as ‘Foods for special medical purposes’ about 30 times. This last example demonstrates once more how improving health and wellbeing is a key target for Novel Foods.

At the same time, ongoing efforts to find new benefits lead to the use of new technologies for food production, including the chemical synthesis of compounds that never existed before, or the exploitation of biomasses not previously used as food sources, including biomasses coming from former food waste. As a result, all the above-combined efforts to find new healthy ingredients come together to transform the food production system into a healthier and more sustainable one, reducing food waste, preserving traditional sources of food, and securing new compounds that can increase the health level of the entire human population. Every Novel Food is a small but essential step towards the Sustainable Development Goals outlined at the beginning of this chapter.

The last consideration to be made, even if it is beyond the scope of this chapter, concerns the perception of the public towards Novel Foods: are they perceived in the way they should be? Is the average consumer aware that Novel Foods are not an attempt by large companies to subvert local traditions, and even less an attempt to eliminate our beloved traditional foods from our diet, but simply the addition of new foods bringing new possibilities for how we can maintain our health and wellbeing? Novel Foods are not the substitute for what we have always had in our diets, but

rather an addition, intended to improve and increase our choices for a better world for us and everyone. Consumers should be aware of these realities if we are to ease our transition towards a new food production system.³⁹

References

- Almeida ES, de Oliveira D, Hotza D (2019) Properties and applications of *Morinda citrifolia* (Noni): a review. *Comprehensive Rev Food Sci Food Saf* 18:883–809
- Ambrogì V, Bottacini F, Cao L, Kuipers B, Schoterman M, van Sinderen D (2021) Galacto-oligosaccharides as Infant Prebiotics: production, application, bioactive activities and future perspectives. *Crit Rev Food Sci Nutr* 3:1953437
- Amine H, Benomar Y, Haimour A, Messaoui H, Meskini N, Taouis M (2016) *Odontella aurita*-enriched diet prevents high fat diet-induced liver insulin resistance. *J Endocrinol* 228:1–12
- Chiu SY, Kao CY, Chen TY, Chang YB, Kuo CM, Lin CS (2015) Cultivation of microalgal *Chlorella* for biomass and lipid production using wastewater as nutrient resource. *Bioresour Technol* 184:179–189
- Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R2470>. Accessed 7 Feb 2022
- Da Silva JC (2022) Feeding the World Sustainably. United Nations, <https://www.un.org/en/chronicle/article/feeding-world-sustainably#:~:text=According%20to%20estimates%20compiled%20by,world%20population%20of%209.3%20billion>. Accessed 24 Jan 2022
- FAO, IFAD, UNICEF, WFP, WHO (2021) The State of Food Security and Nutrition in the World 2021. Transforming food systems for food security, improved nutrition and affordable healthy diets for all, <https://www.fao.org/documents/card/en/c/cb4474en/>. Accessed 24 Jan 2022
- Flachowsky G, Meyer U, Südekum KH (2017) Land use for edible protein of animal origin—a review. *Animals* 7:25
- Gawel E, Grzelak M, Janyszczek M (2017) *Lucerne* (*Medicago sativa* L.) in the human diet—case reports and short reports. *J Herbal Med* 10:8–16
- Gotoh A, Katoh T, Sakanaka M, Ling Y, Yamada C, Asakuma S, Urashima T, Tomabechi Y, Katayama-Ikegami A, Kurihara S, Yamamoto K, Harata G, He F, Hirose J, Kitaoka M, Okuda S, Katayama T (2018) Sharing of human milk oligosaccharides degradants within bifidobacterial communities in faecal cultures supplemented with *Bifidobacterium Bifidum*. *Sci Rep* 8:13958
- Gustavsson J, Cederberg C, Sonesson U (2011) Global food losses and food waste: Extent, causes and prevention. FAO, <https://www.fao.org/3/i2697e/i2697e.pdf>. Accessed 24 Jan 2022
- Hemdane S, Jacobs PJ, Domez E, Verspreet J, Delcour JA, Courtin CM (2016) Wheat (*Triticum aestivum* L.) bran in breadmaking: a critical review. *Comprehensive Rev Food Sci Food Saf* 15: 28–42
- Jackson AA, Truswell S (2007) Protein. In: Mann J, Truswell S (eds) *Essentials of human nutrition*, 3rd edn. Oxford University Press, Oxford, pp 53–72
- Khan UM, Sevindik M, Zarrabi A, Nami M, Ozdemir B, Nur Kaplan D, Selamoglu Z, Hasan M, Kumar M, Alshehri MM, Sharifi-Rad J (2021) Lycopene: food sources, biological activities, and human health benefits. *Oxi Med Cell Longev* 2021:2713511

³⁹On this point, with specific reference to insects as food, see *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook*, by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

- Kikukawa K, Sakuradani E, Ando A, Shimizu S, Ogawa J (2018) Arachidonic acid production by the Oleaginous Fungus *Mortierella Alpina* 1S-4: a review. *J Adv Res* 11:15–22
- Kouřimská L, Adámková A (2016) Nutritional and sensory quality of edible insects. *NFS J* 4:22–26
- Leni G, Caligiani A, Sforza S (2021) Bioconversion of agri-food waste and by-products through insects: a new valorization opportunity. In: Rajeev B (ed) *Valorization of agri-food wastes and by-products*. Academic Press Elsevier, Cambridge, pp 809–828
- Mekonnen MM, Hoekstra AY (2010) The green, blue and grey water footprint of farm animals and animal products. UNESCO-IHE, Value of Water Research Report Series no. 48, https://waterfootprint.org/media/downloads/Report-48-WaterFootprint-AnimalProducts-Vol1_1.pdf. Accessed 15 Feb 2022
- Mulder AM, Connellan PA, Oliver CJ, Morris CA, Stevenson LM (2008) Bovine Lactoferrin supplementation supports immune and antioxidant status in healthy human males. *Nutr Res* 28: 583–589
- Nair R, Maseeh A (2012) Vitamin D: The “Sunshine” Vitamin. *J Pharmacol Pharmacother* 3:118–126
- Oliveros E, Vázquez E, Barranco A, Ramírez M, Guart A, Delgado-García JM, Buck R, Rueda R, Martín MJ (2018) Sialic Acid and Sialylated Oligosaccharide supplementation during lactation improves learning and memory in rats. *Nutrients* 10:1519
- Pollard CM, Booth S (2019) Food insecurity and hunger in rich countries—it is time for action against inequality. *Int J Environ Res Public Health* 16:1804
- Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food ingredients, <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A31997R0258>. Accessed 15 Feb 2022
- Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, <https://eurlex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32015R2283>. Accessed 15 Feb 2022
- Ritchie R, Roser M (2017) “Diet Compositions”. Published online at OurWorldInData.org. Retrieved from: <https://ourworldindata.org/diet-compositions>. Accessed 22 Jan 2022
- Springmann M, Clark M, Mason-D’Croz D, Wiebe K, Bodirsky BL, Lassaletta L, de Vries W, Vermeulen SJ, Herrero M, Carlson KM, Jonell M, Troell M, DeClerck F, Gordon LJ, Zurayk R, Scarborough P, Rayner M, Loken B, Fanzo J, Godfray H CJ, Tilman D, Rockström J, Willett W (2018) Options for keeping the food system within environmental limits. *Nature* 562:519–525
- Toro V, Siquier-Coll J, Bartolomé I, Robles-Gil MC, Rodrigo J, Maynar-Mariño M (2020) Effects of *Tetraselmis chuii* microalgae supplementation on ergospirometric, haematological and biochemical parameters in amateur soccer players. *Int J Environ Res Public Health* 17:6885
- Ullah R, Nadeem M, Khalique A, Imran M, Mehmood S, Javid A, Hussain J (2016) Nutritional and therapeutic perspectives of Chia (*Salvia hispanica* L.): a review. *J Food Sci Technol* 53:1750–1758
- United Nations (2015) A/Res/70/1: resolution adopted by the general assembly on 25 September 2015. Transforming our World: the 2030 agenda for sustainable development, https://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E. Accessed 13 Jan 2022
- United Nations Environment Programme (2021) Food Waste Index Report 2021, <https://www.unep.org/resources/report/unep-food-waste-index-report-2021>. Accessed 3 Feb 2022
- Van den Abbeele P, Duysburgh C, Vazquez E, Chow J, Buck R, Marzorati M (2019) 2-’-Fucosyllactose alters the composition and activity of gut microbiota from formula-fed infants receiving complementary feeding in a validated intestinal model. *J Funct Foods* 61:103484
- WHO (2020) Malnutrition, <https://www.who.int/news-room/questions-and-answers/item/malnutrition>. Accessed 24 Jan 2022
- World Commission on Environment and Development (1987) *Our Common Future, From One Earth to One World*, <http://www.un-documents.net/our-common-future.pdf>. Accessed 22 Jan 2022

Xie D, Gong M, Wei W, Jin J, Wang X, Wang X, Jin Q (2019) Antarctic Krill (*Euphausia Superba*) Oil: a comprehensive review of chemical composition, extraction technologies, health benefits, and current applications. *Comprehensive Rev Food Sci Food Saf* 18:514–534

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



Why ‘New’ Foods Are Safe and How They Can Be Assessed



Chiara Dall’Asta

Abstract The chapter presents an overview of the safety assessment process for Novel Foods within the European Union. The main steps are presented and discussed together with the applied methodologies. Bottlenecks and limitations are examined, also in view of increasing transparency in consumer communication and improving overall consumer trust in Novel Foods.

Keywords Novel food · Risk assessment · Allergenicity · Safety assessment

1 The Safety Assessment Process in the European Union

Ensuring food safety from farm to fork is a founding principle of the European Union.¹ It is also the fundamental aim of the extensive body of EU laws and standards covering the agri-food sectors as well as imported and exported goods within the Member States. However, many foodborne illness outbreaks that have occurred in recent years compounded by the pressure—intentional or unintentional—caused by misinformation circulating through social media (so-called “fake news”), have generated an increasing mistrust among EU consumers in the capability of the food system to deliver safe food.^{2,3,4} At the same time, global concern about climate change and the effects of globalization are driving lifestyle changes towards more sustainable patterns, and a consequent growing demand for healthier and less processed food.⁵ At an industrial level, this

¹ Regulation (EC) 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

² De Jonge et al. (2007).

³ Van Kleef et al. (2006).

⁴ De Jonge et al. (2008).

⁵ Grunert et al. (2014).

C. Dall’Asta (✉)

University of Parma, Department of Food and Drug, Parma, Italy

e-mail: chiara.dallasta@unipr.it

demand translates into a need for product differentiation on the global market and, therefore, a call for innovation.

Novel Foods—especially those derived from less exploited resources or biomasses—may offer a great opportunity to the food industry for innovation while at the same time meeting sustainability needs.⁶ While the potential sources of Novel Foods are countless, their safety assessment according to EU regulation requires a case-by-case approach. Safety evaluations include a toxicological and a nutritional assessment, an analysis of the way the Novel Food will be processed and used, as well as a description of its intended intake.

Although the effort required to assess and ensure the safety of Novel Foods is enormous and is encoded by a well-established process,⁷ consumers still perceive these foods with distrust, often due to communication campaigns on social media. It can be noted indeed that also accountable media reporting news on Novel Foods often make use of images that can drive disgust among readers, and thus causing mistrust. A recent work based on longitudinal- and cross-cultural studies reported on the significant correlation between food disgust and risk perception among adult consumers, pointing out the importance of food disgust sensitivity for the acceptance of Novel Foods.⁸ This neophobia⁹ attitude is higher for those Novel Foods obtained from sources that are alien to Europeans, such as insects or algae, or sources that are produced using radically new technologies (i.e., cultured meat). A better response is observed for Novel Foods obtained from known sources (i.e., those derived from cocoa or coffee biomasses) or resembling foods common in Europe (i.e., juices or infusions from novel berries).^{10,11} It is therefore important to provide an overview of the safety assessment required for Novel Food, to demonstrate the rigorous procedure required for approval and the high standards requested for entering the market.

⁶On this point, see *Food (In)Security: the Role of Novel Foods on Sustainability* by S. Sforza in this volume.

⁷EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), et al. (2016).

⁸Siegrist et al. (2020)

⁹Jaeger et al. (2022). See also *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook*, by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

¹⁰Coulthard et al. (2022).

¹¹Tuorila and Hartmann (2020).

2 Safety Assessment Requirements for Novel Foods

It is important to underline that Novel Foods should be at least as safe as their traditional counterparts, where extant, and should not present any dietary risks. This is the underpinning principle for the safety assessment procedure leading to the approval of a Novel Food.¹²

The risk assessment performed by the European Food Safety Authority (EFSA), based on the scientific evidence provided by the food business operator, enables the European Commission to decide whether a Novel Food product or ingredient can be placed on the EU market.¹³ It should be noted that such premarket authorisation¹⁴ is not only requested for Novel Foods, but is also a prerequisite for the commercialization of other regulated products (i.e., food enzymes, improvement agents). Authorisation is also required for the use of health claims on food labels, and it is clearly aimed at both ensuring the safety of the product as well as at enabling consumers to make informed choices.

The safety assessment procedure for Novel Foods is established by law in Regulation (EU) 2015/2283, while the main scientific requirements for a Novel Food application are outlined in EFSA's "Guidance on the preparation and presentation of an application for authorization of a Novel Food in the context of Regulation (EU) 2015/2283". EFSA's specific role is to identify and characterise any hazards linked to the consumption of Novel Foods, and assess the risk associated with their consumption under the proposed conditions of use. It should be noted, however, that it is the applicant's responsibility to provide sufficient and sound evidence to support the safety of the proposed Novel Food. When scientific data provided by the applicant are not sufficient to rule out any potential health concern, the Novel Food cannot be approved for the market.

In order to ensure the overall transparency of the process, all Novel Food applications received by EFSA are publicly available via the EFSA Register of Questions (ROQ) database,¹⁵ while all the published technical reports on the risk assessment of these products are published in the EFSA Journal.¹⁶ In addition, all the Novel Foods in the European Union authorised so far are compiled into the Union List,¹⁷ which includes their conditions of use, labelling requirements, and their

¹²Regulation (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) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

¹³EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), et al. (2016).

¹⁴For an in-depth analysis, see *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, by A. Volpato in this volume.

¹⁵See <http://registerofquestions.efsa.europa.eu/roqFrontend/login?0>, last accessed 15 February 2022.

¹⁶See <https://efsa.onlinelibrary.wiley.com/journal/18314732>, last accessed 15 February 2022.

¹⁷See https://ec.europa.eu/food/safety/novel-food/authorisations/union-list-novel-foods_en, last accessed 15 February 2022.

specifications. Moreover, the EU Commission also makes publicly available the summaries of applications and notifications.¹⁸

Certain background information on the denomination/identity of the Novel Food or ingredients, its source, and intended use, is necessary to establish its safety profile. This information also helps to identify potential knowledge gaps, and any ensuing need for additional toxicological or nutritional studies. A Novel Food or ingredient can be obtained from a plant, animal, or micro-organism, or can derive from chemical synthesis. Accordingly, different strategies should be put in place for the assessment of the safety profile. For Novel Foods or ingredients obtained from biological sources, details of any previous use as a food or feed should be provided, together with information about the history of use outside the EU. Such information will help in the evaluation of previous adverse effects in the target human population, and in the definition of the boundaries of the intended use.

Novel Foods can be ingredients with complex mixtures or whole foods. Examples of whole foods are the recently authorised lyophilised pulp and skin of pitted fruits of *Synsepalum dulcificum*,¹⁹ intended as a food supplement, or the partially defatted rapeseed powder from *Brassica rapa L.* and *Brassica napus L.*²⁰ On the contrary, extracts or fractions can be regarded as complex mixtures, i.e., the recently authorised astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae.²¹

The complex nature of such systems, usually formed by hundreds of different substances over a large range of concentrations, is the main constraint to providing a comprehensive chemical characterization of the Novel Food. A comprehensive (physico)-chemical characterization of the Novel Food is indeed the groundwork for a critical evaluation of any possible adverse health effects in humans, providing essential information for the design and interpretation of toxicological studies.

In addition to proximate analysis, the applicant should provide qualitative and, when possible, quantitative data on components of biological interest, so as to minimize the percentage of unidentified substances. In addition, chemical information about the potential occurrence of residues, contaminants, or inherent compounds of biological interest are required. For instance, the applicant should provide data about residues, natural toxins, nutrients, and antinutritional factors known to be associated with the source of the Novel Food or ingredient, or contaminants that might arise from the production process. The analytical plan should be decided on a case-by-case basis, taking into account the source of the Novel Food or ingredient and its processing history.

As an example, in the recently authorised *Coffea arabica L.* and/or *Coffea canephora Pierre ex A. Froehner* dried cherry pulp,²² caffeine was clearly the

¹⁸See https://ec.europa.eu/food/safety/novel-food/authorisations/summary-applications-and-notifications_en, last accessed 15 February 2022.

¹⁹Commission Implementing Regulation (EU) 2021/1974.

²⁰Commission implementing regulation (EU) 2021/120.

²¹Commission Implementing Regulation (EU) 2021/1377.

²²Commission Implementing Regulation (EU) 2022/47.

main inherent compound of interest. An accurate quantification in different batches allowed for the extrapolation of potential intake in the target population according to the proposed use. The provisional intake was then compared to the caffeine threshold of concern according to EFSA to assess any potential risk deriving from the consumption of the Novel Food. When the Novel Food has had, instead, a high fat content which is known to be highly degradable, as in the case of coriander seed oil,²³ the possible formation of hazardous compounds during storage following lipid peroxidation was thoroughly assessed.

In addition to its composition, the production process can significantly impact the safety profile of a Novel Food, leading to changes in composition (i.e., dilution and/or concentration of compounds of interest in extracts) or degradation of unstable compounds. Therefore, production processes cannot be overlooked in the safety assessment.

The toxicological profile of a Novel Food is probably the most cumbersome step in the safety assessment, especially when there is no substantial information available about the history of use. Methodologies for the evaluation of toxicokinetic, toxicological, and allergenic aspects are not univocally defined.^{24,25} To properly guide the process, EFSA has recently proposed a tiered approach based on the use of *in silico*, *in vitro* and *in vivo* studies.^{26,27} In particular, the integration of computational approaches and physicochemical data can support a more precise design of experimental trials, thus allowing for the limitation of the number of animal trials according to the 3R principle.²⁸

Finally, all the data obtained from the (physico)-chemical characterization and the toxicological assessment is used to set appropriate specifications and to define the intended role of the Novel Food or ingredient in the diet as well as its potential intake and target population. The specification is aimed at ensuring the observance of the general conditions of inclusion of Novel Foods in the Union list, as established by Regulation (EU) 2015/2283.

3 Assessing the Allergenic Potential: The Big Constraint

As required by Regulation (EU) No 1169/2011, allergens must be indicated on food product labels to provide consumers with information about potential allergens. Therefore, the evaluation of potential allergens occurring in Novel Foods is essential

²³ Commission Implementing decision 2014/155/EU.

²⁴ Blaauboer et al. (2016).

²⁵ Edwards (2005).

²⁶ EFSA Scientific Committee et al. (2019).

²⁷ Benfenati et al. (2016).

²⁸ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on protecting animals used for scientific purposes.

to carrying out an accurate risk assessment and meeting the general conditions of inclusion in the Union list. However, there are no validated predictive tests for assessing the allergenicity of proteins from sources that are not commonly recognized as allergens.

While a comprehensive and robust chemical characterization is possible, and the methodologies for a sound toxicological evaluation are often available, the allergenic potential of a certain food or ingredient is still difficult to be defined in the absence of a history of use. For this reason, the assessment of allergenic potential is the main bottleneck and one of the major limitations in the risk assessment of many Novel Food candidates.

Since food allergens are mainly proteins, any Novel Food containing proteins or protein fractions may elicit an allergenic response. Therefore, as a general assumption, when proteins are determined in the compositional analysis of a Novel Food or ingredient, these proteins must be regarded as potentially allergenic.²⁹ A novel protein may present a risk due to de novo sensitisation or cross reactivity.^{30,31} The term sensitisation refers to the initiation of an allergic immune response following from the intake of an allergen. It can be caused via multiple routes of exposure, i.e., ingestion, respiratory tract, or dermal exposure. In terms of mechanism, the allergen intake leads to a hypersensitive immune response, which in typical food allergies is IgE mediated. De novo sensitisation indicates that a new protein causes such an allergic reaction, while in cross-reactivity, a protein which is homologous to a known allergen causes an allergic reaction similar to that of the known allergen (i.e., birch pollen allergens cross-reacting with apple allergens). If the Novel Food or ingredient is expected to contain proteins from sources known to be associated with food allergy, more information can be collected from specific chemical and immunological tests. In case of a positive result, the Novel Food should be labelled to indicate the source of the allergenic protein in question.

If the history of the Novel Food or ingredient does not suggest the presence of proteins from sources known to be associated with food allergy, an alternative strategy is required. While it is unlikely that a new protein will elicit an allergic reaction in a large proportion of the population, a comparison of the properties of any new proteins in the Novel Food with those of known allergens may prove valuable in assessing the likelihood that the new protein will express allergenic potential. Potential cross-reactivity can be analysed by homology searches, i.e., the comparison of the protein chemical structure with a dataset of sequences of known allergens, and serological testing such as immunoblotting. Once novel proteins are introduced in the diet, however, their capability to cause de novo sensitisation is difficult to analyse.³²

²⁹EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), et al. (2016).

³⁰Ladics and Selgrade (2009).

³¹Valenta et al. (2015).

³²Verhoeckx et al. (2016).

A consensus protocol for determining the allergenicity of Novel Foods is still lacking. However, current approaches are based on weight-of-evidence.³³ A sound evaluation of the history of use of the protein (or the source material containing the protein), also in relation to the specific environmental and geographical factors, is of utmost importance. A taxonomical analysis of the source organism (i.e., plants, microorganisms, or animals) may reveal a relationship with sources of known allergens, thus indicating potential allergens. This can be also supported by the structural characterization of the protein and its comparison to known allergens. In addition, the IgE-binding capacity of the Novel Food should be tested using human sera from allergic patients to check possible cross-reactivity or following a primary sensitisation. When an IgE-binding protein is identified, its biological activity should be carefully assessed so as to clarify whether it could activate an immunologic response. As a complementary strategy, protein thermal stability and its resistance to enzymatic digestion should be also considered.^{34,35}

4 New Methodologies to Improve Risk Assessment

The EFSA guidance document³⁶ provides suggestions for which tests can be used to evaluate the kinetic, toxicological, and allergenic properties of the Novel Food, as well as its chemical characterization. Suggested methodologies are usually based on well-established approaches with a large consensus within the scientific community. However, a range of novel methods based on cutting edge technologies—with high potential to improve the chemical and toxicological characterization of a food—are becoming available to the scientific community. Among them, *in silico* modelling and omics technologies are already considered by the EU animal welfare Directive.³⁷ The integration of *in vitro* and *in silico* methods to evaluate the biological activity of certain food components is widely suggested in the recent literature, especially to refine the identification of potential biological targets and reduce the number of animal experiments.^{38,39,40} Computational methods based on quantitative structure-activity relationship (QSAR) analysis,⁴¹ physiologically based

³³Ribeiro et al. (2021).

³⁴Westerhout et al. (2019).

³⁵Mazzucchelli et al. (2018).

³⁶EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), et al. (2016).

³⁷Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

³⁸Hartung (2011).

³⁹Lo Piparo et al. (2011).

⁴⁰Schilter et al. (2014).

⁴¹Dorne et al. (2021).

toxicokinetic modelling (PBTK),⁴² and the Threshold of Toxicological Concern (TTC)⁴³ have recently been included in EFSA guidance documents, attesting to the great potential for their exploitation in risk assessment.⁴⁴ These alternative methods take advantage of the computational calculation available in the “big data” era, allowing for the high throughput safety evaluation of large batches of chemicals. Although animal studies cannot be completely replaced by computational modelling, such alternative methods may provide a prioritization criterion, thus contributing to the identification of the main biological targets and endpoints to be further tested. In the end, this may lead to a significant reduction in animal testing, as well as reducing the cost and effort required for toxicological studies.

The combination of data from *in vitro* toxicity experiments, ADME data, *in silico* experiments, and *in vivo* dose-response curves may represent an innovative pipeline to reduce or replace tests with experimental animals while providing a robust risk assessment; the main limitation is so far still represented by the difficulty of the *in vitro*–*in vivo* extrapolation of toxicological data. The integration of system biology and toxicogenomics is also increasingly gaining interest in risk assessment work, although the lack of consensus workflow is constraining the wide uptake of such methodologies into general risk assessment processes.⁴⁵ Once the predictive capacity of these methodologies is improved and consensus workflows are available for the scientific community, the inclusion of alternative methods into the current risk assessment procedure will pave the road to more informed and thorough safety and nutritional assessment.⁴⁶

5 Safety Assessment of Insects As Novel Food

Insects are probably among the most controversial Novel Foods in terms of consumer perception. While their relevance for sustainability from a circular economy perspective is undeniable,⁴⁷ their acceptance as food or food ingredients among consumers is low, also due to the wide use of misleading and disgust-provoking images in social media communication campaigns.⁴⁸

⁴²Grech et al. (2017).

⁴³Reilly et al. (2019).

⁴⁴A description of the integration of alternative methods in risk assessment protocols, together with the link to relevant literature can be found here: <https://www.efsa.europa.eu/en/news/chemical-hazards-data-and-modelling-boost>, last accessed 15 February 2022.

⁴⁵Black et al. (2022).

⁴⁶Zare Jeddi et al. (2022).

⁴⁷For a thorough treatment of this issue not only for insects but for all Novel Foods see, *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume.

⁴⁸Faccio and Fovino (2019).

Three insect species have been approved as Novel Foods so far, namely *Tenebrio molitor* larva,⁴⁹ *Locusta migratoria*,⁵⁰ and *Acheta domesticus*.⁵¹ For all of them a sound safety assessment has been performed before authorization based on a wide body of evidence from the scientific literature. Due to controversies in consumer perception and wide debate around them, the number of studies published in scientific journals over the past decade significantly exceeds those related to any other Novel Food. Therefore, the risk assessment performed by EFSA has strong foundations, and the uncertainties around insect safety profiles are limited to a few specific issues.

The advantages related to the use of edible insects as a source of alternative proteins for humans have been widely discussed and demonstrated in the scientific literature, from low input farming requirements to the nutritional and technological values of the protein and lipid fractions of interest. A comprehensive overview, which is beyond the scope of this chapter, can be found in recent reviews from Gravel and Doyen,⁵² Baiano,⁵³ and van Raamsdonk and coauthors,⁵⁴ as well as in the fourth chapter of this volume, where Sforza focuses on the importance of these proteins for global human health.

Concerning the safety aspects, the risk assessment process of authorised edible insects is described in detail elsewhere this volume.⁵⁵ However, it is worth noting that the safety profile of edible insects has already been challenged on several occasions, mainly focusing on the accumulation of contaminants from substrates in reared insects.^{56,57,58} Although available data are often fragmented over a wide range of contaminants and insect species, there is general agreement that limiting the uptake of contaminants from the rearing substrate during the rearing phase is crucial towards ensuring insect safety. While the occurrence of pesticides and veterinary drugs in the rearing substrate may affect insect growth, bioaccumulation of heavy metals, cadmium, and lead has been proven to vary based on the insect species. Bioaccumulation may occur to a certain extent also for environmental residues, such as dioxins and PAH. As for mycotoxins, several species of edible insects have demonstrated the ability to decrease their amount in the biomass without giving rise to significant bioaccumulation. This could be explained through the uptake and

⁴⁹ Commission Implementing Regulation (EU) 2021/882.

⁵⁰ Commission Implementing Regulation (EU) 2021/1975.

⁵¹ Commission Implementing Regulation (EU) 2022/188.

⁵² Gravel and Doyen (2020).

⁵³ Baiano (2020).

⁵⁴ van Raamsdonk et al. (2017). See also *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume.

⁵⁵ *The Safety Assessment of Insects and Products Thereof as Novel Foods in the European Union* by G. Precup, E. Ververis, D. Azzollini, F. Rivero-Pino, P. Zakidou, A. Germini in this volume.

⁵⁶ Meyer et al. (2021).

⁵⁷ Van der Fels-Klerx et al. (2018).

⁵⁸ Poma et al. (2017).

further metabolism of mycotoxins, although the biological pathways are still unknown.^{59,60,61} Whether this metabolism leads to a bioactivation or a detoxification needs further attention, not only for a better safety assessment of edible insects, but mainly in view of the biotechnological exploitation of insect enzymes in the detoxification of non-compliant batches.

When edible insects are reared on biomasses compliant with EU regulations, the main food and feed contaminants such as pesticides, mycotoxins, heavy metals, or industrial residues are not accumulated in the fractions of interest. As with any other food of animal origin, the crucial point in the safety of edible insects is the implementation of severe controls for the rearing of biomasses, and not on the insects themselves.

On the contrary, it must be underlined that the main safety issue related to edible insects is their allergenic potential.^{62,63} A paradigmatic example of the challenges in assessing allergenic potential is represented by edible insects such as the recently authorised *Tenebrio molitor*.⁶⁴ Although no specific information can be derived about the allergenic potential of Yellow mealworm based on the history of use, the taxonomical analysis returned a proximity with shrimp and house dust mites, well known allergenic agents.⁶⁵ Experimental trials were performed on human sera by immunoblotting and basophil activation, showing that there is a realistic possibility that house dust mites and crustacean allergic patients may react to food containing yellow mealworm proteins as a cross-reactivity effect. Based on this evidence, proper labelling should be implemented when dried yellow mealworm is commercialised as Novel Food. A similar approach can be extended to other edible insects, as well as Novel Foods in general, as reported by the recent ImpARAS COST action.⁶⁶

With respect to the safety assessment of edible insects, gaps in the understanding of allergenic potential, especially in terms of de novo sensitization, are probably in most urgent need of addressing. However, considering the current regulation on food allergens in the European Union, providing accurate information to consumers and applying correct labelling are appropriate measures to limit adverse allergic effects.

⁵⁹Bosch et al. (2017).

⁶⁰Leni et al. (2019).

⁶¹Meijer et al. (2019).

⁶²Ribeiro et al. (2018).

⁶³Pali-Schöll et al. (2019).

⁶⁴Commission Implementing Regulation (EU) 2021/882.

⁶⁵Verhoeckx et al. (2014).

⁶⁶Verhoeckx et al. (2020).

6 Is an Approved Novel Food Really Safe?

As described in the previous sections, the safety assessment of a Novel Food is a structured process, aimed at providing a comprehensive evaluation of the risk posed by the Novel Food to the target population. The applicant is asked to collect and provide scientific evidence supporting the safe placing on the market of the Novel Food. Given the thorough regulatory umbrella and the accurate risk assessment required for premarket authorisation, there is no coherent reason to undermine consumer confidence towards an approved Novel Food.

Although the current safety assessment procedure for Novel Foods has some limitations and bottlenecks, mainly in the evaluation of allergenic potential and in the comprehensive toxicological assessment, innovative cutting-edge methodologies based on the integration of system biology, omics techniques, and computational approaches may offer great opportunities for a relevant improvement in better informed risk assessment.

However, it should be said that it is impossible to ensure that a food will never pose a risk to any consumer. This consideration, inherently linked to the dynamism of science, is often the basis for a misleading perception of risk that is hard for consumers to accept.

As the Organisation for Economic Co-operation and Development (OECD) stated in 1993, food safety policies are designed to establish “a reasonable certainty that no harm will result from the intended uses”.⁶⁷ The risk assessment of a certain food is therefore based on the scientific evidence available within a specific timeframe. Any further change in the body of evidence resulting from advancements in the scientific community may therefore lead to different conclusions. For this reason, risk assessment is often repeated over time (e.g., regulated contaminants for which maximum permitted limits are issued are reassessed in due time), or whenever relevant scientific data are made available.

It is important that the regulator and the scientific community pay close attention to the proper communication of this continuous refinement process through public engagement initiatives. At the same time, the industry is asked to describe the innovation strategies at the basis of the introduction of Novel Foods to the market, while also providing unbiased information about technological opportunities and benefits in relation to sustainability. Only through a transparent and open narrative of the risk assessment process and its limitations will the food system be able to restore consumer trust and dismantle misperceptions of Novel Food.

⁶⁷ OECD (1993).

References

- Baiano A (2020) Edible insects: an overview on nutritional characteristics, safety, farming, production technologies, regulatory framework, and socio-economic and ethical implications. *Trends Food Sci Technol* 100:35–50
- Benfenati E, Berggren E, Fritsche E, Hartung T, Slikker W Jr, Spielmann H, Testai E, Tice RR, Tiramani M, Villenave R (2016) Special issue: novel chemical hazard characterisation approaches. *EFSA J* 14(S1):s0506
- Blauboer BJ, Boobis AR, Bradford B, Cockburn A, Constable A, Daneshian M, Schuermans J (2016) Considering new methodologies in strategies for safety assessment of foods and food ingredients. *Food Chem Toxicol* 91:19–35
- Black MB, Stern A, Efremenko A, Mallick P, Moreau M, Hartman JK, McMullen PD (2022) Biological system considerations for application of toxicogenomics in next-generation risk assessment and predictive toxicology. *Toxicol In Vitro* 80:105311
- Bosch G, Van der Fels-Klerx HJ, De Rijk TC, Oonincx DGAB (2017) Aflatoxin B1 tolerance and accumulation in black soldier Fly Larvae (*Hermetia illucens*) and Yellow Mealworms (*Tenebrio molitor*). *Toxins* 9(6):185
- Commission Implementing Regulation (EU) 2021/120 of 2 February 2021 authorising the placing on the market of partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. 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
- Commission Implementing Regulation (EU) 2021/1377 of 19 August 2021 authorising the change of the conditions of use of the Novel Food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470
- Commission Implementing Regulation (EU) 2021/1974 of 12 November 2021 authorising the placing on the market of dried fruits of *Synsepalum dulcificum* 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
- Commission Implementing Regulation (EU) 2021/1975 of 12 November 2021 authorising the placing on the market of frozen, dried and powder forms of *Locusta migratoria* 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
- 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
- Commission Implementing Regulation (EU) 2022/188 of 10 February 2022 authorising the placing on the market of frozen, dried and powder forms of *Acheta domesticus* 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
- Commission Implementing Regulation (EU) 2022/47 of 13 January 2022 authorising the placing on the market of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner dried cherry pulp and its infusion as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470
- Commission Regulation 2014/155/EU: Commission Implementing Decision of 19 March 2014 authorising the placing on the market of coriander seed oil as a Novel Food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2014) 1689)
- Coulthard H, Aldridge V, Fox G (2022) Food neophobia and the evaluation of novel foods in adults; the sensory, emotional, association (SEA) model of the decision to taste a novel food. *Appetite* 168:105764

- De Jonge J, Van Trijp H, Jan Renes R, Frewer L (2007) Understanding consumer confidence in the safety of food: its two-dimensional structure and determinants. *Risk Anal* 27(3):729–740
- de Jonge J, van Trijp JCM, van der Lans IA, Renes RJ, Frewer LJ (2008) How trust in institutions and organizations builds general consumer confidence in the safety of food: a decomposition of effects. *Appetite* 51(2):311–317
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes
- Dorne JLCM, Richardson J, Livaniou A, Carneseccchi E, Ceriani L, Baldin R, Kovarich S, Pavan M, Saouter E, Biganzoli F, Pasinato L, Zare Jeddi M, Robinson TP, Kass GEN, Liem AKD, Toropov AA, Toropova AP, Yang C, Tarkhov A, Georgiadis N, Di Nicola MR, Mostrag A, Verhagen H, Roncaglioni A, Benfenati E, Bassan A (2021) EFSA's OpenFoodTox: an open source toxicological database on chemicals in food and feed and its future developments. *Environ Int* 146:106293
- Edwards G (2005) Safety assessment of novel foods and strategies to determine their safety in use. *Toxicol Appl Pharmacol* 207(2):623–627
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson JL, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch Ernst KI, Mangelsdorf I, McArdle H, Naska A, Neuhäuser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Siani A, Sjödin A, Stern M, Tomé D, Vinceti M, Willatts P, Engel K-H, Marchelli R, Pötting A, Poulsen Schlatter Turla E, van Loveren H (2016) Scientific opinion on the safety of EstroG-100™ as a novel food pursuant to regulation (EC) No 258/97. *EFSA J* 14(10):e04589
- EFSA Scientific Committee, More S, Bampidis V, Benford D, Boesten J, Bragard C, Halldorsson T, Hernandez-Jerez A, Hougaard-Bennekou S, Koutsoumanis K, Naegeli H, Nielsen SS, Schrenk D, Silano V, Turck D, Younes M, Aquilina G, Crebelli R, Gurtler R, Hirsch-Ernst KI, Mosesso P, Nielsen E, Solecki R, Carfi M, Martino C, Maurici D, Parra Morte J, Schlatter J (2019) Genotoxicity assessment of chemical mixtures. *EFSA J* 17(1):5519
- Faccio E, Fovino LGN (2019) Food neophobia or distrust of novelties? Exploring consumers' attitudes toward GMOs, insects and cultured meat. *Appl Sci* 9(20):4440
- Gravel A, Doyen A (2020) The use of edible insect proteins in food: challenges and issues related to their functional properties. *Innov Food Sci Emerging Technol* 59:102272
- Grech A, Brochot C, Dorne JL, Quignot N, Bois FY, Beaudouin R (2017) Toxicokinetic models and related tools in environmental risk assessment of chemicals. *Sci Total Environ* 578:1–15
- Grunert KG, Hieke S, Wills J (2014) Sustainability labels on food products: consumer motivation, understanding and use. *Food Policy* 44:177–189
- Hartung T (2011) From alternative methods to a new toxicology. *Eur J Pharm Biopharm* 77:338–349
- Jaeger SR, Prescott J, Worch T (2022) Food neophobia modulates importance of food choice motives: replication, extension, and behavioural validation. *Food Qual Prefer* 97:104439
- Ladics GS, Selgrade MK (2009) Identifying food proteins with allergenic potential: evolution of approaches to safety assessment and research to provide additional tools. *Regul Toxicol Pharmacol* 54:S2–S6
- Leni G, Cirlini M, Jacobs J, Depraetere S, Gianotten N, Sforza S, Dall'Asta C (2019) Impact of naturally contaminated substrates on *Alphitobius Diaperinus* and *Hermetia Illucens*: uptake and excretion of mycotoxins. *Toxins* 11(8):476
- Lo Piparo E, Worth A, Manibusan M, Yang C, Schilter B, Mazzatorta P, Jacobs MN, Steinkellner H, Mohimont L (2011) Use of computational tools in the field of food safety. *Regul Toxicol Pharmacol* 60:354–362
- Mazzucchelli G, Holzhauser T, Cirkovic Velickovic T, Diaz-Perales A, Molina E, Roncada P, Rodrigues P, Verhoeckx K, Hoffmann-Sommergruber K (2018) Current (Food) allergenic risk assessment: is it fit for novel foods? Status quo and identification of gaps. *Mol Nutr Food Res* 62:1700278
- Meijer N, Stoopen G, Van der Fels-Klerx HJ, van Loon J, Carney J, Bosch G (2019) Aflatoxin B1 conversion by black soldier fly (*Hermetia Illucens*) Larval enzyme extracts. *Toxins* 11(9):532

- Meyer AM, Meijer N, van den Hil EFH, van der Fels-Klerx HJ (2021) Chemical food safety hazards of insects reared for food and feed. *J Insects Food Feed* 7(5):823–831
- OECD (1993) Safety evaluation of foods produced by modern biotechnology – concepts and principles, http://dbtbiosafety.nic.in/guideline/OACD/Concepts_and_Principles_1993.pdf. Accessed 15 Feb 2022
- Pali-Schöll I, Verhoeckx K, Mafra I, Bavaro SL, Clare Mills EN, Monaci L (2019) Allergenic and novel food proteins: state of the art and challenges in the allergenicity assessment. *Trends Food Sci Technol* 84:45–48
- Poma G, Cuykx M, Amato E, Calaprice C, Focant JF, Covaci A (2017) Evaluation of hazardous chemicals in edible insects and insect-based food intended for human consumption. *Food Chem Toxicol* 100:70–79
- 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
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
- Reilly L, Serafimova R, Partosch F, Gundert-Remy U, Cortiñas Abrahantes J, Dorne JMC, Kass G (2019) Testing the thresholds of toxicological concern values using a new database for food-related substances. *Toxicol Lett* 314:117–123
- Ribeiro JC, Cunha LM, Sousa-Pinto B, Fonseca J (2018) Allergic risks of consuming edible insects: a systematic review. *Mol Nutr Food Res* 62(1):170003
- Ribeiro JC, Sousa-Pinto B, Fonseca J, Fonseca SC, Cunha LM (2021) Edible insects and food safety: allergy. *J Insects Food Feed* 7(5):833–847
- Schilter B, Benigni R, Boobis A, Chiodini A, Cockburn A, Cronin MTD, Worth A (2014) Establishing the level of safety concern for chemicals in food without the need for toxicity testing. *Regul Toxicol Pharmacol* 68(2):275–296
- Siegrist M, Bearth A, Hartmann C (2020) Food disgust sensitivity influences the perception of food hazards: results from longitudinal and cross-cultural studies. *Appetite* 153:104742
- Tuorila H, Hartmann C (2020) Consumer responses to novel and unfamiliar foods. *Curr Opin Food Sci* 33:1–8
- Valenta R, Hochwallner H, Linhart B, Pahr S (2015) Food allergies: the basics. *Gastroenterology* 148(6):1120–1131e4
- van der Fels-Klerx HJ, Camenzuli L, Belluco S, Meijer N, Ricci A (2018) Food safety issues related to uses of insects for feeds and foods. *Comprehensive Rev Food Sci Food Saf* 17(5):1172–1183
- van Kleef E, Frewer LJ, Chrysoschoidis GM, Houghton JR, Korzen-Bohr S, Krystallis T, Lassen J, Pfenning U, Rowe G (2006) Perceptions of food risk management among key stakeholders: results from a cross-European study. *Appetite* 47(1):46–63
- van Raamsdonk LWD, van der Fels-Klerx HJ, de Jong J (2017) New feed ingredients: the insect opportunity. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* 34(8):1384–1397
- Verhoeckx KC, van Broekhoven S, den Hartog-Jager CF, Gaspari M, de Jong GA, Wichers HJ, van Hoffen E, Houben GF, Knulst AC (2014) House Dust Mite (Der p 10) and crustacean allergic patients may react to food containing yellow mealworm proteins. *Food Chem Toxicol* 65:364–373

- Verhoeckx K, Broekman H, Knulst A, Houben G (2016) Allergenicity assessment strategy for novel food proteins and protein sources. *Regul Toxicol Pharmacol* 79:118–124
- Verhoeckx K, Bøgh KL, Constable Q, Epstein MM, Hoffmann Sommergruber K, Holzhauser T, Houben G, Kuehn A, Roggen E, O'Mahony L, Remington B, Crevel R (2020) COST action 'ImpARAS': what have we learnt to improve food allergy risk assessment. A summary of a 4 year networking consortium. *Clin Translational Allergy* 10:13
- Westerhout J, Krone T, Snippe A, Babe L, McClain S, Ladics GS, Houben GF, Verhoeckx KC (2019) Allergenicity prediction of novel and modified proteins: not a mission impossible! development of a random forest allergenicity prediction model. *Regul Toxicol Pharmacol* 107:104422
- Zare Jeddi M, Boon PE, Cubadda F, Hoogenboom R, Mol H, Verhagen H, Sijm DTHM (2022) A vision on the 'Foodture' role of dietary exposure sciences in the interplay between food safety and nutrition. *Trends Food Sci Technol* 120:288–300

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



Part II

Edible Insects

Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU



Giulia Formici

Abstract The chapter presents an overview of the legislative regime regulating insects for human consumption in the EU territory. The analysis aims at underlining both the legal issues deriving from the previous EU Novel Foods Regulation 258/97 and the difficulties and concerns characterising the legislative evolutive path and the current Regulation (EU) 2015/2283. An examination of the recent CJEU intervention in the so-called Entoma case will lead to some conclusive remarks, intended to highlight open issues and possible future developments.

Keywords EU novel food regulation · Novel foods definition · Regulatory issues · Entoma case · Transitional measures

1 Marketing Edible Insects in the EU: Sustainability, Food Security, Food Safety and Regulatory Issues

A constantly increasing population and a consequently expanding food demand, limited natural resources, climate changes and other dramatic global events, such as pandemic¹ are profoundly affecting food productivity in its entirety. These phenomena are compounded by the globalisation of markets, alongside economic and social changes—such as “climate migration”²—making it impossible to provide access to adequate, safe and sufficient food for all. In recent years, Governments and Legislators have been asked with increasing urgency to ensure food security while limiting environmental impact and guaranteeing sustainable food systems.³ It is not by chance that the Nobel Peace Prize for 2020 was awarded to the World

¹United Nations (2020), OECD (2020) and Albisinni (2021).

²Migali and Natale (2021).

³FAO (2021), FAO, IFAD, UNICEF, WFP, WHO (2021), Behnassi et al. (2011) and Mattas et al. (2020).

G. Formici (✉)

Department of Italian and Supranational Public Law, University of Milan, Milan, Italy

e-mail: giulia.formici@unimi.it

Food Programme, one of the largest humanitarian organisations combating hunger. This choice clearly reflected the relevance of and the pressing need to safeguard the right to food for both present and future generations.

In this complex and challenging scenario, insects for both human consumption and animal feed are attracting ever-growing attention: “In face of increasing environmental, biodiversity and welfare concerns associated with traditional animal-based food production, (...) alternative plant, insect and lab-based protein sources (...) have not only the potential to replace traditional meat products designated for human consumption, but also to direct the use of feeds in animal production towards more sustainable practices and contribute through better exploitation of side streams towards a more sustainable circular economy.”⁴ The significant and documented environmental impact of conventional livestock⁵ imposes a concrete and serious search for sustainable solutions capable of responding to a mounting demand for protein—specifically meat—while reducing the exploitation of natural resources and the production of greenhouse gases.⁶

The Food and Agriculture Organization of the United Nations (FAO) alongside other non-profit or lobbying organizations (such as the International Platform of Insects for Food and Feed, IPIFF) have begun to underline the benefits and potentialities of insect production through the publication of important studies and documents.⁷ Universities and Research Centres have also been involved, developing specific competences in the study of entomophagy and its impact on the economy, consumer health, animal welfare, as well as the environment.⁸

In the last few years, the opportunity to produce and market insect-based food or feed has been highly debated in the European Union territory. Although the human consumption of insects represents a consolidated practice in many parts of the world, especially in Africa, Asia and Latin America,⁹ in Western Countries entomophagy is regarded with scepticism, mistrust, as well as—at least in the majority of the population—disgust.¹⁰ Given this aspect, the possibility of introducing insect-based foods in our diets as an alternative sustainable solution to growing protein

⁴Vauterin et al. (2021), p. 1; see also *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume.

⁵Alexander et al. (2017), Halloran et al. (2016) and Ordoñez-Araque and Egas-Montenegro (2021).

⁶Melgar-Lalanne and Hernandez-Alvarez (2019); see also Van Huis and Ooninx (2017) and Halloran et al. (2018).

⁷FAO (2013, 2021) and IPIFF (2020a, b, c). More recently, see also the consideration on insect consumption expressed by the EU Commission (European Union Commission 2022).

⁸Wageningen University, for example, collaborated with FAO in the elaboration of studies regarding insects as food and feed and founded a Journal specifically dedicated to studies devoted to the topic: the Journal of Insects as Food and Feed. See also Payne et al. (2019).

⁹According to Halloran, more than two billion people in the world habitually consumes insect products, Halloran et al. (2016); as reported by FAO, insects-as-food are consumed in about 140 Countries in the world, FAO (2021).

¹⁰For more information on this highly debated point, see *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook*, by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

demand has provoked profound doubts in both EU Institutions and Member States, raising questions related not only to food safety¹¹ and consumer health but also to ethical, cultural, and economic aspects. On the one hand, the potential social and economic effects on traditional breeding and farming practices are still at the centre of an intense discussion, while on the other hand the strict link between food and cultural identity¹² leads to forms of diffidence against ‘new’ and ‘unknown’ food practices, seen as ‘external’ if compared to traditional diets and habits. All these serious aspects produce significant consequences not only on the regulatory and legislative approach adopted both at supranational and national levels, as will be further elucidated below, but also on European-based food companies. Given scarce consumer acceptance of insect-based products, business operators willing to market such products must evaluate technical and scientific options aimed at producing insect-based foods in non-recognizable shapes, such as flours or powders employed as components of ‘usual’ and already consumed foods (pasta, crackers, bread or burgers), thus adding to them alternative protein sources.¹³

The European debate over such a delicate topic has gained increasing momentum in recent decades, receiving a strong acceleration in 2014, when the EU Commission mandated the European Food Safety Authority (EFSA) to issue a first scientific opinion evaluating possible risks connected to the human consumption of insects and insect-based products.¹⁴ The growing tension around the need for sustainable solutions to food insecurity and climate change has contributed to energizing a complex and—for certain aspects—still pending regulatory debate involving legislators and policy-makers, both at the supranational and national levels, and requiring the intervention of national and European Union Courts.

Having not been used for human consumption to a significant degree within the EU before 15 May 1997 and appearing primarily in foods or food ingredients isolated from animals (Art. 1, para. 2, letter e), insect-based products were considered to be included in the definition of Novel Foods according to the previous Regulation (EC) 258/97, now replaced by Regulation (EU) 2015/2283. Nevertheless, the 1997 Regulation did not provide precise rules on insects-as-food. Significant doubts regarding the exact scope of application of the EU regime on Novel Foods were derived from the abovementioned Art. 1, para. 2, letter e), especially with reference to foods consisting of animals, such as whole insects or parts of them. A confused and fragmented regulatory scenario then emerged, also reflecting Member States’ cultural differences and diverse approaches to ‘new’ food products. In

¹¹On the issues and questions regarding Novel Foods’ and edible insects’ food safety, see *Why “New” Foods Are Safe and How They Can Be Assessed* by C. Dall’Asta in this volume.

¹²Lanni (2020); on the strict link between food and cultural identity and traditions, see Molinari (2006) and Cavaggion and Luther (2018).

¹³Melgar-Lalanne and Hernandez-Alvarez (2019) and Mancini et al. (2022). For more on ‘entomophagy by stealth’ see *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook* by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

¹⁴EFSA (2015) and Paganizza (2016).

this context, the intervention of national and supranational Courts became crucial. In France, the *Conseil d'État* promoted a preliminary ruling to the Court of Justice of the European Union (CJEU), resulting in a landmark decision published in October 2020.¹⁵ Notwithstanding the legislative efforts to include an express reference to insects as well as a more comprehensive definition of foods 'deriving' from animals in the current EU Regulation on Novel Foods, the Luxembourg Judges' decision regarding the 1997 provisions remains of great relevance, due to the important transitional measures established by Art. 35 Regulation (EU) 2015/2283.

The present chapter is therefore intended to present an overview of the legal issues and challenges deriving from past Novel Foods Regulation that is still causing significant impacts on the present regulatory regime. Mainly focusing on the provisions regarding insects for human consumption,¹⁶ the next sections will be devoted to an in-depth analysis of the interpretative issues derived from the first Novel Foods legislation and the difficulties and concerns characterising its legislative evolution (Sects. 2 and 3). An examination of the recent CJEU intervention (Sect. 4) will lead to some conclusive remarks (Sect. 5), intended to underline open issues and possible future developments.

2 The First Attempt to Regulate Insects-as-Food and the Doubts Regarding the Scope of Application of 1997 Novel Foods Legislation: Fragmented National Approaches

Investigating the legislative framework covering the marketing of insects and insect-based products for human consumption, the first relevant legislation applied in the European Union context is Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food ingredients. As already analysed in the previous chapters of this volume, the 1997 Regulation imposed a pre-market approval for foods qualified as 'novel'. The complex balance point between free circulation of 'new' goods and consumer protection was determined by the long, costly, and in some ways uncertain authorisation procedure aimed at verifying the food safety of the Novel Food on the basis

¹⁵CJ Judgement 1 October 2020 Case C-526, *Entoma SAS v Ministre de l'Économie et des Finances, Ministre de l'Agriculture et de l'Alimentation*.

¹⁶The present chapter focuses on insects for human consumption rather than the use of insects as feed, which represents a different yet fascinating topic. In particular, the analysis here proposed mainly examines the rules concerning the authorization procedure necessary to market an insect-based product on the EU market, so that rules concerning the rearing or the production phases are only marginally evaluated. For some preliminary observations regarding insects as feed, see *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook* by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

of scientific data and documents presented by the producer.¹⁷ Regarding the scope of application of the first Novel Food Regulation, two criteria were defined: a temporal one, establishing that the legislation “shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto [15 May 1997, determining the entry into force of the Regulation] been used for human consumption to a significant degree within the Community” (Art. 1, Para. 2),¹⁸ and a substantial one, requiring the food to fall under one of the specific categories listed in Art. 1, Para. 2.¹⁹

In this regulatory context—characterised by emerging definitory issues, also due to the difficulty faced by the legislator in defining fixed normative categories for the fast-paced scientific and technological evolution of the food sector²⁰—relevant problems and doubts soon emerged specifically regarding the qualification of insects-as-food in their different forms (whole insects, their parts or products, and ingredients isolated or derived from insects). The category provided for in Art. 1, Para. 2, lett. e) of 1997 Regulation referred to “foods and food ingredients *consisting of or isolated from plants and food ingredients isolated from animals.*” As the text clearly reveals, there was a substantial difference between the definition of vegetal foods or ingredients and those concerning animals. While the first category included foods *consisting of or isolated from plants*, the only foods included with reference to animals were those *isolated from animals*, with no mention of food *consisting of animals*. This distinction, far from being a mere formal aspect, was of enormous importance for insect producers: considering only the text of the abovementioned norm, food *consisting of animals* such as whole insects appeared to be excluded from the scope of application of the Novel Food Regulation, with the relevant consequence of exempting the marketing of such products from the complex and expensive prior authorisation procedure. This ‘literal’ interpretation was all but pacifically accepted, and soon raised serious concerns: according to an

¹⁷ A vast and comprehensive dossier should be presented, ensuring a complete risk assessment and the absence of safety risks as well as providing clear descriptions of the measures adopted to guarantee production control and food safety, the conditions of intended uses, product specifications, as well as labelling requirements. In the 2015 Scientific Opinion (see *supra* note 14), EFSA established useful guidance and details regarding the content of the dossier and necessary studies, by also identifying potential hazards related to the consumption of farmed insects, among which allergic reactions. Moreover, after the entry into force of the 2015 Regulation, the Implementing Regulation (EU) 2017/2469 listed all scientific data requirements to be included in the application and the structure and content of the dossier. The complexity of the documents and studies required of food producers interested in marketing insects in the EU territory clearly emerges also from the guidelines and analysis elaborated by IPIFF (2018).

¹⁸ As also confirmed by the CJEU, “15 May 1997 is the reference date for the purpose of determining the extent of human consumption of that food or food ingredient”, CJ Judgment 9 June 2005 Joint Cases C-211/03, C-299/03, C-316/03 and C-318/03, *HLH Warenvertriebs GmbH and Orthica BV v Bundesrepublik Deutschland*, para. 88.

¹⁹ For an in-depth analysis of the 1997 Regulation, see Rizzoli (2016), Pisanello and Caruso (2018) and Scaffardi (2020).

²⁰ Volpato (2015).

opposite ‘protective’ interpretation, the ‘strict’ reading based on the provision’s text ended up unreasonably restricting the scope of application of Novel Food Regulation thus creating a profound contrast with the *ratio* of the legislation itself; indeed, if the latter aimed at imposing a preventive and cautious risk assessment on foods not habitually consumed in the EU territory, there was no reason to exclude from these prior food safety controls whole insects which, similarly to insects-based products, were not part of the European diet before 1997.

The abovementioned conflicting interpretative approaches were at the basis of an intense and heated debate, which resulted in a fragmented and disparate regulatory landscape, with a significant impact on the guarantee of a harmonized single European food market. The decentralised procedure characterising the 1997 legislation surely contributed to the creation of this controversial and problematic situation. In the absence of a unique and centralized authority—even when EFSA was instituted, it was asked to intervene in the authorisation procedure only in specific cases—every single national authority identified as responsible for the authorisation procedure was required not only to provide a careful risk assessment, but also to evaluate the acceptability and correctness of the applications and, therefore, to determine whether a food product could be considered to fall under the scope of application of the EU Novel Food Regulation or not.

Without entering into excessive detail, it is important to underline how ‘patchy’ the European Union scene appeared under the 1997 provisions. Despite “a general choice to limit insects as they were Novel Food,” it was possible to identify “several spots that allowed their free movement or their marketability under certain conditions.”²¹ In fact, Austria, the United Kingdom (UK), Denmark, and more recently Finland adopted the already mentioned ‘literal’ interpretation of Art. 1, para. 2, lett. e): whole insects were considered excluded from the Novel Food definition and, for this reason, marketable without the prior authorisation established by 1997 Regulation. Instead, products derived from insects—such as flours or extracted proteins—fell under the scope of application of the Novel Food regime.

Differently from that interpretation, and strictly based on the wording employed by the EU legislator, other States promoted more ‘systematic’ approaches which, looking at the context and the final objective of the Regulation, arrived at two different—or better, opposed—visions. The Netherlands, for example, considered that the wording ‘isolated from,’ was not expressly defined by the legislator and therefore could be interpreted as only including products ‘extracted’ or ‘obtained’ through the use of specific technically and technologically advanced operations, such as the extraction of proteins. Products or ingredients deriving from the use of common and ‘traditional’ production processes such as the production of insect flour, on the contrary, were not viewed as falling under the definition of ‘isolated from animals,’ and were consequently excluded from the complex preventive authorisation procedure.²² This approach resulted in a more tolerant interpretation

²¹ Paganizza (2016), p. 28.

²² Paganizza (2019).

of the debated provision of Art. 1, para. 2, lett. e), probably reflecting a more permissive vision of the Novel Food Regulation and objective; the preventive risk assessment imposed by the legislator could be considered proportionate and justified only with reference to ‘innovative’ foods considered *per se* and not also to foods ‘traditionally’ produced and deriving from traditionally bred and already ‘known’ animals.

Opposite to this approach, Italy and Portugal supported a more ‘protective’ interpretation of both the abovementioned norm and the 1997 Regulation in its entirety. The lack of a specific reference to products or ingredients ‘consisting of’ animals was not considered sufficient to exclude whole insects from the scope of application of Novel Foods regulatory provisions. By providing a ‘temporal criterion,’ the legislator established that food not commonly consumed as of 1997 should be considered ‘new’ and therefore in need of a careful and preventive control as potentially dangerous for human health; with this as the *ratio* behind the regulatory provisions, there was no reason to exempt animals not habitually intended for human consumption from the prior risk assessment provided for in the 1997 Regulation.²³

This brief and concise presentation of the articulated European landscape²⁴ clearly reveals the complexity of definitory issues regarding insects and insect-based products, identifying drastically different approaches significantly affecting the EU market. While in some States commercializing whole insects or even parts of them or derived products and ingredients was allowed without the obligation to follow the prior rigid Novel Foods authorisation procedure, in others this long and difficult process was required, thus impacting on fair competition as well as harmonization of rules in the EU context. A ‘two-speed’ Europe²⁵ emerged, where different interpretations of Art. 1, para. 2, lett. e) as well as of the Novel Food Regulation’s purpose also reflected different national cultural visions and, somehow,

²³This interpretation, based on the rationale of the Regulation, was also motivated by the fact that “at the time of the adoption of the act on Novel Foods, the EC legislator had probably not considered the possibility that new animals could enter the human diet” Paganizza (2020), p. 580.

²⁴The picture here provided simplifies a complex scenario, which nevertheless includes different regulatory ‘nuances.’ In Belgium, for example, “a circular from the Federal Agency for the Safety of the Food Chain (FASFC) provides a list of insects which may be commercialised for human consumption in the national territory. This list only concerns whole insects (e.g., the house cricket, giant mealworm, buffalo worm, and silkworm) and was based on advice from the National Scientific Committee concerning the safety of using these insects. However, this is not applicable to food ingredients isolated from insects such as for example protein isolates, because according to the FASFC these are clearly included in the scope of the Novel Food Regulation. In the UK, the Food Standards Agency (FSA) allowed edible whole species to be sold in the national territory (e.g., Chinese yellow scorpion, mealworm, domestic cricket, and locusts) based on scientific evidence submitted by companies marketing these products and demonstrating their safety. The UK FSA considered that whole animals, and therefore whole insects, are outside the scope, contrary to parts of insects, which are considered as falling within the scope of Reg. 258/97, unless a significant history of consumption is demonstrated prior to 15 May 1997”, Finardi and Derrien (2016), p. 123.

²⁵La Porta (2021), p. 39.

identities. Southern European Countries generally promoted a more ‘protective’ approach, thus ensuring the guarantee of national gastronomic and culinary traditions—also intended as expressions of cultural identity²⁶—over that of ‘new’ and potentially dangerous or ‘revolutionary’ foods.²⁷ Considering this complex and confused scenario, a legislative reform was ever more frequently invoked as a necessary solution to prompt innovation, harmonization, and clarity.

3 Shadows from the Past: Regulation (EU) 2015/2283 Between Clarifications and Persistent Doubts

As clearly seen in the previous analysis,²⁸ the 1997 Regulation and the doubts emerging from its unclear scope of application resulted in a fragmented regulatory landscape. That situation, characterising not only the entry into market of insect-based products but also that of other Novel Food categories as well,²⁹ had a severe practical impact on the functioning and attractiveness of the EU food market. The inhomogeneous national approaches derived from the decentralised application system, together with the uncertain results of the authorisation procedure, acted as a deterrent for food producers interested in introducing Novel Foods in the EU territory. Moreover, the high costs required to both apply and elaborate the studies and documents necessary to prove the food safety of the new product,³⁰ and the long period required to finalize the process and obtain authorisation,³¹ made it economically unsustainable for companies—especially for small and medium enterprises—to invest in innovation and research aimed at developing new foods.³² The limited number of applications presented from 1997 to 2008³³ clearly demonstrated the inefficiency of the Novel Food Regulation and the necessity to rethink the balance point between innovation and free circulation of goods on the one hand, and food safety and consumer protection on the other. Consequently, the European legislator understood the importance of reforming the 1997 Regulation and establishing a new, safe but also simplified and faster authorisation procedure, able to guarantee a

²⁶Molinari (2006), Formici (2020b) and Ichijo and Ranta (2016).

²⁷We can find a similar approach, characterized by significant differences in Member States’ reactions and decisions, when analyzing the intricate legislative and regulatory story of Genetically Modified Organisms’ (GMOs) foods in the EU.

²⁸For an in-depth analysis on this point, see *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, by A. Volpato in this volume.

²⁹The CJEU, for example, was also asked to clarify the definition of ‘new primary molecular structure’, in decision 9 November 2016 Case C-448/14, *Davitas GmbH v Stadt Aschaffenburg*. For a comment on this decision, see Paganizza (2020).

³⁰Brookes (2007).

³¹Hyde (2017).

³²Lahteenmaki-Uutela (2007, 2020).

³³Brookes (2007) and European Union Commission (2008).

harmonized and unified approach based on a central and uniform scientific risk assessment.

Notwithstanding the importance of such a legislative intervention, the reform experienced various twists and turns; the delicacy and complexity of the topic, also involving highly debated economic and ethical issues—such as those concerning traditional foods coming from Third Countries³⁴ or foods deriving from animal clones³⁵—caused the initial 2008 proposed revision to fail.³⁶ This difficult process came to an end only in 2015, with the approval of 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.

The new provisions entered into force on 11 January 2016 but started being applied from 1 January 2018, allowing food producers and public authorities adequate time to conform with the significant modifications introduced; the attempt to create a balanced legislation, able to ensure food safety and, at the same time, fostering innovation and prompting investments in Research and Development (R&D) of new products and production methods, has been clearly recognized in Recital n. 29: “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.”

Along with major procedural changes establishing for the first time a centralised procedure and a unique risk assessment evaluation, as well as providing specific rules for the authorisation process of traditional foods coming from Third Countries,³⁷ the reform also intervened by re-defining Novel Foods: “on the basis of scientific and technological developments that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods” (Recital n. 8). Aiming to clarify doubts and uncertainties linked to the previous Regulation’s scope of application, this definitory effort also directly concerned the much debated and confusing category of insects and insect-based products. Differently from the past, Article 3, para. 2, lett a), n. v) now expressly refers to “food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union.” This precise text leaves no

³⁴See *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* by L. Scaffardi in this volume, but also Formici (2020a).

³⁵Scaffardi (2020) and Coppens (2013).

³⁶Jones (2012), Ballke (2014) and Carreno (2014).

³⁷For a vast analysis of the current Regulation see Pisanello and Caruso (2018), Scaffardi (2020), Montanari et al. (2021) and Lahteenmaki-Uutelala and Gmelova (2016); see also *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, by A. Volpato in this volume.

doubts about the inclusion of insects, parts of insects or products deriving (‘isolated’ or ‘produced’) from insects into the Novel Foods definition; but the legislator, probably conscious of the difficult and fragmented regulatory scenario arisen during the term of the 1997 Regulation, decided to provide a precise specification in Recital n. 8: “Those categories [of Novel Foods] should cover whole insects and their parts,” thus further clarifying the applicability of the new authorisation procedure to this category of animals.

Notwithstanding this important definitory innovation, the problematic landscape characterizing the EU insects-as-food market in 2016 was destined to remain so for a while and to cast a shadow over the useful clarification established by the 2015 Regulation. In fact, according to Article 35, foods lawfully marketed by 1 January 2018 and falling within the scope of the new legislation “may continue to be placed on the market until a decision is taken (..) following an application for authorization of a Novel Food or a notification of a traditional food from a Third Country submitted by the date specified in the implementing rules (..), but no later than 2 January 2020” (Art. 35, para. 2). This transitional measure obviously has a significant economic impact on food producers, “since it guarantees that operators are not compelled to discontinue the production and/or marketing of their products whilst they prepare and submit their application,”³⁸ thus mitigating the impact of the new Regulation. Despite these potentialities, the transitional provision only applies following specific and cumulative conditions. First of all, it is intended to discipline products lawfully placed on the market before 1 January 2018 that did not fall under the scope of application of the previous legislation but are considered Novel Foods according to the 2015 definition; secondly, food producers are asked to submit an authorisation application following the new centralised procedure until 1 January 2019, as established by the Commission through Implementing Regulation (EU) 2017/2469. Looking at the specific case of insects and insect-based products, the enforcement—and benefits—of such an important provision required the prior resolution of a controversial question: could whole insects and derived products be qualified as Novel Foods according to the 1997 Regulation and, consequently, be considered as unlawfully placed on the market by 1 January 2018 in the absence of a prior authorisation? As clearly emerges, the doubts and fragmented interpretations characterising the implementation of the 1997 Regulation ended up causing issues and difficulties in the transitional measure’s practical enforcement. In this highly debated context, the CJEU intervention provided relevant clarifications, upon which I expand below.

³⁸IPIFF (2021), p. 34.

4 A Relevant Decision Influencing the Application of 2015 Regulation’s Transitional Measures: The CJEU Provides Clarifications Upon the Scope of Application of 1997 Novel Food Regulation

In 2019, the French Conseil d’État referred to the CJEU a question concerning the interpretation of the uncertain and debated Art. 1, para. 2, lett. e) of the 1997 Regulation. The so-called Entoma case (CJ Judgement 1 October 2020 Case C-526, *Entoma SAS v Ministre de l’Économie et des Finances, Ministre de l’Agriculture et de l’Alimentation*) originated from a prefectural order adopted in 2016 by the Parisian competent authority and suspending the marketing of whole insects (mealworms, locusts and crickets) commercialized by Entoma. According to the Paris Prefect of Police, the French company had not obtained the necessary prior authorisation required by the 1997 Novel Food Regulation, thus considering whole insects as falling under the scope of application of this provision. After having brought actions for annulment against the abovementioned order before the Administrative Court of Paris (*Tribunal Administratif de Paris*) and, subsequently, the Administrative Court of Appeal of Paris (*Cour Administrative d’Appel de Paris*), both of which were rejected, Entoma promoted before the Council of State (*Conseil d’État*) an appeal on a point of law against the previous judgements. The company specifically opposed the positions expressed by the Administrative Courts with regard to the interpretation of Art. 1, para. 2, lett. e): “relying on recital 8 of Regulation 2015/2283, the inclusion of whole insects in the category of ‘novel foods’ (..) does not clarify the earlier definition, which was limited to parts of animals only, but rather modifies the scope of that previous definition by supplementing it” (para. 18). This approach was firmly countered by the French Minister for Economy and Finance, according to whom there were no health reasons that could legitimately exclude whole insects from the scope of Regulation 258/97, “since the consumption of whole insects poses as many risks for the safety of consumers as the consumption of food ingredients isolated from animals” (para. 19). Recognizing the existence of different approaches promoted by Member State authorities and the consequent doubts concerning the Novel Food definition, the Council of State decided to refer this interpretative question to the EU Court of Justice.

In the October 2020 decision, the Luxembourg Judges promoted an analysis of the debated provision, starting from an examination of the ordinary meaning attributed to the definition “food ingredients isolated from animals.” On this point, the Court very briefly affirmed: “the usual meaning to be attributed to this expression in everyday language is that only food ingredients consisting of parts of animals, excluding whole animals (and accordingly insects), were covered by Art. 1(2)(e)” of the 1997 Regulation (para. 30). If the term “ingredients” usually refers to “a component of a larger, composite end products, in essence, a ‘foodstuff’ or a ‘food’”

(para. 31), whole insects could not be categorized as ‘ingredients.’³⁹ The expression ‘isolated from’ animals was seen to refer to a “process of extraction from the animal” (para. 34) and could not therefore be intended as including whole animals. Furthermore, the EU Judges clearly stated that the significant difference between the terms ‘isolated from’ and ‘consisting of’ could not be ignored. Only the latter expression, employed by the 1997 legislator with regard to plants, micro-organisms or fungi and algae, allowed the inclusion “of foods composed of single parts (for example the whole plant)” (para. 35). In conclusion, the Court recognized that the debated expression employed by the 1997 Regulation had a ‘precise meaning’, thus engaging a literal interpretation.

Nonetheless, the Judges decided to go further by assessing that the exclusion of whole insects from the scope of 258/97 Regulation was perfectly consistent with both the context and the objectives pursued by the legislation itself: “the use of insects in the agri-food industry is a relatively new phenomenon and, as is apparent from recital 8 of the Regulation 2015/2283, it is precisely in the light of scientific and technological developments that have occurred since 1997 that that legislature decided in 2015 (...) to review, clarify and update the categories of food which constitute ‘novel foods’ and to explicitly include ‘whole insects and their parts’” (para. 38). On this specific point and relying on the twofold objective of the 1997 Regulation, consisting of the guarantee of the correct internal market functioning as well as of the protection of public health, the French and Italian Governments’ observations led to different conclusions. In the positions presented in the *Entoma* case, these Governments considered it “illogical, from a health point of view, to seek to subject food ingredients isolated from insects to the rules, while excluding whole insects, since whole insects are composed of all their parts and the whole insect, like its parts, is intended to be ingested by the consumer, which may therefore pose the same risks from the point of view of public health” (para. 40). In other words, treating in different ways similar situations and equal potential dangers—that is, requiring a long and precise authorization procedure for foods isolated from insects while not imposing the same process on whole insects—seemed to lack any logical and coherent justification. Following the Advocate General’s considerations⁴⁰ and contrasting the abovementioned Governments’ positions, the Court clearly considered “such a line of argument” as insufficient to legitimize “a broad interpretation of the unambiguous terms” employed in the 1997 Regulation (para. 41). That clear wording “cannot in principle be called into question by a teleological interpretation of that provision, which would amount to expanding the scope of that regulation and which is for the EU legislature alone to decide” (para. 42). As affirmed by the Advocate General, when teleological interpretations are needed, they can never be inconsistent with the literal meaning of the normative text: this would be *contra*

³⁹The Court also recalled the definition of ‘ingredient’ as emerged from other EU legal provisions related to food, such as Regulation (EU) 1169/2011 on the provision of food information to consumers (para. 33).

⁴⁰Opinion of Advocate General Bobek, delivered on 9 July 2020.

legem and in violation of the principles of legal certainty and foreseeability of the law. In addition, responding to the considerations affirmed by the French and Italian Governments, the Court specified that “an interpretation which leads to the exclusion of whole animals, such as insects, from the scope of Regulation 258/97 does not in itself prejudice the objective of protecting human health.” This consideration implies “a lack of harmonization of the conditions for placing whole insects on the market at EU level and, therefore, that no notification or authorization is necessary under that regulation” (para. 44). In that context, Member States maintained the possibility to require, through the adoption of national measures, prior authorization in case uncertainties persisted over the possible dangers whole insects might cause to public health; in other words, the exclusion of whole insects from the Novel Food definition did not prevent national institutions from adopting specific legislation imposing preventive controls, even if within the limits of the EU requirements disciplining the free movement of goods (para. 44).

The analysed decision was welcomed positively by insect-producers and non-profit organizations representing interested stakeholders, such as the IPIFF.⁴¹ Despite the long-awaited clarification provided by the CJEU decision, some specific aspects and statements raised doubts and critiques. Paganizza, for example, questioned the “clear and unambiguous” nature of the wording attributed by the EU Judges to Art. 1, para. 2, lett. e): “if the regulation were clear, there would not have been such different approaches within the European Union on the theme of insects as food.”⁴² Moreover, “extending the scope of the regulation with the purpose of complying with its rationale is not against the law” and does not represent a “rewriting” of the provision itself, as differently stated by the Court.⁴³

Alongside these criticisms concerning the Judges’ reasoning, other relevant doubts were expressed regarding the consequences this decision could produce on the correct application of Art. 35 Regulation (EU) 2015/2283; in the aftermath of this ruling, it appeared to be even more confusing to determine the cases in which the transitional measures established by the current EU legislation could have been applied and, in particular, whether the exclusion of whole insects from the scope of application of the Novel Food Regulation, as definitively established by the Judges, could result in an extension of the transitional regime’s beneficial effects to the entire EU territory. This specific yet relevant aspect is not easy to solve. Companies that decided not to market whole insects before 1 January 2018—due to the ‘protective’ interpretation provided by certain Member States considering such foods as ‘novel’ and thus imposing the prior authorisation procedure—could face

⁴¹ IPIFF (2021).

⁴² Paganizza (2020), p. 583.

⁴³ Paganizza (2020), p. 584. While recognizing that the conclusion of the Court is certainly the most compatible with the wording of the 1997 Regulation, the author underlines some loopholes and discrepancies in the legal reasoning followed by the Court, for example with reference to the definition of ‘ingredients’ provided by the Judges or the interpretation on the Novel Food Regulation’s rationale promoted by the Advocate General in his Opinion.

severe challenges in their attempts to take advantage of Art. 35.⁴⁴ In those cases, the product should not be considered as lawfully placed on the market by 1 January 2018, so that the eligibility criterion established by the 2015 Regulation would not be considered fulfilled. In cases in which companies were denied the marketing of whole insects on the basis of national authorities' decisions (such as prohibition or suspension orders), public authorities could be asked to comply with the CJEU Judgement and modify the prior decisions, if not definitive.⁴⁵ In that scenario, whole insects should be considered as lawfully placed on the market by 1 January 2018 and food producers should be allowed to benefit from the transitional measure, provided they meet the other requirement included in Art. 35 (specifically having applied for authorisation or notification before 1 January 2019). In conclusion, the implementation of the transitional measure established by the current EU legislative framework seems to be destined to depend on the interpretation Member States adopted in previous years on the *status* of whole insects. Therefore—and until the completion of the authorisation procedures promoted under the current legislation—the transitional measures will probably still reflect the fragmented approaches characterising the previous legislation. Consequently, as denounced by the IPIFF, “the implications of ‘patchwork interpretations’ on the legislative scope of insects as food results in ‘unfair competition’ between insect producers across the EU because of such differentiated treatments.”⁴⁶

5 Legislative Intervention Still Needed: Current Challenges and Future Perspectives

As elucidated by the previous analysis, Regulation (EU) 2015/2283 has clarified most of the doubts related to the specific yet relevant category of insects for human consumption. The EU provisions on Novel Foods now expressly includes whole insects as well as parts and food products consisting of, isolated from, or produced from animals or their parts, thus providing a more comprehensive definition. The merits of the 2015 legislative reform also extend to the procedural aspects, ensuring faster and centralised risk assessment and risk management phases, in the attempt to avoid fragmented national solutions that can affect the correct functioning of the EU food market and negatively impact fair competition and legal certainty. The positive outcomes of such a regulatory evolution are evident if we look at more recent developments. While under the previous 1997 Regulation no authorisation for insect-based foods was obtained or promoted due to both the high costs and timing

⁴⁴IPIFF (2020a, b).

⁴⁵This option remains viable only if the public authorities' decision is not definitive and can still be modified. As clearly recognized also by IPIFF, these complex evaluations require a precise assessment of applicable procedural laws.

⁴⁶IPIFF (2020b).

required and to the definitory uncertainties that resulted from the already described chaotic scenario, in 2021 the first authorization for such products was actually adopted; the EU Commission Implementing Regulation (EU) 2021/882, dated 1 June 2021, allowed the placing on the market of dried *Tenebrio Molitor* larva (mealworm). Other authorisations followed: the Commission Implementing Regulation (EU) 2021/1975 of 12 November 2021 approved the marketing of frozen, dried, and powder forms of *Locusta Migratoria*, whereas through the Commission Implementing Regulation (EU) 2022/188 of 10 February 2022, frozen, dried, and powder forms of *Acheta Domesticus* (house cricket) were authorised.⁴⁷

At the time writing, therefore, three insect species have been approved under the ‘ordinary’ Novel Foods authorisation procedure, while the simplified and less expensive notification for traditional foods coming from Third Countries has not yet been activated. This outcome deserves an in-depth evaluation to help identify and underline some persistent criticalities characterising the current Regulation. First of all, the notification procedure⁴⁸ only applies to foods derived from primary production—e.g., rearing, growing, and harvesting—and to those that have a history of safe use in a Third Country and, more specifically, a continued use for at least 25 years in the customary diet of a significant number of people in at least one Third Country. These strict conditions have raised doubts: if whole insects—dried or frozen—are traditionally consumed in certain areas of the world such as Asia or Africa, and could consequently be, in principle, subject to notification, it is less probable “that a history of safe use may be established for highly processed product derived from insects (including insect meal products) given that the commonly known and documented traditional uses of insects generally entail minimal and/or basic processing steps.”⁴⁹ Considering the distrust but also disgust often manifested by European consumers, less prone to eat whole—hence highly recognizable—insects as food, EU companies are elaborating processed products—such as powder or extracted proteins—which could be more easily ‘accepted.’ As a result, the notification procedure appears applicable and convenient for insects-as-food business operators only in limited cases. Moreover, there is another strongly restricting

⁴⁷Moreover, according to the data provided by IPIFF, “As of 30 August 2021, EFSA has received a total of 17 insect novel food applications of which five are under completeness/suitability check, eight applications are currently in the risk assessment phase, for four applications EFSA has published its opinion (i.e. dried yellow mealworm, locusta migratoria, *Acheta domesticus*, frozen and dried formulations from whole yellow mealworm) of which one application has led to an authorization (dried yellow mealworm)”, IPIFF (2021), p. 6; the four opinions cited above have already been evaluated in recent months by the EU Commission and the Standing Committee on Plants, Animals, Food and Feed, as will be clarified later on in this chapter. On the role of EFSA in the safety assessment of insects, see *The Safety Assessment of Insects and Products Thereof as Novel Foods in the European Union* by G. Precup, E. Ververis, D. Azzollini, F. Rivero-Pino, P. Zakidou, A. Germini in this volume.

⁴⁸On this specific procedure, see *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* by L. Scaffardi in this volume.

⁴⁹IPIFF (2021), p. 13.

element in the specific case of insect-based products: the economic advantages deriving or not from the abovementioned simplified process. Art. 26 Regulation (EU) 2015/2283, establishing rules on data protection, does not apply to notifications concerning the marketing of traditional foods from Third Countries. The latter provision establishes that food producers interested in placing on the market Novel Foods through the ‘ordinary’ authorisation procedure can apply for a five-year period of data protection. This guarantee has been introduced in order to encourage and safeguard investments in research and innovation, by ensuring a sort of ‘personalization’ of the authorization which is, in this way, limited only to the applicant rather than having a general effect. In fact, under Regulation 2015/2283, all authorisations are ‘generic’ and referred to the Novel Food itself and to the approved uses. The generic effect and efficacy of the approval represent a significant reform of the previous legislation, according to which the authorisation was valid exclusively for the specific applicant and not for the ‘new’ food. The limited effect of the final approval caused, in the past, an inefficient and often criticized multiplication of procedures—and consequently of costs and scientific risk assessments—concerning the same Novel Food. In order to overcome this problematic rule, the 2015 legislator opted for a generic approval, thus allowing food operators intending to market a product already included in the Union list and complying with the authorized uses, labelling and other specifications established by the authorization, to commercialize it without submitting a specific application and without the need to notify or demonstrate the substantial equivalence as required by the 1997 Regulation.⁵⁰ If this effect, on the one hand, prevents useless safety evaluations of already assessed and authorized foods, on the other hand it also risks putting major burden on the first applicant, to the benefit of the ‘second-to-market’ food business operators taking advantage of the general authorisation. Aiming at counterbalancing this possible distortion and safeguarding the investments supported by food producers who firstly bear the costs of the complex and expensive dossier and studies required by the Regulation, the 2015 legislator decided to provide specific protection for scientific data, even if under some precise conditions: specifically, data that are considered essential for the safety assessment and are designated as proprietary.⁵¹ The economic relevance of such safeguards is of great importance since it ensures to the applicant a sort of exclusive authorisation and market advantage for 5 years. During this time, other operators interested in marketing the same approved Novel Food are not impeded, but are obliged to produce and submit their own dossier and documents

⁵⁰ On the functioning and effects regarding the ‘substantial equivalence’ criterion, established by the 1997 Regulation, see Lahteenmaki-Uutela (2007) and Brookes (2007).

⁵¹ Art. 26, para. 2 establishes three precise cumulative eligibility criteria: “the newly developed scientific evidence or scientific data [included in the application presented by the applicant] was designated as proprietary by the initial applicant at the time the first application was made; the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and the novel food could not have been assessed by the Authority [European Food Safety Authority] and authorized without the submission of the proprietary scientific evidence or scientific data by the initial applicant”.

(in other words, to bear the costs of their own application) without benefitting from the potential positive effects of a generalized authorisation.

Consequently, it comes as no surprise that all three applications promoted with reference to edible insects were ‘ordinary’ authorisation procedures and contained the request to activate the data protection safeguards established by Art. 26 Regulation (EU) 2015/2283, which were, in all three cases, guaranteed by the Commission, as expressly motivated in the adopted Implementing Regulation. The approval of such a ‘market exclusive’ helps explain why, on 8 February 2022, the Commission Implementing Regulation (EU) 2022/169 approved the marketing of frozen, dried, and powder forms of yellow mealworm (*Tenebrio Molitor larva*), a Novel Food already included, in June 2021, in the Union list. In that case, the applicant, Fair Insects BV, was obliged to bring forward its request—notwithstanding the authorisation of the same food product—because the first applicant, SAS EAP Group, benefitted, as anticipated, from the five years data protection and, therefore, from a ‘personalized’ approval. As clearly emerges from the considerations here presented, the above analysed provision are characterized by pro and cons: if it represents an incentive for first-movers, who can capitalise on the advantage of a market ‘exclusive’ by recouping some of the previous investments, it could also result in seriously limiting the Novel Food market’s expansion and production, by multiplying costs and procedures not motivated by a real need for a food safety assessment. As underlined by some authors, this legislative choice could be questioned for different reasons.⁵² While the duration of the data protection measure has been considered by some parties as too short to allow applicants to concretely and significantly benefit from it,⁵³ the importance of such a limited term has been considered justified in order to “avoid the unnecessary repetition of studies and trials, and to facilitate [marketing of novel foods] by small and medium-sized enterprises (SMEs), which rarely have the financial capacity to carry out research activities.”⁵⁴

The debate over this provision and its efficacy is important not only for a better understanding of the possible developments of insect-based products’ marketing in the EU territory, but also for the implementation of the highly discussed transitional measure presented in Paragraph 4. As affirmed by the Belgian Federal Public Service Health, Food Chain Safety and Environment, if data protection for a Novel Food application is granted by the Commission, “other operators placing the same insects and products thereof on the market based on the transitional measures will have to stop the marketing.”⁵⁵ As a consequence, the vast application of data protection measures and their effects appear to be extremely relevant and worth particular

⁵² According to La Porta, the data protection provision could severely impact the capacity of insects-as-food to represent a sustainable answer to the increasing protein demand (La Porta 2021).

⁵³ “One effect of a short data protection period is that competitors will more likely decide to wait out the period until the authorisation becomes generic rather than seek access to the data during the period, in turn reducing the initial applicant’s prospects of recovering its investment through data access fees”, Simpson (2016), p. 312.

⁵⁴ As reported by Simpson (2016), p. 311; on the complex topic of data protection for Novel Foods, see also Holle (2014).

⁵⁵ Belgian Federal Public Service Health (2021).

attention, especially with regard to the creation of possible ‘market distortions’ resulting in a disincentive to innovation or in a rigid and factual barrier to the marketing of Novel Foods which have already passed the food safety risk assessment.

In conclusion, the first and recent approvals of whole insects and insects-based products certainly prove both the interest demonstrated by food business operators for this evolving sector and the positive impact of the legislative reform resulting from the 2015 Regulation. Notwithstanding these encouraging aspects, the creation of a large-scale insect and insect-based product market in the European Union still seems to require multiple regulatory efforts which should initially start with a serious observation and discussion over the impact and consequences produced by the 2015 Regulation as well as by other relevant legislations currently in place on the insect industry.

In order to represent a real and valid alternative to ‘traditional’ protein sources, insect farming and insects-as-food production need to seriously address research gaps and the possibilities for scaling up production.⁵⁶ To ensure this result, current limits and barriers to the growth of the insect industry should be reconsidered or at least, carefully evaluated. First of all, clarifications on the established limits regarding the use of insect proteins or insect larvae, live insects, frozen whole insects, or insect proteins as feed for farmed and non-farmed animals are of fundamental importance to exploit the full potentialities of insects’ production, which could represent a useful solution to reduce the environmental impact of animal breeding. In fact, in the EU several legislations impose severe restrictions on feeds materials: notably—and directly impacting insects-as-feed—the so-called TSE Regulation,⁵⁷ back in 2001 prohibited the use of processed animal proteins (PAPs) deriving from farmed animals as feed materials for ruminants and non-ruminants farmed animals. This vast prohibition, mainly motivated by the strong need to prevent and eradicate transmissible spongiform encephalopathies, highly affected the use of insects-as-feed and its potential market and only in recent times it has gradually been revised by

⁵⁶FAO (2021). As underlined by van Huis and Ooninex, “The high environmental impacts connected with meat production and the increase in demand up till 2050 require dietary changes. Insect-based meat substitutes are potentially more sustainable but require more advanced cultivation and processing techniques (Smetana et al. 2016). Such advancement is expected as the whole sector of insects as food and feed is just emerging. In comparison to current production practices, this potential abundant food source can contribute to a more sustainable food and feed production, as certain insects can be reared on organic side streams, including manure. However, food and feed safety issues need to be considered. Insect production has great potential with respect to sustainably providing food for the growing population. However, further technological development of this sector and monitoring of the effects of these developments on the environmental impact of insect production are needed”, van Huis and Ooninex (2017), p. 9. See also van Huis and Tomberlin (2017). For an analysis of the edible-insects industry in the EU territory see also Pippinato et al. (2020).

⁵⁷Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

the European Institutions: in 2017, Regulation (EU) 2017/893⁵⁸—subsequently amended in 2021—authorized the use of specific species of insects-as-feed in aquaculture, for farmed fish, while Regulation (EU) 2021/1372 of 17 August 2021 [amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals] has relaxed the abovementioned ban by allowing insect, pig, and poultry processed animal proteins as swine feed and feed for poultry. Although these reforms have been welcomed by insects producers as a significant milestone, opening new scenarios for insects-based feed, other key-steps are still required: studies and comprehensive evaluations should be developed in order to establish the opportunity to further lift the existing ban, based on scientifically justified motivations able to properly consider the persistent risks for animal welfare and human health deriving from the employment of animal proteins as feed.

Another problematic aspect, negatively affecting the potential insects market is to be identified in the legislative prohibitions⁵⁹ against feeding insects on substrates of waste derived from urban or domestic waste, catering, restaurant waste, or other former foodstuffs or unsold products from supermarkets or industries containing meat and/or fish⁶⁰ (such that insects, at the time of this writing, can only be fed with vegetables or materials of vegetal origins): these provisions have a strong impact on the sustainability of insect farming and on the promotion of an effective circular economy.

More generally, it is important to underline that insects' producers are required to follow the exact same rules applying to other food or feed business operators, such as the General Food Law (Regulation 178/2002/EC) as well as the Hygiene Package (Regulation 853/2004/EC and 1831/2003/EC) but also the Regulation (EU) 2016/429 on transmissible animal diseases or Regulation 1069/2009/EC laying down health rules as regards animal by-products and derived products not intended for human consumption. These provisions, as it is easily understandable, were not originally intended to include also insects-based products for animal or human consumption; this aspect represents a critical point, able to influence insects' market in the EU: while a draft Regulation amending Regulation 853/2004/EC—proposed in 2018 and aimed at establishing specific hygiene rules for insects' producers—has not been implemented yet, the need to adopt precise hygiene requirements able to address and properly target the peculiar conditions, characteristics and risks of the insects-production processes seems to represent one of the main challenges the EU is asked to face in order to promote a comprehensive legislative framework capable of both protecting consumers' health and supporting the insects-based products marketing in the European territory.

⁵⁸Regulation (EU) 2017/893 amending Annexes I and IV to Regulation (EC) 999/2001 and Annexes X, XIV and XV to Regulation (EU) 142/2011.

⁵⁹See in particular Regulation (EC) 767/2009 (the so-called Feed marketing regulation) and Regulation (EC) 1069/2009.

⁶⁰This list is only illustrative; for more exhaustive information on this point, see IPIFF (2022).

In other words, while food safety must be regarded as the primary objectives of food and feed regulations, policy makers and legislators should nonetheless consider the importance of prompt, innovative, and sustainable solutions, and carefully reconsider or revise regulatory limits and prohibitions. Such reforms and critical evaluations should be based on scientific data and studies which should also properly take into account as an important element worthy of protection the always more urgent need to promote alternative food practices and habits. To do so, legislators should consider the possibility of reforming existing rules as well as fostering actions and efforts aimed at recognizing the specificities of insect production and the need for appropriate and dedicated legislative regimes. Such regimes must be able, for example, to determine comprehensive rules regarding the production phase (which substrate to be used, hygiene practices etc.) and insect welfare.⁶¹

Clear, comprehensive and harmonized administrative rules and procedures should be developed to face the practical and concrete challenges deriving from applicative doubts and complex and articulated legislative requirements.⁶² Given the multiple regulatory provisions regarding and affecting the insect market,⁶³ it appears of paramount importance to encourage an effective dialogue between legislators and different stakeholders and to ensure a correct balance point between the guarantee of a high level of food safety and the promotion of new, alternative, and sustainable solutions that address food insecurity and environmental limitations.

In this challenging context, the contribution of the EU legislator as well as of national policy makers and authorities will certainly be crucial in the determination

⁶¹This specific aspect has not been deeply studied yet and has not drawn the attention of researchers and policy makers: the EU legislation concerning animal welfare (Directive 98/58/EC concerning the protection of animals kept for farming purposes) does not apply to insects' producers since invertebrate animals do not fall under the scope of application of such provisions. At the moment, no mandatory rules on insects welfare are established in the EU, although IPIFF tried to promote a debate on this relevant topic by adopting a reflection paper on "Animal welfare in insect production", clearly underlining that "welfare standards are adapted to the specificities of insect production. Vertebrated and invertebrates are fundamentally different and it's our mission to respect each species' physiological needs. (...) Insect producers have to overcome very specific challenges linked to some species' natural instincts, cannibalism being one of them (...). Exsanguination with prior sedation, stunning or anaesthetic, is often used to ensure the least suffering as possible during the killing process of animals. However, this is not applicable for insects for which other methods should be applied (e.g. freezing, heating or mincing) in order to ensure a quick death and reduce potential pain risk" IPIFF (2022).

⁶²Back in 2017, the DG Sante too recognized the existence of concrete limits and barriers to the growth of insect industry (DG Sante 2017).

⁶³It is worth briefly mentioning that the regulatory regime concerning the imports of insects-based products is regulated by the EU Commission Implementing Regulation (EU) 2021/405, that establishes a list of Third Countries from which insects authorized as Novel Food and included in the Union List can be imported. The legislation on official controls (Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law) also provides specific conditions for insects to be imported, ensuring the respect of food safety requirements determined in the EU territory.

of the future of insects-as-food (and feed). Through these regulatory efforts, as well as through an appropriate dissemination of consumer information⁶⁴ and a serious consideration of scientific assessments and evaluations, the European Union and its Member States have the chance to make demonstrable progress towards a more sustainable and safe food system that can extend to foods “beyond the humans’ needs to connect them to the ecological dimension.”⁶⁵

References

- Albisinni F (2021) Rules, responsibilities and governance facing Covid-19 in the agri-food sector: EU and Italian perspectives. *Rivista di Diritto Alimentare* 1:11–24
- Alexander P, Brown C, Armeth A, Dias C, Finnigan J, Moran D, Rounsevell M (2017) Could consumption of insects, cultured meat or imitation meat reduce global agricultural land use? *Glob Food Sec* 15:22–32
- Ballke C (2014) The new novel food regulation. *Reform 2.0. Eur Food Feed Law Rev* 5:285–292
- Behnassi M, Draggan S, Yaya S (2011) Global food insecurity. Rethinking agricultural and rural development paradigm and policy. Springer, Cham
- Belgian Federal Public Service Health, Food Chain Safety and Environment (2021) Application of “Novel Food” regulation regarding insects for Human Consumption in Belgium. Questions and answers and application of the transition period, https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/2021_01_qna_novel_foods_insects_final_eng.pdf. Accessed 15 Feb 2022
- Bonara G (2016) I Novel Foods nel Reg. (UE) n. 2015/2283 e gli insetti: una possibile evoluzione dei costumi alimentari? *Rivista di Diritto Alimentare* 1:42–54
- Brookes G (2007) Economic impact assessment of the way in which the European Union novel food regulatory approval procedures affect the European Food Sector. Briefing Paper for the Confederation of the Food and Drink Industries of the European Union CIAA and the Platform for Ingredients in Europe (PIE), <https://www.pgeconomics.co.uk/pdf/novelfoods.pdf>. Accessed 15 Feb 2022
- Carreno I (2014) European Commission proposes to revise the EU’s legislative framework on novel food and animal cloning. *Eur J Risk Regul* 5(3):362–365
- Cavaggon G, Luther G (2018) *Alimentare i diritti culturali*. Aracne Editrice, Rome
- Coppens S (2013) The revision of the novel food regulation: forget about cloning and nanotechnology, let’s focus on the scope. *Eur Food Feed Law Rev* 8:238–246
- DG Sante European Commission (2017) Strategic safety concept for insect as feed, https://ec.europa.eu/food/system/files/2018-04/animal-feed_marketing_concept-paper_insects_201703.pdf. Accessed 15 Feb 2022
- EFSA (2015) Scientific opinion on risk profile related to production and consumption of insects as food and feed, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4257>. Accessed 15 Feb 2022
- European Union Commission (2008) Commission Staff Working Document - Draft report on impact assessment for a Regulation replacing Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients [COM(2007) 872 final] [SEC(2008) 13]

⁶⁴On this point see Bonara (2016) but also *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook*, by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume.

⁶⁵Lanni (2020), p. 78.

- European Union Commission (2022) Approval of third insects as a novel food. Questions and Answers, https://ec.europa.eu/food/safety/novel-food/authorisations/approval-insect-novel-food_en. Accessed 15 Feb 2022
- FAO (2013) Edible insects: future prospects for food and feed security, <https://www.fao.org/3/i3253e/i3253e.pdf>. Accessed 15 Feb 2022
- FAO (2021) Looking at edible insects from a food safety perspective, <https://www.fao.org/3/cb4094en/cb4094en.pdf>. Accessed 15 Feb 2022
- FAO, IFAD, UNICEF, WFP, WHO (2021) The state of food security and nutrition in the World. Transforming food systems for food security, improved nutrition and affordable healthy diets for all, <https://www.fao.org/documents/card/en/c/cb4474en/>. Accessed 15 Feb 2022
- Finardi C, Derrien C (2016) Novel food: where are insects (and Feed. . .) in Regulation 2015/2283? *Eur Food Feed Law J* 2:119–129
- Formici G (2020a) Novel Food tra esigenze di mercato, sicurezza alimentare e sviluppo sostenibile: la complessa disciplina degli alimenti tradizionali provenienti da Paesi terzi. *BioLaw J* 2:67–87
- Formici G (2020b) Novel Food e insetti per il consumo umano tra interventi legislativi e Corte di giustizia: alla ricerca di un difficile equilibrio. *Rivista di diritto alimentare* 4:48–68
- Halloran A, Roos N, Eilenberg J, Cerutti A, Bruun S (2016) Life cycle assessment of edible insects for food protein: a review. *Agron Sustain Dev* 36:1–13
- Halloran A, Flore R, Vantomme P, Roos N (eds) (2018) *Edible insects in sustainable food systems*. Springer, Cham
- Holle M (2014) The protection of proprietary data in novel foods. How to make it work. *Eur Food Feed Law Rev* 5:280–284
- Hyde R, Hartley S, Millar K (2017) European novel foods policy at a critical juncture: drawing lessons for future novel food governance through a retrospective examination of regulation 258/97. *Food Drug Law J* 72:472–505
- Ichijo A, Ranta R (2016) *Food, National Identity and Nationalism. From everyday to global politics*. Palgrave Macmillan, New York
- IPIFF (2018) IPIFF report on approaches to addressing data requirements for insects as novel food, https://ipiff.org/wp-content/uploads/2018/06/ipiff_summary_180516.pdf. Accessed 15 Feb 2022
- IPIFF (2020a) IPIFF position paper. The contribution of the European insect sector to improving sustainability from ‘Farm to Fork’, <https://ipiff.org/wp-content/uploads/2020/02/18-02-2020-IPIFF-Position-Paper-on-the-F2F.pdf>. Accessed 15 Feb 2022
- IPIFF (2020b) IPIFF contribution paper: application of the novel food transitional measure, <https://ipiff.org/wp-content/uploads/2020/12/10-12-2020-IPIFF-Contribution-paper-novel-food-transitional-measure.pdf>. Accessed 15 Feb 2022
- IPIFF (2020c) Briefing note: impact of the CJEU judgement on the novel food status of edible insects in the EU, <https://ipiff.org/wp-content/uploads/2020/10/Briefing-note-Impact-of-the-CJEU-judgement-on-the-novel-food-status-of-edible-insects-in-the-EU.pdf>. Accessed 15 Feb 2022
- IPIFF (2021) Briefing paper on the provisions relevant to the commercialisation of insect-based products intended for human consumption in the EU, https://ipiff.org/wp-content/uploads/2019/08/ipiff_briefing_update_03.pdf. Accessed 15 Feb 2022
- IPIFF (2022) Guide on good hygiene practices for EU producers of insects as food and feed, <https://ipiff.org/wp-content/uploads/2019/12/IPIFF-Guide-on-Good-Hygiene-Practices.pdf>. Accessed 15 Feb 2022
- Jones C (2012) The novel food regulation: revisions required. A view from a regulator. *Eur Food Feed Law Rev* 7(2):81–83
- La Porta B (2021) Gli insetti edibili alla prova del mercato. Il regolamento di esecuzione (UE) 2021/882 relativo all'immissione in commercio della larva di *Tenebrio molitor* essiccata: criticità. *Rivista di Diritto Alimentare* 2:35–51

- Lahteenmaki-Uutela A (2007) European novel food legislation as a restriction to trade. Poster for the 106th Seminar of the EAEE, <https://ideas.repec.org/p/ags/ea106/7909.html>. Accessed 15 Feb 2022
- Lahteenmaki-Uutela A, Gmelova N (2016) European law on insects in food and feed. *Eur Food Feed Law Rev* 2:2–8
- Lahteenmaki-Uutela A, Marimuthu SB, Meijer N (2020) Regulations on insects as food and feed: a global comparison. *J Insects Food Feed* 7(5):849–856
- Lanni S (2020) Not just a bug: brief remarks of legal anthropology for new food choices. In: Scaffardi L, Zeno-Zencovich V (eds) *Cibo e diritto. Una prospettiva comparata*. Rome, RomaTrE-Press, pp 65–79
- Mancini S, Sogari G, Espinosa Diaz S, Menozzi D, Paci G, Moruzzo R (2022) Exploring the future of edible insects in Europe. *Foods* 11:1–12
- Mattas K, Kievit H, van Dijk G, Baourakis G, Zopounidis C (2020) Sustainable food chains and ecosystems. Cooperative approaches for a changing World. Springer, Cham
- Melgar-Lalanne G, Hernandez-Alvarez S-CA (2019) Edible insects processing: traditional and innovative technologies. *Comprehensive Rev Food Sci Food Saf* 0:1–26
- Migali S, Natale F (eds) (2021) Population exposure and migrations linked to climate change in Africa. Publications Office of the European Union, Luxembourg
- Molinari M (2006) *Food is culture*. Columbia University Press, New York
- Montanari F, Pinto de Moura A, Cunha LM (2021) Production and commercialization of insects as food and feed. Identification of the main constraints in the European Union. Springer, Cham
- OECD (2020) Covid-19 and the food and agriculture sector: issues and policy responses, https://read.oecd-ilibrary.org/view/?ref=130_130816-9uut45lj4q&title=Covid-19-and-the-food-and-agriculture-sector-Issues-and-policy-responses. Accessed 15 Feb 2022
- Ordoñez-Araque R, Egas-Montenegro E (2021) Edible insects: a food alternative for the sustainable development of the planet. *Int J Gastronomy Food Sci* 23:1–6
- Paganizza V (2016) Eating insects: crunching legal clues on entomophagy. *Rivista di diritto alimentare* 1:16–41
- Paganizza V (2019) Bugs in law. *Insetti e regole: dai campi alla tavola*. Cedam, Padova
- Paganizza V (2020) Are insects novel foods? *Eur Food Feed Law Rev* 6:579–587
- Payne C, Caparros Megido R, Dobermann D, Frédéric F, Shockley M, Sogari G (2019) Insects as food in the Global North. The evolution of the entomophagy movement. In: Sogari G, Mora C, Menozzi D (eds) *Edible insects in the food sector*. Springer, Cham, pp 11–26
- Pippinato L, Gasco L, Di Vita G, Mancuso T (2020) Current scenario in the European edible-insect industry: a preliminary study. *J Insects Food Feed* 6(4):371–381
- Pisanello D, Caruso G (2018) Novel foods in the European Union. Springer, Cham
- Rizzoli S (2016) Novel food. In: Costato L, Albinini F (eds) *European and global food law*. Wolters Kluwer, Milano, pp 487–504
- Scaffardi L (2020) I Novel Food, un futuro ancora da definire. *BioLaw J* 2:43–66
- Simpson C (2016) Data protection under food law post: in the aftermath of the novel food regulation. *Eur Food Feed Law Rev* 4:309–314
- Smetana S, Palanisamy M, Mathys A, Heinz V (2016) Sustainability of insect use for feed and food: life cycle assessment perspective. *J Clean Prod* 137:741–751
- United Nations (2020) The impact of COVID-19 on food security and nutrition, <https://unsdg.un.org/sites/default/files/2020-06/SG-Policy-Brief-on-COVID-Impact-on-Food-Security.pdf>. Accessed 15 Feb 2022

- Van Huis A, Oninex D (2017) The environmental sustainability of insects as food and feed. A review. *Agron Sustain Dev* 37:1–14
- Van Huis A, Tomberlin JK (2017) *Insects as food and feed: from production to consumption*. Wageningen Academic Publishers, Wageningen
- Vauterin A, Steiner B, Sillman J, Kahiluoto H (2021) The potential of insect protein to reduce food-based carbon footprints in Europe: the case of broiler meat production. *J Clean Prod* 320:1–12
- Volpato A (2015) La riforma del Regolamento sui Novel Food: alla ricerca di un impossibile equilibrio? *Rivista di Diritto Alimentare* 4:26–43

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



The Safety Assessment of Insects and Products Thereof As Novel Foods in the European Union



Gabriela Precup, Ermolaos Ververis, Domenico Azzollini, Fernando Rivero-Pino, Panagiota Zakidou, and Andrea Germini

Abstract In the European Union, insects and products thereof fall under Regulation (EU) 2283/2015 on Novel Foods, as they were not consumed to a significant degree within the EU before 15 May 1997. This chapter elucidates the risk assessment process performed by EFSA, highlighting the various elements considered when assessing the safety of insect-derived foodstuffs. The information discussed stems from EFSA outputs on the safety evaluation of such products, which have confirmed the safety of their consumption under the proposed conditions of use.

Keywords EFSA · Risk assessment · Insects · Safety · Novel foods

The original version of this chapter was revised: the affiliation details for author Ermolaos Ververis has been updated. The correction to this chapter can be found at https://doi.org/10.1007/978-3-031-13494-4_9

G. Precup

University of Agricultural Sciences and Veterinary Medicine (USAMVCN), Faculty of Food Science and Technology, Cluj-Napoca, Romania
e-mail: gabriela.precup@usamvcluj.ro

E. Ververis

National and Kapodistrian University of Athens (NKUA), Department of Hygiene, Epidemiology and Medical Statistics, School of Medicine, Athens, Greece

EFSA, Nutrition and Food Innovation Unit, Novel Foods Team, Parma, Italy

e-mail: ermolaos.ververis@efsa.europa.eu

D. Azzollini · P. Zakidou · A. Germini (✉)

EFSA, Nutrition and Food Innovation Unit, Novel Foods Team, Parma, Italy

e-mail: domenico.azzollini@efsa.europa.eu; panagiota.zakidou@ext.efsa.europa.eu; andrea.germini@efsa.europa.eu

F. Rivero-Pino

Department of Chemical Engineering, University of Granada, Granada, Spain

e-mail: frivero@ugr.es

© The Author(s) 2022, corrected publication 2022

L. Scaffardi, G. Formici (eds.), *Novel Foods and Edible Insects in the European Union*, https://doi.org/10.1007/978-3-031-13494-4_7

1 Introduction

Innovation in the food sector is fostered by the growing consumer interest in dietary choices with a potentially more environmentally sustainable profile compared to the currently existing ones, and by the various challenges that the food system is facing. Among these challenges lies the constantly growing world population, predicted to reach 9.7 billion by 2050, as forecasted by the Food and Agriculture Organization (FAO) of the United Nations.¹ Since existing agricultural land is insufficient to satisfy the global demand for meat production,² alternative protein sources, novel or traditional ones, could represent an opportunity for more sustainable choices considering animal welfare aspects, while addressing consumer needs. Among these, algae, fungi, cultured meat, plants, and insects appear promising.

Entomophagy, i.e., the consumption of insects by humans, has gained increasing interest lately due to the nutrient composition of certain insect species, as well as due to their food technological potential. Several insects have been consumed by various population groups since prehistory. Moreover, insects have been reported as part of the habitual diet of over two billion people worldwide.^{3,4} Evidence of ancient entomophagy has been found in the United States of America (USA) and Mexico, through the analysis of fossilized fecal material.⁵ Additionally, insect consumption by humans has been documented in the Middle East since ancient times (eighth century B.C.), while in Europe, there is proof that ancient Greeks and Romans consumed insects as ingredients of certain recipes.⁶

Recent estimations of edible insects worldwide approximate that about 1600 insect species, are consumed in approximately 140 countries in Asia, Africa, Australia, North America and South America.⁷ The most commonly consumed insect species belong taxonomically to the orders of Coleoptera (beetles) (31%), Lepidoptera (caterpillars) (18%), Hymenoptera (ants, bees and wasps) (14%), Orthoptera (grasshoppers, locusts and crickets) (13%), Hemiptera (cicadas, leafhoppers, planthoppers) (10%), Isoptera (termites) (3%), Odonata (dragonflies) (3%) and Diptera (flies) (2%)⁸ (Fig. 1). In terms of production origin, 92% are wild harvested, 6% are semi-domesticated, and 2% are farmed.^{9,10}

The use of insects and products thereof as food differs across the world when it comes to regulatory aspects. Existing legislative frameworks on insects as food and

¹FAO (2019).

²OECD and FAO (2021).

³Huis et al. (2013).

⁴Lange and Nakamura (2021).

⁵Mitsuhashi (2016), Mitsuhashi and Capinera (2008).

⁶Bodenheimer (1951).

⁷Van Itterbeeck and Pelozuelo (2022).

⁸Kouřimská and Adámková (2016) and Goumperis (2019).

⁹FAO (2021).

¹⁰Jongema (2017).

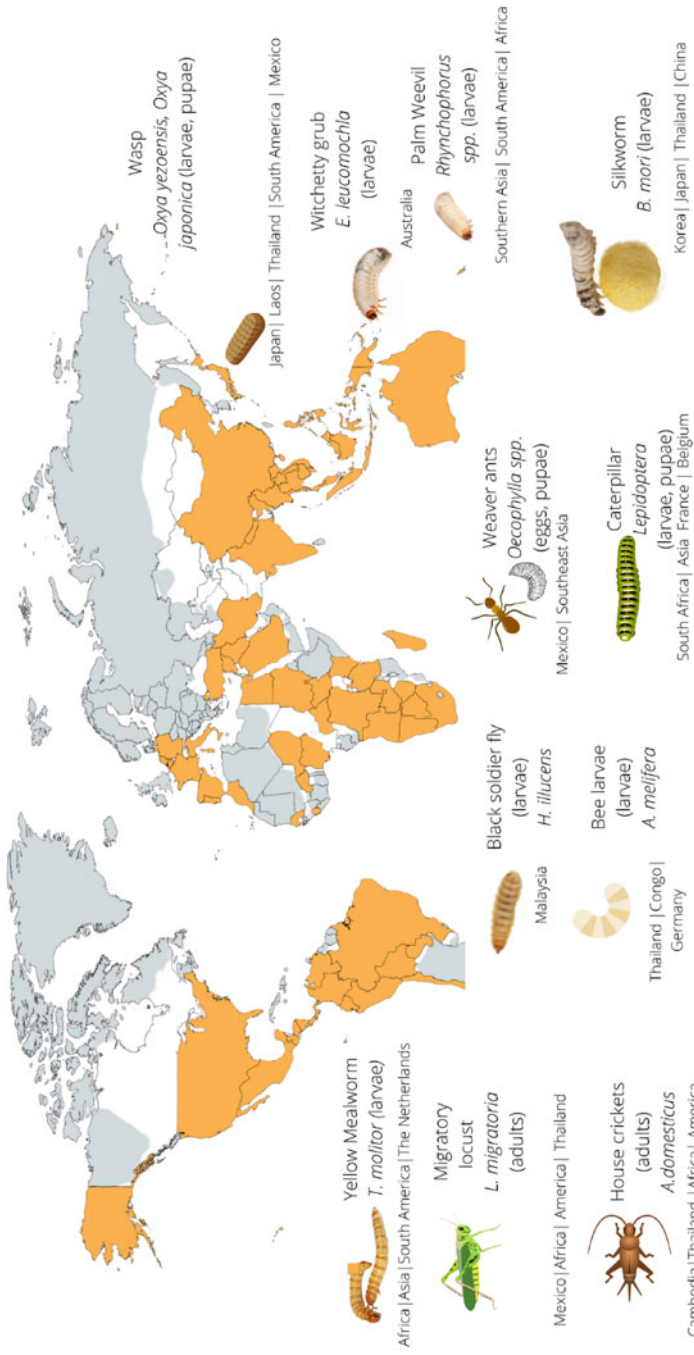


Fig. 1 Examples of insect species consumed as food around the world

feed were recently compared by Lähteenmäki-Uutela (2021).¹¹ For instance, in the United States, edible insects and insect-derived foods fall under the ‘Food, Drug and Cosmetic Act’,¹² requiring approval from the Food and Drug Administration (FDA) before being marketed in the US market. An insect-derived protein is considered a food additive unless it has GRAS status (Generally Recognized as Safe). In Canada, the ‘Food and Drugs Act’ sets various requirements for foods sold in the Canadian market, setting pre-market notification requirements for infant formulas and for Novel Foods (Division 25 and Division 28). The safety and nutritional adequacy of Novel Foods in Canada must be evaluated before such products may enter the market.¹³ In Australia and New Zealand insects intended for human consumption are regulated in general as ‘Novel Foods’.¹⁴ Nevertheless, the food safety agency of Australia and New Zealand (Food Standards Australia New Zealand—FSANZ) categorized three insect species as non-novel: super mealworm (*Zophobas morio*); house cricket (*Acheta domesticus*); and yellow mealworm (*Tenebrio molitor*). In several Asian countries (e.g., China, Japan, Thailand), entomophagy has a long tradition. In China, there are no harmonized national laws for edible insects, however insects are traditionally consumed in both households and restaurants.¹⁵ The Chinese Ministry of Health is responsible for authorizing new food raw materials based on local food safety standards, such as the one for edible frozen fresh silkworm pupae. To date, silkworm pupae and earthworm protein powder have been authorized as food ingredients.^{16,17} In Japan, various insect species such as the larvae and pupae of the wasp species *Oxya yezoensis* or *Oxya japonica*, and the pupae and female adults of the domestic silkworm (*Bombyx mori*) are considered traditional foods. In 2016, the Korean Food and Drug Administration classified house crickets (*A. domesticus*) and yellow mealworms (*T. molitor*) as non-novel. The Thai Food and Drug Administration released the guidelines for cricket farming¹⁸ in 2017, with Thailand being the world’s biggest cricket producer.

In the European Union (EU), the entry into force of the new Regulation 2283/2015¹⁹ on Novel Foods and the implementation of Regulations 2468/2017²⁰ and

¹¹ Lähteenmäki-Uutela (2021).

¹² Food, Drug and Cosmetic Act.

¹³ Canada Gazette Part II, Division 28: Novel Foods, October. 27, 1999 Vol. 133, No. 22 (1999).

¹⁴ Australia New Zealand Food Standards Code—Standard 1.5.1—Novel foods (2016).

¹⁵ Guiné et al. (2021).

¹⁶ Belluco et al. (2013).

¹⁷ Shen (2014).

¹⁸ Thai Agricultural Standard 8202. Good Agricultural Practices for Cricket Farm. Royal Gazette, Announcement and General Publication, Volume 134 Special Section 293 D (2017).

¹⁹ Regulation (EU) 2015/2283 (2015) 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 (Text with EEA relevance).

²⁰ Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

2469/2017²¹ clarified and harmonized rules concerning insects and products thereof as food, specifying that Novel Foods cover whole insects, their parts and products thereof, since such products were not consumed to a significant degree within the EU before 15 May 1997.²² From 1 January 2018, insects and insect-derived products must obtain an authorization as Novel Foods before being placed on the EU market.

Since the implementation of the new Novel Foods regulation,²³ an increasing trend can be observed regarding the number of applications of insects and products thereof as Novel Foods that aspire to enter the EU market. To date, the European Food Safety Authority (EFSA) has received several Novel Food applications for products derived from insect species of differing developmental stages. The concerned insect species comprise *T. molitor* larvae (yellow mealworm), *Alphitobius diaperinus* larvae (lesser mealworm), *A. domesticus* adults (house cricket), *Locusta migratoria* adults (migratory locust), *Hermetia illucens* larvae (black soldier fly larvae), male larvae of *Apis mellifera* (honeybee drones), and *Gryllobates sigillatus* adults (banded cricket or Indian cricket). As of March 2022, the risk assessment process has been finalized for four of these applications.^{24,25,26,27} The authorization process by the European Commission (EC) has been completed, meaning that they can be legally marketed in the EU.^{28,29,30,31} Specifically, the authorized Novel Foods

²¹ Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

²² For an in-depth analysis of the previous debate on whole insects' Novel Foods status, see *Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU* by G. Formici in this volume.

²³ For an examination of the current Regulation, see *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, by A. Volpato in this volume and *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* by L. Scaffardi in this volume.

²⁴ EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), et al. (2021).

²⁵ EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), et al. (2021a).

²⁶ EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), et al. (2021b).

²⁷ EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), et al. (2021c).

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.

²⁹ 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.

³⁰ Commission Implementing Regulation (EU) 2022/188 of 10 February 2022 authorising the placing on the market of frozen, dried, and powder forms of *Acheta domesticus* 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.

³¹ Commission Implementing Regulation (EU) 2021/1975 of 12 November 2021 authorising the placing on the market of frozen, dried and powder forms of *Locusta migratoria* as a novel food

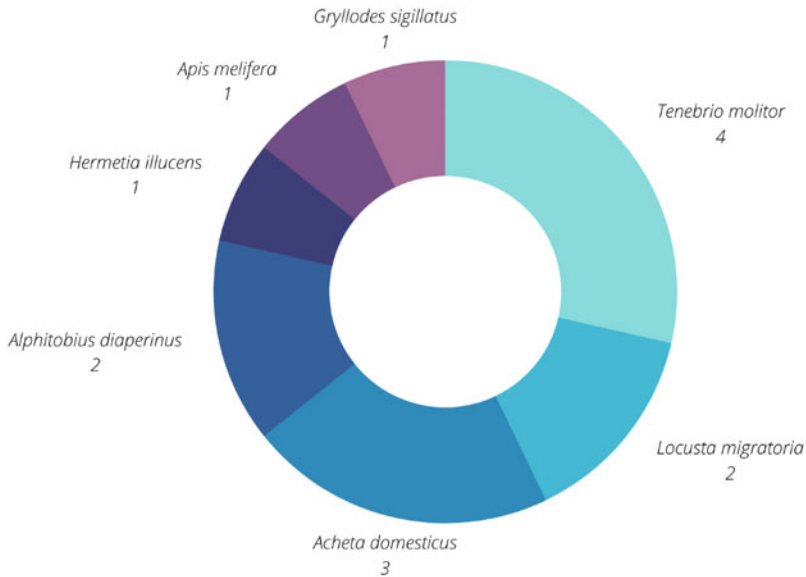


Fig. 2 Applications for insects and products thereof as Novel Foods received by EFSA from January 2018 until February 2022

comprise products derived from the yellow mealworm, the migratory locust and the house cricket, following EFSA's risk assessments which concluded that these products are safe for human consumption under the proposed conditions of use (Fig. 2).

2 Overview of the Risk Assessment Process of Insects and Products Thereof As Novel Foods in the EU

2.1 Authorization Procedure for Novel Foods in the EU and Principles of the Risk Assessment Process

Before a Novel Food, including insects and products thereof, can be placed on the EU market, an authorization procedure based on a risk analysis is required. In this context, risk analysis encompasses three main areas: risk assessment, risk management and risk communication. The steps reflecting the authorization procedure of Novel Foods in the EU are presented in Fig. 3.

In practical terms, a Food Business Operator (FBO) who intends to place a Novel Food on the EU market, should submit an application to the European Commission

under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

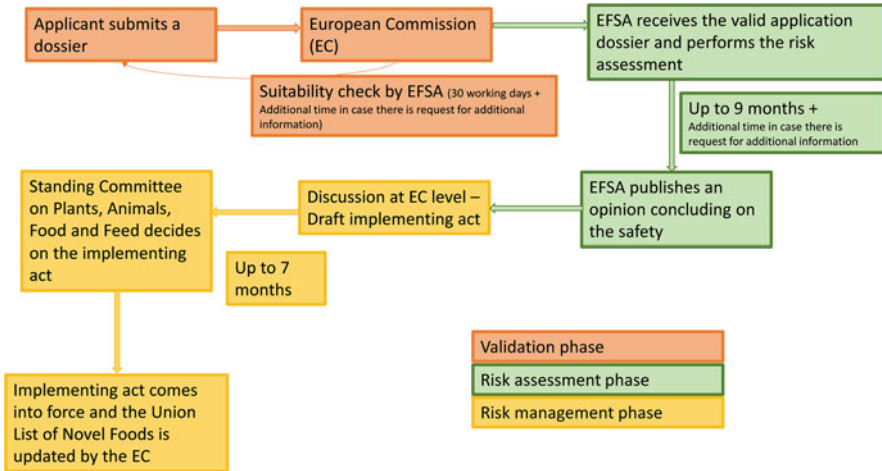


Fig. 3 The Novel Foods applications workflow

that, together with the EU Member States, has risk management responsibilities. Within this framework, EFSA may be mandated by the European Commission to carry out the risk assessment of the technical dossiers submitted in the context of the application. Finally, the European Commission and EFSA share the responsibility to provide appropriate risk communication to inform any interested parties, mitigating any food safety-related issues.

Under the Regulation (EU) 2015/2283 on Novel Foods, FBOs are responsible for verifying with their national authorities whether the product that they intend to market falls within the Novel Food categories defined by the Regulation and therefore would require an application for authorization. Member States can be consulted to support this decision, following the procedure laid down in Commission Implementing Regulation (EU) 2018/456.³² After issuing the validity of the application with respect to the requirements laid down in the Regulation (EU) 2015/2283 on Novel Foods, the European Commission makes the technical dossier available to the Member States and may mandate EFSA to carry out the risk assessment, in accordance with Article 10 of the respective Regulation.

For the preparation of the technical dossier in support of their Novel Food application, applicants are recommended to follow the main scientific requirements outlined in EFSA’s ‘Guidance on the preparation and presentation of an application for authorization of a novel food in the context of Regulation (EU) 2015/2283’.³³ The guidance document was recently updated following the implementation of the

³²Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for the determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

³³EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), et al. (2016).

Regulation (EU) 2019/1381,³⁴ which aims at increasing the transparency of the EU risk assessment in the food chain, and at strengthening the reliability, objectivity, and independence of the studies used by EFSA. Additionally, further information on the major challenges encountered during the risk assessment of Novel Food applications was also recently published.³⁵

EFSA's mandate in the risk assessment of Novel Foods includes an assessment of the safety of the product for the general EU population or for specific segments of it, including an evaluation on whether the product could be nutritionally disadvantageous for the consumer. EFSA must adopt its scientific opinion within nine months of the date of receipt of a valid application from the European Commission. However, if additional information to support the assessment is requested from the applicant by EFSA, the assessment is suspended until the applicant replies.

Assessing the risk arising from the consumption of Novel Foods encompasses the four steps involved in a regular risk assessment process:

1. Hazard identification—the identification of biological, chemical, and physical agents capable of causing adverse health effects which may be present in a particular food or group of foods.
2. Hazard characterisation—the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard.
3. Exposure assessment—a qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food, as well as exposures from other sources, if relevant.
4. Risk characterisation—a process of determining the qualitative and/or quantitative estimation, including attendant uncertainties of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.³⁶

EFSA's risk assessment of Novel Foods ends with the adoption of the scientific opinion on the safety of the product in question by the external experts that constitute the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), supported by a Working Group of external experts and by EFSA scientific officers. The scientific opinion is then published in the EFSA Journal.

Following the adoption of EFSA's scientific opinion, the European Commission and the EU Member States act as risk managers of the process by evaluating the risk posed to consumers as assessed in EFSA's opinion and by implementing appropriate

³⁴Regulation (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.

³⁵Ververis et al. (2020).

³⁶FAO, WHO (1997); CAC (2015) Codex Alimentarius Commission Procedural Manual. 23rd edition; Joint FAO, WHO Food Standards Programme Codex Alimentarius Commission (CAC) (1999). Principles and guidelines for the conduct of microbiological risk assessment, cac/gl-30, WHO (2008).

measures or monitoring plans when needed. Within seven months of the date of publication of EFSA's opinion, the European Commission submits a draft to the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) implementing an act authorizing the placing on the market within the Union of a Novel Food and updating the Union list of Novel Foods³⁷ in line with Regulation (EU) 2017/2470.³⁸

According to Article 10, Regulation 2015/2283, the Novel Food applications workflow includes the following steps:

2.2 Main Challenges During the Safety Assessment of Insects

During the safety assessment process of insects and products thereof, several challenges may arise related to the production process, the compositional and nutritional analysis of the products, as well as aspects related to toxicological information and allergenicity potential.

Production Process

The production process can have a significant impact on the safety of insects and products thereof as Novel Foods and shall be described in detail. The conditions used in the manufacturing process of insects influence their compositional and nutritional analysis and *a priori* their safety. The NF's source, i.e., the insect species, must be identified.

Thus, certificates from national repositories or documentation on genetic techniques evidencing the identity of the insect species could represent proofs on this aspect. Furthermore, eggs or larvae purchased from various suppliers that are intended to be used in the rearing and processing steps should be accompanied by quality and safety certificates from all the companies that provided the initial livestock.

Generally, the production process of insects consists of three main steps: farming, harvesting, and postharvest processing, each bearing potential hazards. As described in the published opinions, farming includes the mating of the adult insect population and rearing of the larvae. Eggs should be separated from the adult insects to avoid any contamination, for instance through faeces. It is therefore important that larvae are reared in disinfected, certified food-contact containers. Ingestion of soft-type

³⁷ https://ec.europa.eu/food/safety/novel-food/authorisations/union-list-novel-foods_en, last accessed 25 February 2022.

³⁸ 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.

plastic has been reported and may represent a potential physical hazard if it ends up in the final food product.^{39,40} Additionally, the feeding substrate could contain chemical and microbiological contaminants (e.g., heavy metals, pesticides residues, mycotoxins) that need to be monitored and must be compliant with European feed regulations (e.g., Directive 2002/32/EC).⁴¹ It is recommended that substrates have not been in contact with other livestock animals (e.g., egg cartons).

During farming, insects can be infected by or become hosts for biological hazards such as bacteria, parasites, fungi and viruses (e.g., cricket paralysis virus and citrobacter for *A. domesticus*, tapeworms for *T. molitor*, virus Cricket iridovirus (CrIV) for *L. migratoria*). Their presence should be detected or documented by evidence in the literature. However, it has been reported that some of these pathogens (i.e., cricket paralysis virus and Cricket iridovirus) represent hazards for other insects, rather than for humans or other vertebrates due to phylogenetic differences, thus the risk of transmitting zoonotic infections is limited.^{42,43} Moreover, insects can also produce or accumulate from the environment substances such as antinutrients (phytic acid, quinones, cyanogenic glycosides), which inhibit the bioavailability of nutrients. In addition, as part of their defence mechanism, *T. molitor* adult insects can secrete chemical substances such as benzoquinones with potentially toxic effects.^{44,45} Such findings refer to *T. molitor* adult insects (beetles), but not to larvae. As a result, it should be noted that larvae should be reared separately from adult insects.

Furthermore, during harvesting insects are separated from frass, substrate, and dead insects to reduce the microbiological load and the presence of other hazards, as well as to avoid further deterioration. They usually undergo a one-day fasting step to discard their bowel content, which is a source of microbiological hazards. During post-harvest processing, thermal treatments are used to enhance the microbiological and chemical stability of the insect as Novel Foods (e.g., freezing/freeze drying, blanching, UV-treatment). For example, a blanching step could contribute to eliminating potentially present zoonotic agents such as parasites and viruses, but also inactivating or reducing the activity of enzymes (e.g., tyrosinase/phenoloxidase) that could cause enzymatic browning in larvae.⁴⁶ However, those methods are not fully effective to heat-resistant endospore-forming bacteria, which may produce toxins.⁴⁷

³⁹Brandon et al. (2018).

⁴⁰Yang et al. (2018).

⁴¹Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed—Council statement.

⁴²Ulrich et al. (1981).

⁴³EFSA Scientific Committee (2015).

⁴⁴Dzerefos et al. (2013).

⁴⁵Rumpold and Schlüter (2013a, b).

⁴⁶Janssen et al. (2017), Nappi and Vass (1993), Nappi and Ottaviani (2000), Sugumaran et al. (2000), Nappi and Christensen (2005) and Vigneron et al. (2014).

⁴⁷Kooh et al. (2019, 2020).

Drying steps are needed to reach a low water activity in the final product, since the presence of moisture is known to favour microbial growth.

In the case of insect fractions or extracts as Novel Foods, enzymes are often used to hydrolyse the macromolecules. If the safety of such enzymes has not yet been assessed by EFSA, analytical data demonstrating the absence of viable cells of the enzyme-producing microorganisms in the novel food or/and the enzyme preparations should be provided. If enzymes derive from genetically modified microorganisms, then analytical data demonstrating the absence of recombinant DNA are additionally needed. Considering the qualified presumption of safety (QPS) status of certain microorganisms (e.g., *Bacillus licheniformis*, *Aspergillus niger*), the absence of toxigenic potential (absence of food poisoning toxins, absence of surfactant activity, and absence of enterotoxic activity) in the corresponding enzyme preparations should be demonstrated according to EFSA's Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) (2014).⁴⁸

Additionally, FBOs producing insects for human consumption should describe the measures implemented for ensuring the quality and safety of the novel foods and how their production control is assured (e.g., Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Points (HACCP), and International Organization for Standardization (ISO) principles). Therefore, any potential risk could be mitigated via specific measures and actions that control the occurrence of possible contaminants such as solvents, pesticides, antimicrobial substances, or veterinary medicinal products.

Compositional Characterisation and Specifications of Insects and Products Thereof

In terms of compositional analysis, insects can be considered as whole foods, meaning that all their constituents cannot be fully characterised and/or identified. In this respect, insects as Novel Foods are characterised by a qualitative and quantitative assessment of the main constituents and proximate analysis parameters, of constituents of nutritional relevance and of compounds of possible concern for human health. The analytical data should be generated from experimental analysis and be further compared with data from the scientific literature, collected following the respective methodology developed by EFSA.⁴⁹

Nevertheless, providing definitive figures on the nutritional quality of insects is difficult due to the large taxonomic diversity of these organisms. Generally, the nutrient composition of insects spans a broad range of protein, fat, and dietary fibre. Insects are considered a source of protein with amino acid compositions that are

⁴⁸EFSA FEEDAP Panel (2014).

⁴⁹European Food Safety Authority (EFSA) (2010). Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal; 8(6):1637. [90 pp.]. <https://doi.org/10.2903/j.efsa.2010.1637>.

generally balanced for humans. With regard to insects as Novel Foods assessed by EFSA, the larvae of dried *T. molitor* had an average of 57 g/100 g of crude protein. In *L. migratoria* the dried formulation ranged from 48.1 g/100 g to 48.9 g/100 g, and finally *A. domesticus* had an average of 60.3 g/100 g. Similarly, variability in fat, chitin, and digestible carbohydrates were observed in the different insect species assessed.

It is worth mentioning that the compositional value of insects is not only species specific but may largely depend on other factors such as rearing conditions. Determining factors include the feed used, the developmental stage of the insects at the time of harvesting, and the ambient conditions.⁵⁰ As an example, the quantitative and qualitative lipid profile in *T. molitor* can vary when larvae are reared at different temperatures, while a change in feed protein concentration can result in different protein content in the final product.⁵¹ In additional studies, the fatty acid profile of *A. domesticus* was found to have a specific polyunsaturated fatty acids profile as a result of the feed used,⁵² with the quantity of fat in *A. domesticus* adults being correlated with the one present in the feed.⁵³

Changes in the micronutrient composition of the feed have also been shown to affect the final composition of insects. For example, the addition of carrots to the diet of *T. molitor* has been shown to affect the total carotenoid content of the harvested insect,⁵⁴ and can change the content of calcium (Ca), potassium (K), magnesium (Mg), and sodium (Na) in adults of *L. migratoria*.⁵⁵

The protein conversion factor is a largely debated point in protein quantification in whole insects and certain products thereof. In foods, protein content is generally estimated by multiplying the nitrogen content measured by the Kjeldahl method with a nitrogen-to-protein conversion factor of 6.25, resulting in the so-called crude protein content⁵⁶ (Regulation (EU) No 1169/2011 (2011) on the provision of food information to consumers). However, in whole insects, as well as in insect-derived products containing chitin, this factor leads to an overestimation of the protein content due to the presence of non-protein nitrogen derived mainly from chitin. More accurate conversion factors were reported for insects and other food products.⁵⁷ For instance, Janssen et al. 2017 proposed an alternative conversion factor of

⁵⁰Ooninx and van der Poel (2011), Ooninx et al. (2015).

⁵¹Adámková et al. (2020).

⁵²Ooninx et al. (2019).

⁵³Pastell et al. (2021).

⁵⁴Rovai et al. (2021).

⁵⁵Ooninx and van der Poel (2011).

⁵⁶Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

⁵⁷FAO (2013).

4.76 based on amino acid data on the larvae of yellow mealworms, lesser mealworms and black soldier flies.⁵⁸ Other studies from 20 insect samples including 13 species and different developmental stages, resulted in an average protein conversion factor of 5.81; ranging from 4.56 to 6.45, confirming an overestimation of true protein content.⁵⁹

In addition to the nutritional characterisation of insects, a qualitative and quantitative characterisation of other substances such as heavy metals, undesirable substances, or processing contaminants is an essential part of risk assessment. This is performed by means of literature review and chemical analyses. For instance, since the bioaccumulation of heavy metals (e.g., arsenic, lead, cadmium) can occur if the larvae of *T. molitor* are fed with contaminated substrates,⁶⁰ their content is reported and discussed during the risk assessment and reported in the specifications.

Finally, the stability of insects and products thereof is assessed both after production and during their shelf life. Two main aspects are investigated: microbiological stability and oxidative stability of fats. It is in fact important that the microbiological count and lipid oxidation in insects is within specific ranges throughout their shelf life, to ensure safe consumption. Assessment of the stability and behaviour of the Novel Foods in food matrices is required when the novel food is intended to be used as a food ingredient. For example, the levels of acrylamide in biscuits containing yellow mealworm powder were investigated and found to be below the levels set by EU legislation for other products. However, it could not be concluded whether the Novel Foods contributes to the formation of the acrylamide or not, due to absence of appropriate control samples.⁶¹

Proposed Uses, Use Levels

Depending on their phylogenetic order, insects are consumed at different developmental stages, as eggs, pupae, larvae, or adults. As Novel Foods, insects are typically consumed as a whole food or else are incorporated in other foodstuffs as a food ingredient, for example in the form of a powder. They can also be consumed as a food supplement. In some cases, the hard parts of insects, such as spines, wings, or rostrums, which can be considered physical hazards, are removed to limit the risk of intestinal constipation caused by ingestion.⁶² An example is the removal of the legs and wings of the insect *L. migratoria*.

In the case of the application for dried and/or frozen yellow mealworm, the applicants proposed to use the Novel Food in the form of whole, dried and/or frozen

⁵⁸ Janssen et al. (2017).

⁵⁹ Oonincx et al. (2020).

⁶⁰ van der Fels-Klerx et al. (2016).

⁶¹ Acrylamide formation can be induced due to the presence of the amino acid asparagine or from amino acids that can produce acrylic acid.

⁶² FAO (2021).

insect, and as a food ingredient (powdered) in a number of food products (e.g., snacks such as chips, biscuits, legumes-based dishes, pasta, cereal bars, pasta, meat imitates and bakery products). In the case of the frozen and dried formulations from migratory locust, the applicant proposed to use the Novel Food in the form of frozen, dried and ground insect, as snack, and as a food ingredient in various food categories (e.g., soups, frozen yogurt, and beverages). Finally, in the case of the frozen and dried formulations from house crickets, the applicant proposed to use the Novel Food as a snack, and as a food ingredient in 40 different food categories (among others, meat imitations, whey powder, tortilla chips, snacks other than chips, chocolate, and mixed alcoholic drinks).

Estimations of the anticipated daily intake of the Novel Food, as well as exposure of consumers to nutrients and substances of concern after consumption of an insect as novel food are both considered in the risk assessment. Exposure refers to the concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration.⁶³ To estimate the chronic intake (average and high percentiles) and acute intake when acute effects may be of concern, the following tools and databases are made available to the public by EFSA: the Food Additives Intake Model (FAIM), the Dietary-Exposure tool (DietEx), FoodEx2 and the EFSA Comprehensive European Food Consumption Database.

Based on the applicant's choice of the intended uses and maximum use levels, it is possible to calculate the respective intake of the Novel Food in the different target population groups in the EU. One important point to be taken into consideration is that if a Novel Food is intended to be used as food ingredient, a safe level of consumption should be proven for the general healthy population,⁶⁴ whereas in the case of food supplements it is possible to establish a specific target population (e.g., adults).

As such, based on the highest percentile (P95th intake estimate), the estimate of exposure to undesirable substances (e.g., heavy metals, mycotoxins) is calculated for all population groups considering the specified limits for the concentrations of the respective substances of possible concern. However, it was noted in the published outputs on the safety of insects and products thereof as Novel Foods that the consumption of the Novel Food under the proposed uses and use levels did not contribute significantly to the overall exposure to the analysed undesirable substances through diet.

⁶³FAO, WHO (2008).

⁶⁴Commission 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.

Nutritional Information

When assessing the nutritional aspects of an insect-based product as Novel Food, two important elements must be considered to investigate whether the consumption of the product is not nutritionally disadvantageous under the proposed conditions of use: its role in the diet in terms of dietary supply of nutrients and its possible interaction with nutrient absorption. Specifically, an insect-based product as Novel Food could be nutritionally disadvantageous if its consumption may significantly impact the nutrient supply of consumers or if the tolerable upper intake levels (ULs)⁶⁵ for nutrients are exceeded under the proposed use levels. This is of particular concern in the case of Novel Foods intending to substitute products that are already part of the European diet, as may be the case for new protein sources intending to replace meat, for example. The nutrient composition and the bioavailability of nutrients can be impacted by the farming aspects (e.g., feed substrate, developmental stage of the insect, environmental factors), stability, as well as processing, as previously stated in this chapter.

Protein quality is an important factor to be investigated in safety assessment. To conclude on protein quality, the amino acid profile as well as the digestibility of the protein are primarily considered. The amino acid profile must be defined qualitatively and quantitatively, using methods in accordance with ISO 13903:2005 and/or Commission Regulation (EC) 152/2009 (2009).⁶⁶ Digestibility studies should be performed according to the report by FAO (2013).⁶⁷ In its report FAO recommends the use of a new method to evaluate protein, namely, the digestible indispensable amino acid score (DIAAS)⁶⁸ instead of the protein digestibility-corrected amino acid score (PDCAAS),⁶⁹ since it has been shown to better reflect the amounts of amino acids absorbed from proteins.

In the case of yellow mealworms (freeze-dried), the study by Jensen et al. (2019)⁷⁰ reported a protein digestibility-corrected amino acid score (PDCAAS) of 76% that was comparable to the PDCAAS value of 73% reported on average for vegetables⁷¹ but lower than those for beef at 92% and soy at 91%.⁷² In another study by Oibiokpa et al. (2018),⁷³ crickets (*Gryllus assimilis*), were shown to have a higher

⁶⁵The Tolerable Upper Intake Level (UL) is the maximum level of total chronic intake of a nutrient from all sources judged to be unlikely to pose a risk of adverse health effects in humans.

⁶⁶European Commission (2009). Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed.

⁶⁷FAO (2013).

⁶⁸DIAAS is defined as: $\text{DIAAS \%} = 100 \times [(\text{mg of digestible dietary indispensable amino acid in 1 g of the dietary protein}) / (\text{mg of the same dietary indispensable amino acid in 1 g of the reference protein})]$.

⁶⁹PDCAAS -the ratio of the first-limiting amino acid in a gram of target food protein to that in a reference protein or requirement value.

⁷⁰Jensen et al. (2019).

⁷¹Suárez et al. (2006).

⁷²Schaafsma (2000).

⁷³Oibiokpa et al. (2018).

protein quality and digestibility (measured as protein digestibility-corrected amino acid score or PDCAAS) as compared to the protein quality of other insects analyzed (grasshopper—*Melanoplus foedus*, termite—*Macrotermes nigeriensis* and moth caterpillar—*Cirina fforda*).

The literature reports that some insect species contain micronutrients like minerals (iron, zinc, magnesium, manganese, phosphorus and selenium) and vitamins (riboflavin, pantothenic acid, biotin). Rumpold and Schlüter (2013a, b) compiled the nutrient composition of 236 edible insect species and noted that in general, 100 g of edible insects did not meet the daily requirements for Ca and K for instance, but could provide specific levels of other micronutrients such as copper, iron, magnesium, manganese, phosphorous, selenium, and zinc. As already mentioned, the intakes of micronutrients from the background diet are considered in the safety assessment of insects as Novel Foods for establishing the mean and high daily intake scenarios. The resulting estimates are further discussed in the context of available dietary reference values including the ULs.

Regarding the content of these micronutrients in the insects assessed by EFSA up to date, considering the mean and the estimated P95th percentile of exposure to the Novel Food, it was stated that none of the existing ULs for the analyzed micronutrients in the respective insect species (e.g. calcium, copper, iron, magnesium, zinc, iodine, selenium, molybdenum, folate, riboflavin) was expected to be exceeded, for any population group.⁷⁴ However, at present there is insufficient information as to the bioavailability of these micronutrients from insects.

Insects may contain antinutritional factors (ANFs) such as tannins, oxalates, phytate, and hydrogencyanide,⁷⁵ thiaminases,⁷⁶ and protein inhibitors.⁷⁷ These substances can be produced by insects or be accumulated from the environment.⁷⁸ Some of them can negatively impact the bioavailability of nutrients from insects, for example by interfering with the absorption of minerals. From a nutritional perspective, consumption of such substances may have adverse health effects for people who consume insufficient amounts of nutrients. For instance, the levels of oxalic acid were below 0.04 g/100 g in the dried yellow mealworm larvae and below 0.01 g/100 g in the dried and ground formulations of the migratory locust and house crickets assessed. The phytic acid content had ranges between 1.0 and 2.5 g/kg in the dried forms of the insect species assessed, while the total polyphenol content (mg/kg gallic acid) ranged from 0.44 mg/kg gallic acid in the dried, frozen, and ground migratory locust to 1.04 mg/kg gallic acid in the frozen and dried yellow mealworm larvae. However, the levels of these substances in the insect species assessed by

⁷⁴EFSA (2017).

⁷⁵Jonathan et al. (2012) and Shantibala et al. (2014).

⁷⁶Nishimune et al. (2000).

⁷⁷Eguchi (1993).

⁷⁸EFSA Scientific Committee (2015).

EFSA are relatively low, being comparable to the occurrence levels of these compounds in other foodstuffs.⁷⁹

Toxicological Information

To date, the nutrient and microbiological profiles for a variety of insect species and products thereof intended for human consumption, as well as the occurrence level of contaminants, have been broadly investigated. Nonetheless, the existing evidence on genotoxicity, subchronic toxicity, and toxicokinetics is currently limited.

Such toxicological information contributes to the safety assessment of Novel Foods by EFSA. The strategy for the generation of toxicological data to support the safety of insects and products thereof as Novel Foods should be carefully considered, taking into account various aspects such as the compositional profile of the food under-assessment, and the history of use of the food/food ingredient *per se* and of its source.

EFSA proposes a tiered toxicity testing approach, which can also be applicable to insect-derived products.⁸⁰ It should be taken into consideration that insects and insect-derived ingredients are complex matrices that cannot be readily tested using the classic toxicity approaches. The scientific limitations and hurdles to be carefully considered and overcome are linked to the sensitivity and the selectivity of toxicological methods, as well as to practical issues such as the difficulty to administer toxicologically meaningful amounts of insects to test animals. For example, regarding genotoxicity, since insects are whole foods, it should be considered that the classic genotoxicity approaches are usually not easily applicable, and instead, genotoxicity testing on their fractions could be performed.

In the case of dried, frozen and powder forms of *T. molitor* larvae, toxicological data retrieved from the literature contributed to the risk assessment. The studies retrieved from the literature investigated subchronic toxicity,⁸¹ *in vitro* and *in vivo* genotoxicity, and subacute toxicity⁸² of lyophilised (freeze-dried) powder of the *T. molitor* larvae. The EFSA NDA Panel concluded that the testing material used in those studies could not be considered representative of novel foods from a processing point of view (differences in rearing, processing); nevertheless, the test item was considered representative of novel foods as far as the occurrence of endogenously produced compounds was concerned.

It has been reported⁸³ that *T. molitor* adults secrete benzoquinones, compounds with demonstrated toxic effects, as part of their defence mechanism.⁸⁴ Nevertheless,

⁷⁹Rao and Prabhavathi (1982), Gupta (1987), Holmes and Kennedy (2000), EFSA CONTAM Panel (2019) and Shantibala et al. (2014).

⁸⁰EFSA ANS Panel (2012), EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), et al. (2016) and EFSA Scientific Committee (2018).

⁸¹Han et al. (2016).

⁸²Han et al. (2014).

⁸³Ladisich et al. (1967), Attygalle et al. (1991) and Brown et al. (1992).

⁸⁴Wirtz and Fruin (1982) and Lis et al. (2011).

the secretion of these compounds has been reported only in *T. molitor* adults, and not in *T. molitor* larvae, i.e., the source of the novel foods assessed by EFSA. In *T. molitor* larvae, the excretion of β -carboline, as well as its precursor, the essential amino acid tryptophan, have been reported as part of their defence mechanisms.⁸⁵ The presence of β -carbolines has been reported in fruits, juices, and breakfast cereals. Considering the results of the toxicological studies, the described production process (i.e., that the larvae are reared separately from the adults), alongside the history of use, no safety concerns were raised from a toxicological point of view for these novel foods.

In the assessment of dried, frozen, and powder forms of *L. migratoria* adults, EFSA identified two studies providing additional toxicological information. Kwak et al. (2020)⁸⁶ performed a 28-day repeated-dose oral toxicity study with the powder of lyophilised *L. migratoria* as testing material whereas Ochiai et al. (2020)⁸⁷ conducted acute, subacute and subchronic oral toxicity studies using again powder of *L. migratoria*. The EFSA NDA Panel identified certain limitations in the two studies and used them only as supportive evidence towards the assessment of the toxic potential of the Novel Food. In the case of dried, frozen, and powder forms of *A. domesticus* adults, it was considered that the production of endogenously produced compounds as part of the defence mechanism of *A. domesticus* was not reported.

For the risk assessment of both the *A. domesticus* and *L. migratoria* forms, no further additional toxicological studies with the novel food as testing material were requested. This was due to the fact that no safety concerns arose from the compositional data of the Novel Foods and from the history of use of their source, i.e., *L. migratoria* adults and *A. domesticus* adults, as food in other parts of the world.

The absence of any history of safe use of the Novel Food *per se* and/or its source, and the nature and levels of compounds of possible toxicological concern, particularly in fractionated products such as insect-derived oils or insect protein preparations (e.g., hydrolysates, isolates, and concentrates), may trigger the need for additional toxicological studies. The effect of the production process on the chemical composition of the final products must be considered, alongside the insect species (physiology and developmental stage), the feed used, and the farming and processing methods. Regarding insects and products thereof as whole foods, if the need to perform an *in vivo* subchronic toxicity study cannot be ruled out based on the available body of evidence, further guidance is provided by EFSA on how to conduct such a study with a whole food as testing material.⁸⁸

⁸⁵ Kotanen et al. (2003).

⁸⁶ Kwak et al. (2020).

⁸⁷ Ochiai et al. (2020).

⁸⁸ EFSA Scientific Committee (2011).

Allergenicity

Insects belong to the Hexapoda (Insecta) class, a subphylum of Arthropoda. Tropomyosin, arginine kinase, and glutathione S-transferase are among the allergens reported within arthropods. Additionally, the enzymes that degrade chitin, i.e., chitinases, also have allergenic potential.⁸⁹ In its safety assessments of insects and products thereof as Novel Foods, the EFSA NDA Panel concluded that the consumption of such products may cause allergic reactions to individuals through sensitisation to insect proteins, as well as via cross-reactivity of insect protein in individuals allergic to crustaceans, molluscs, and dust mites. Moreover, allergens from the feed (e.g., soy, gluten) can end up in these Novel Foods, since insects are consumed alongside their intestinal tract. Additionally, it was noted that allergic reactions can occur in individuals via skin contact and/or inhalation (occupational exposure). The allergenicity potential of insects, including cross-reactivity to other allergens, should be further investigated, noting also that the current epidemiological evidence regarding allergic reactions induced due to insect consumption is limited.

3 Conclusions and Future Prospects

There is growing interest in insects as alternative food sources in Europe and other parts of the world, driven by factors including, among others, the sustainability of food production, interest in alternative protein sources, and new consumer trends.^{90,91,92} Since 2018, when the new Novel Food regulation came into force, an increasing number of applications regarding insects and products thereof has been noted through the centralization of the safety assessment process executed by EFSA. A multifaceted risk assessment of these products is needed to investigate their safe consumption before such products are put on the market. Recent EFSA outputs have not raised safety concerns regarding the consumption of insect-derived products under the proposed conditions of use.

When assessing the safety of insects and products thereof, several aspects need to be addressed related to farming, harvesting, and processing practices. The work carried out by EFSA on the risk assessment of insect-derived products as Novel Foods provides scientific input to the decision by risk managers (European Commission, Member States) on the market authorization of such products. Furthermore,

⁸⁹Paoletti et al. (2009).

⁹⁰For an analysis of these aspects, see also *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume; but also *Consumer Perceptions and Acceptance of Insects as Feed and Food: Current Findings and Future Outlook*, by G. Sogari, H. Dagevos, M. Amato, D. Taufik in this volume and *Why “New” Foods Are Safe and How They Can Be Assessed* by C. Dall’Asta in this volume.

⁹¹Boehm et al. (2021).

⁹²van Huis (2021).

EFSA's outputs can provide advice and raise awareness regarding the safety aspects to be considered during the production of similar foodstuffs for FBOs willing to market products. Moreover, aspects discussed in EFSA's outputs in the remit of edible insects can help consumers to make more informed dietary choices.

Disclaimer The authors Ermolaos Ververis, Domenico Azzollini, Fernando Rivero-Pino, Panagiota Zakidou, Andrea Germini are employed by EFSA in the Nutrition and Food Innovation Unit, provides scientific and administrative support to the Panel on Nutrition, Novel Foods and Food Allergens. However, the present work is published under the sole responsibility of the authors and may not be considered as an EFSA scientific output. The positions and opinions presented in this work are those of the authors alone and do not necessarily represent the views or scientific work of EFSA. To learn about the views or scientific outputs of EFSA, please consult its website at <http://www.efsa.europa.eu>.

Disclaimer The author Gabriela Precup is currently employed by Randstad (c/o EFSA) in the Nutrition and Food Innovation Unit that provides scientific and administrative support to the Panel on Nutrition, Novel Foods and Food Allergens in the area "Safety Assessment of Novel Foods." However, the present article is published under the sole responsibility of the authors and may not be considered as an EFSA scientific output. The positions and opinions presented in this article are those of the author/s alone and are not intended to represent the views/any official position or scientific works of EFSA. To know about the views or scientific outputs of EFSA, please consult its website at <http://efsa.europa.eu>.

Note to the reader The information provided in this chapter refers to the activities of EFSA in the area of insects and products thereof as novel foods up to February 2022. Any pertinent future risk assessment activities by EFSA will be available through the OpenEFSA portal at the following link: <https://open.efsa.europa.eu/>.

References

- Adámková A, Mlček J, Adámek M, Borkovcová M, Bednářová M, Hlobilová V, Knížková I, Juríková T (2020) *Tenebrio Molitor* (Coleoptera: Tenebrionidae)-optimization of rearing conditions to obtain desired nutritional values. *J Insect Sci* 20(5):24
- Attygalle AB, Blankespoor CL, Meinwald J, Eisner T (1991) Defensive secretion of *Tenebrio molitor* (Coleoptera:Tenebrionidae). *J Chem Ecol* 17:805–809
- Belluco S, Losasso C, Maggioletti M, Alonzi CC, Paoletti MG, Ricci A (2013) Edible insects in food safety and nutritional perspective. *Comprehensive Rev Food Sci Food Saf* 12:296–313
- Bodenheimer FS (1951) Insects as human food; A chapter of the ecology of man. Dr. W. Junk Publishers, The Hague
- Boehm E, Borzekowski D, Ververis E, Lohmann M, Gaby-Fleur B (2021) Communicating food risk-benefit assessments: edible insects as red meat replacers. *Front Nutr* 8:749696
- Brandon AM, Gao SH, Tian R, Ning D, Yang S, Zhou J, Wu W, Criddle CS (2018) Biodegradation of polyethylene and plastic mixtures in mealworms (Larvae of *Tenebrio Molitor*) and effects on the gut microbiome. *Environ Sci Technol* 52(11):6526–6533
- Brown WV, Doyen JT, Moore BP, Lawrence JF (1992) Chemical composition and taxonomic significance of defensive secretions of some Australian Tenebrionidae (Coleoptera). *Australian J Entomol* 31:79–89
- CAC (2015) Codex Alimentarius Commission Procedural Manual, 23rd edn
- Dzerefos CM, Witkowski ETF, Toms R (2013) Comparative ethnoentomology of edible stinkbug in Southern Africa and sustainable management considerations. *J Ethnobiol Ethnomed* 9:20

- EFSA (2010) Application of systematic review methodology to food and feed safety assessments to support decision making. *EFSA J* 8(6):1637
- EFSA (2017) Dietary reference values for nutrients summary report. *EFSA J* 12:e15121E
- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food) (2012) Guidance for submission for food additive evaluations. *EFSA J* 10(7):2760
- EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain) (2019) Evaluation of the health risks related to the presence of cyanogenic glycosides in foods other than raw apricot kernels. *EFSA J* 17(4):5662
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed) (2014) Guidance on the assessment of the toxigenic potential of *Bacillus* species used in animal nutrition. *EFSA J* 2(5):3665
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson JL, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArdle H, Naska A, Neuhäuser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Siani A, Sjödin A, Stern M, Tomé D, Vinceti M, Willatts P, Engel K-H, Marchelli R, Pöting A, Poulsen M, Salminen S, Schlatter J, Arcella D, Gelbmann W, de Sesmaisons-Lecarre A, Verhagen H, van Loveren H (2016) Guidance on the preparation and presentation of an application for authorization of a novel food in the context of regulation (EU) 2015/2283. *EFSA J* 14(11):e04594
- EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Kearney J, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Prieto Maradona M, Schlatter JR, van Loveren H, Ververis E, Knutsen HK (2021) Scientific Opinion on the Safety of Dried Yellow Mealworm (*Tenebrio Molitor* Larva) as a Novel Food Pursuant to Regulation (EU) 2015/2283. *EFSA J* 19(1):6343
- EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Bohn T, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Prieto Maradona M, Schlatter JR, van Loveren H, Ververis E, Knutsen HK (2021a) Scientific opinion on the safety of frozen and dried formulations from whole Yellow Mealworm (*Tenebrio Molitor* Larva) as a novel food pursuant to regulation (EU)2015/2283. *EFSA J* 19(8):6778
- EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Kearney J, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Maradona MP, Schlatter JR, van Loveren H, Azzollini D, Knutsen HK (2021b) Scientific opinion on the safety of frozen and dried formulations from migratory locust (*Locusta Migratoria*) as a novel food pursuant to regulation (EU) 2015/2283. *EFSA J* 19(7):6667
- EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Bohn T, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Prieto Maradona M, Schlatter JR, van Loveren H, Goumperis T, Knutsen HK (2021c) Scientific opinion on the safety of frozen and dried formulations from whole house crickets (*Acheta Domesticus*) as a novel food pursuant to regulation (EU) 2015/2283. *EFSA J* 19(8):6779
- EFSA Scientific Committee (2011) Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. *EFSA J* 9(12):2438
- EFSA Scientific Committee (2015) Risk profile related to production and consumption of insects as food and feed. *EFSA J* 13(10):4257
- EFSA Scientific Committee (2018) The principles and methods behind EFSA's guidance on uncertainty analysis in scientific assessment. *EFSA J* 16(1):e05122
- Eguchi M (1993) Protein protease inhibitors in insects and comparison with mammalian inhibitors. *Comp Biochem Physiol Part B Comp Biochem* 105:449–456

- FAO (2013) Dietary protein quality evaluation in human nutrition: report of an FAO expert consultation, 31 March–2 April, 2011, Auckland, New Zealand, <https://www.fao.org/documents/card/fr/c/ab5c9fca-dd15-58e0-93a8-d71e028c8282/>. Accessed 15 Feb 2022
- FAO (2019) High Level Expert Forum - How to Feed the World in 2050 Office of the Director, Agricultural Development Economics Division Economic and Social Development Department, <https://www.fao.org/wsfs/forum2050/wsfs-background-documents/hlef-issues-briefs/en/>. Accessed 15 Feb 2022
- FAO (2021) Looking at edible insects from a food safety perspective. Challenges and Opportunities for the Sector, <https://www.fao.org/policy-support/tools-and-publications/resources-details/es/c/1394684/>. Accessed 15 Feb 2022
- FAO, WHO (1997) Risk Management and Food Safety. Report of a Joint FAO/ WHO Consultation, Rome, 27–31 January 1997. FAO Food and Nutrition Paper 65, <http://www.fao.org/docrep/W4982E/w4982e00.HTM>. Accessed 15 Feb 2022
- FAO, WHO (2008) Food and Agriculture Organization of the United Nations/World Health Organization exposure assessment of microbiological hazards in foods: guidelines. Microbiological Risk Assessment Series 7:1–92
- Goumperis T (2019) Insects as food: risk assessment and their future perspective in Europe. In: Sogari G, Mora C, Menozzi D (eds) Edible insects in the food sector. Springer, Cham, pp 1–9
- Guiné RP, Correia P, Coelho C, Costa CA (2021) The role of edible insects to mitigate challenges for sustainability. *Open Agric* 6(1):24–36
- Gupta YP (1987) Antinutritional and toxic factors in food legumes: a review. *Plant Foods Human Nutr* 37:201–228
- Han SR, Yun EY, Kim JY, Hwang JS, Jeong EJ, Moon KS (2014) Evaluation of genotoxicity and 28-day oral dose toxicity on freeze-dried powder of *Tenebrio Molitor* Larvae (Yellow Mealworm). *Toxicol Res* 30(2):121–130
- Han SR, Lee BS, Jung KJ, Moon KS (2016) Safety assessment of freeze-dried powdered *Tenebrio Molitor* Larvae (Yellow Mealworm) as novel food source: evaluation of 90-day toxicity in Sprague-Dawley Rats. *Regul Toxicol Pharmacol* 77:206–212
- Holmes RP, Kennedy M (2000) Estimation of the oxalate content of foods and daily oxalate intake. *Kidney Int* 57:1662–1667
- Huis AV, Itterbeek JV, Klunder H, Mertens E, Halloran A, Muir G, Vantomme P (2013) Edible insects: future prospects for food and feed security. FAO Forestry Paper 171:1–187
- Janssen RH, Lakemond CM, Fogliano V, Vincken JP (2017) Involvement of phenoloxidase in browning during grinding of *Tenebrio Molitor* Larvae. *PLoS ONE* 13(1):e0189685
- Jensen LD, Miklos R, Dalsgaard TK, Heckmann LH, Nørgaard JV (2019) Nutritional evaluation of common (*Tenebrio molitor*) and lesser (*Alphitobius diaperinus*) mealworms in rats and processing effect on the lesser mealworm. *J Insects Food Feed* 5:257–266
- Jonathan SG, Popoola KOK, Olawuyi OJ, Oyelakan AO (2012) Insect and fungal pests of some mushrooms collected from University of Ibadan, Nigeria Campus. *Nat Sci* 10(9):142147
- Jongema Y (2017) List of edible insect species of the World. Laboratory of Entomology. Wageningen University Press, Wageningen, <https://www.wur.nl/en/Research-Results/Chair-groups/Plant-Sciences/Laboratory-of-Entomology/Edibleinsects/Worldwide-species-list.htm>. Accessed 15 Feb 2022
- Kooh P, Ververis E, Tesson V, Boué G, Federighi M (2019) Entomophagy and public health: a review of microbiological hazards. *Health* 11(10):1272–1290
- Kooh P, Jury V, Laurent S, Audiat-Perrin F, Sanaa M, Tesson V, Federighi M, Boué G (2020) Control of biological hazards in insect processing: application of HACCP method for Yellow Mealworm (*Tenebrio Molitor*) powders. *Foods* 9(11):1528
- Kotanen S, Huybrechts J, Cerstiaens A, Schoofs L (2003) Identification of Tryptophan and B-carboline as paralytins in Larvae of the Yellow Mealworm, *Tenebrio Molitor*. *Biochem Biophys Res Commun* 310:64–71
- Kouřimská L, Adámková A (2016) Nutritional and sensory quality of edible insects. *NFS J* 4:22–26
- Kwak KW, Kim SY, An KS, Kim YS, Park K, Kim E, Hwang JS, Kim MA, Ryu HY, Yoon HJ (2020) Subacute oral toxicity evaluation of freeze-dried powder of *Locusta Migratoria*. *Food Sci Animal Resour* 40(5):795–812

- Ladisch RK, Ladisch SK, Howe PM (1967) Quinoid secretions in grain and flour beetles. *Nature* 215:213–219
- Lähteenmäki-Uutela A, Marimuthu SB, Meijer N (2021) Regulations on insects as food and feed: a global comparison. *J Insects Food Feed* 7(5):849–856
- Lange KW, Nakamura Y (2021) Edible insects as future food: chances and challenges. *J Future Foods* 1:38–46
- Lis L, Bakula T, Baranowski M, Czarnewicz A (2011) The carcinogenic effects of benzoquinones produced by the flour beetle. *Polish J Veterinary Sci* 14(1):159–164
- Mitsuhashi J (2016) Edible insects of the World. CRC Press, London
- Mitsuhashi J, Capinera JL (2008) Entomophagy: human consumption of insects. In: *Encyclopedia of entomology*. Springer, Heidelberg, pp 1341–1343
- Nappi AJ, Christensen BM (2005) Melanogenesis and associated cytotoxic reactions: applications to insect innate immunity. *Insect Biochem Mol Biol* 35(5):443–459
- Nappi AJ, Ottaviani E (2000) Cytotoxicity and cytotoxic molecules in invertebrates. *BioEssays* 22: 469–480
- Nappi AJ, Vass E (1993) Melanogenesis and the generation of cytotoxic molecules during insect cellular immune-reactions. *Pigment Cell Res* 6:117–126
- Nishimune T, Watanabe Y, Okazaki H, Akai H (2000) Thiamin is decomposed due to *Anophe* Spp. entomophagy in seasonal ataxia patients in Nigeria. *J Nutr* 130:1625–1628
- Ochiai M, Inada M, Horiguchi S (2020) Nutritional and safety evaluation of locust (*Caelifera*) powder as a novel food material. *J Food Sci* 85(2):279–288
- OECD/FAO (2021) OECD-FAO Agricultural Outlook, OECD Agriculture statistics (Database), https://www.oecd-ilibrary.org/agriculture-and-food/data/oecd-agriculture-statistics_agr-data-en. Accessed 15 Feb 2022
- Oibiokpa FI, Akanya HO, Jigam AA, Saidu AN, Egwim EC (2018) Protein quality of four indigenous edible insect species in Nigeria. *Food Sci Human Wellness* 7(2):175–183
- Ooninx DG, van der Poel AF (2011) Effects of diet on the chemical composition of migratory locusts (*Locusta migratoria*). *Zoo Biol* 30(1):9–16
- Ooninx DG, Van Broekhoven S, Van Huis A, van Loon JJ (2015) Feed conversion, survival and development, and composition of four insect species on diets composed of food by-products. *PLoS One* 14(10):e0222043
- Ooninx DG, van Broekhoven S, van Huis A, van Loon JJ (2019) Correction: feed conversion, survival and development, and composition of four insect species on diets composed of food by-products. *PLoS One* 14(10):e0222043
- Ooninx DG, Laurent S, Veenbos ME, van Loon JJ (2020) Dietary enrichment of edible insects with Omega 3 fatty acids. *Insect Sci* 27(3):500–509
- Paoletti MG, Norberto L, Cozzarini E, Musumeci S (2009) Role of Chitinases in human stomach for chitin digestion: AMCCase in the gastric digestion of chitin and chit in gastric pathologies. *Ann Nutr Metab* 51:244–251
- Pastell H, Mellberg S, Ritvanen T, Raatikainen M, Mykkanen S, Niemi J, Latomaki I, Wirtanen G (2021) How does locally produced feed affect the chemical composition of reared house crickets (*Acheta Domesticus*)? *ACS Food Sci Technol* 1(4):625–635
- Rao BSN, Prabhavathi T (1982) Tannin content of foods commonly consumed in India and its influence on ionisable iron. *J Sci Food Agriculture* 33:89–96
- Rovai D, Orgies M, Amin S, Kuwahara S, Schwartz G, Lesniauskas R, Garza K, Lammert A (2021) Utilization of carrot pomace to grow mealworm larvae (*Tenebrio Molitor*). *Sustainability* 13(16):9341
- Rumpold BA, Schlüter OK (2013a) Potential and challenges of insects as an innovative source for food and feed production. *Innov Food Sci Emerging Technol* 17:1–11
- Rumpold BA, Schlüter OK (2013b) Nutritional composition and safety aspects of edible insects. *Mol Nutr Food Res* 57:802–823
- Schaafsma G (2000) The protein digestibility–corrected amino acid score. *J Nutr* 130:1865–1867
- Shantibala T, Lokeshwari RK, Debaraj H (2014) Nutritional and antinutritional composition of the five species of aquatic edible insects consumed in Manipur, India. *J Insect Sci* 14:14

- Shen R (2014) China regulations on new food raw materials, <https://food.chemlinked.com/foodpedia/china-regulations-new-food-raw-materials>. Accessed 15 Feb 2022
- Suárez ML, Kizlansky A, Lopez LB (2006) Assessment of protein quality in foods by calculating the amino acids score corrected by digestibility. *Nutr Hosp* 21:47–51
- Sugumaran M, Nellaiappan K, Valivittan K (2000) A new mechanism for the control of phenoloxidase activity: inhibition and complex formation with quinone isomerase. *Archiv Biochem Biophys* 379:252–260
- Ulrich RG, Buthala DA, Klug MJ (1981) Microbiota associated with the gastrointestinal tract of the common house cricket, *Acheta Domestica*. *Appl Environ Microbiol* 41(1):246–254
- van der Fels-Klerx HJ, Camenzuli L, van der Lee MK, Oonincx DGAB (2016) Uptake of Cadmium, Lead and Arsenic by *Tenebrio Molitor* and *Hermetia Illucens* from contaminated substrates. *PLoS ONE* 11(11):e0166186
- van Huis A (2021) Prospects of insects as food and feed. *Org Agric* 11(2):301–308
- Van Itterbeeck J, Pelozuelo L (2022) How many edible insect species are there? A not so simple question. *Diversity* 14(2):143
- Ververis E, Ackerl R, Azzollini D, Colombo PA, de Sesmaisons A, Dumas C, Fernandez-Dumont-A, Ferreira da Costa L, Germini A, Goumperis T, Kouloura E, Matijevec L, Precup G, Roldan-Torres R, Rossi A, Svejtil R, Turla E, Gelbmann W (2020) Novel foods in the European Union: scientific requirements and challenges of the risk assessment process by the European Food Safety Authority. *Food Res Int* 137:109515
- Vigneron A, Masson F, Vallier A, Heddi A (2014) Insects recycle endosymbionts when the benefit is over. *Curr Biol* 24:2267–2273
- WHO (2008) Principles and methods for the risk assessment of chemicals in food. A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization, <https://www.who.int/publications/i/item/9789241572408>. Accessed 15 Feb 2022
- WHO Food Standards Programme Codex Alimentarius Commission (CAC) (1999) Principles and guidelines for the conduct of microbiological risk assessment, *cac/gl-30*
- Wirtz RA, Fruin JT (1982) Mutagenicity of tenebrionid flour beetle secretions using drosophila melanogaster sex-linked recessive lethal test. *J Food Protect* 45:1084–1086
- Yang SS, Wu WM, Brandon AM, Criddle CS (2018) Ubiquity of polystyrene digestion and biodegradation within yellow mealworms, Larvae of *Tenebrio Molitor* Linnaeus (Coleoptera: Tenebrionidae). *Chemosphere* 212:262–271

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



Consumer Perceptions and Acceptance of Insects As Feed and Food: Current Findings and Future Outlook



Giovanni Sogari, Hans Dagevos, Mario Amato, and Danny Taufik

Abstract In recent years, the use of insects as food and feed has gained widespread attention from industry, policy makers, the scientific community, and the general public globally. This chapter is devoted to providing insights on the current state-of-the-art around edible insects and the interlinkages among market, legislation and consumer acceptance. Future research developments are also explored.

Keywords Entomophagy · Neophobia · Novel foods · Behaviour · Legislation

1 Introduction

It is widely recognized that the Food and Agriculture Organisation (FAO) report “Edible insects: future prospects for food and feed security”¹ was a landmark publication in the field of human consumption of insects (i.e., entomophagy). Much has changed in the past decade, particularly concerning the production and introduction of edible insects in parts of the (Western) world where insect eating was

¹ van Huis et al. (2013).

G. Sogari (✉)

University of Parma, Department of Food and Drug, Parma, Italy

e-mail: giovanni.sogari@unipr.it

H. Dagevos

Wageningen University and Research, Wageningen Economic Research, The Hague, The Netherlands

e-mail: hans.dagevos@wur.nl

M. Amato

University of Naples Federico II, Department of Political Science, Naples, Italy

e-mail: mario.amato@unina.it

D. Taufik

Wageningen University and Research, Wageningen Economic Research, Wageningen, The Netherlands

e-mail: danny.taufil@wur.nl

not previously part of the food system and food consumption pattern. Surely, developments are still in their infancy, but it is unmistakably true that in recent years the use of insects as food and feed has gained increasing attention from industry, policy makers, and the scientific community.² In the European Union, there has been growing interest and financial investment in this sector from multiple small companies, start-ups, and entrepreneurs.³ The development of this emerging sector in Europe is also favoured by many research teams who are actively involved in projects related to edible insects across a wide range of disciplines ranging from food safety microbiology, farming, and food processing to social, psychological and economic expertise.⁴ Moreover, in the European Union the regulatory framework shaped by Novel Food authorization and ‘feed ban rules’⁵ controlling the use of insect processed animal proteins (PAPs), has strongly influenced the dynamics of the insect sector.⁶

Indeed, in the European context, the introduction of insects on the food market is a novelty and has a particular profile in terms of both regulation and the motivations behind consumption. Food safety guarantees (Sect. 2) are needed, given the focus on the establishment of a structured insect indoor farming sector (Sect. 3) (as opposed to the harvesting of insects in the natural environment). Likewise, insect consumption in Europe will not be motivated by food scarcity or nutritional deficiencies endangering food security. Instead, health and sustainability issues will likely drive efforts to overcome European consumers’ reluctance to eat insects (Sect. 4). In fact, today’s policymakers, scholars, and practitioners in ‘minilivestock’ farming as a complement to conventional livestock farming are motivated by just these issues. At a time when Sustainable Development Goals (SDGs) and the evolution of a circular economy (CE) are valued notions, the growth of the insect sector and the promotion of insect consumption fit perfectly to contribute to both SDGs and CE as well as boost the popularity of both concepts in the near future.⁷

This chapter covers recent regulatory milestones at the European level linked to Novel Food approvals from 2021 and the development of the insect industry both as food and feed, including various agri-food stakeholder activities (Sect. 2). Sections 3 and 4 of the chapter focus on the state of the art in terms of consumer acceptance of animals fed with insects (insects as feed) and consumer acceptance of edible insects and insect-based foods (insects as food), respectively. Finally, Sect. 5 offers discussion and conclusions, providing linkages between the production and consumption of edible insects, as well as future research developments.

²Payne et al. (2019) and Pippinato et al. (2020).

³Derrien and Boccuni (2018) and Montanari et al. (2021b).

⁴Payne et al. (2019) and Sogari et al. (2019c).

⁵Regulation (EC) 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

⁶Lotta (2019).

⁷Moruzzo et al. (2021b) and Sogari et al. (2019a).

2 Market of Insects As Food and Feed

2.1 EU Market of Insects As Food

According to the current Novel Food Regulation, after a positive assessment on safety from EFSA, the European Commission (EC) can decide whether to authorise the commercialization of a Novel Food.⁸ In this context, the first authorisation regarding insects-as-food—notably included in the Novel Foods definition—was approved in June 2021 for the dried *Tenebrio molitor* larva to be used as a whole, dried insect in the form of snacks, and as a food ingredient in several food products (applicant SAS Agronutris EAP). Then, in November 2021, the frozen and dried migratory locust *Locusta migratoria* (applicant Fair Insects B.V.) was authorised. Finally, in December 2021, the EU Standing Committee on Plants, Animals, Food and Feed voted favourably on the frozen and dried formulations from the whole yellow mealworm (*Tenebrio molitor*), and frozen and dried formulations from the whole house cricket (*Acheta domestica*) (applicant Fair Insects B.V.).⁹ Once authorised, insect-based products are subject to specific labelling requirements, including mandatory labelling specifications (e.g., allergen labelling, among others).¹⁰

Even if still limited, insect farming is an emerging and growing industry in the European Union (EU)¹¹ with currently around 70 companies operating in the sector of insects for human consumption.¹² This niche market is supported by a generally positive media coverage and changing dietary habits towards a more sustainable and balanced diet with varied protein sources.¹³ For instance, recently there has been an increase in demand for high protein food for sports nutrition, dietetic food, and food supplements to improve physical performance.¹⁴ This trend is likely to create opportunities for insect-based food such as protein pasta, energy or protein bars, as well as more mainstream snacks (e.g., chips) with varying percentages of insect powder.¹⁵ In fact, insects are highly versatile and can be incorporated in familiar

⁸For a detailed analysis on Novel Foods Regulation in the European Union, see in particular *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective* by A. Volpato, *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* by L. Scaffardi and *Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the CJEU* by G. Formici in this volume.

⁹Mancini et al. (2022).

¹⁰IPIFF (2020a).

¹¹Montanari et al. (2021b).

¹²IPIFF (2020b).

¹³Pippinato et al. (2020).

¹⁴Placentino et al. (2021).

¹⁵Pippinato et al. (2020).

foods, granular powders, or extracts to increase nutritional value or functionality,¹⁶ reducing the risk of consumer rejection as compared to attitudes towards eating whole insects.¹⁷

The International Platform of Insects for Food and Feed (IPIFF)¹⁸ estimates that in the EU by 2025 the category of speciality food ingredients (e.g., sports nutrition, food supplements) will represent the highest market share, followed by snacks and bars. Moreover, paleo diet-specific food products, functional food, baked products, and meat-like products will also experience a growth in terms of market share.¹⁹ Currently the main distribution channel is e-commerce,²⁰ but it is likely that in the coming years these insect products will be also available in brick-and-mortar retail stores.

The IPIFF forecasted that by 2030, the insect European Food Business Operators' (iFBOs) will produce about 260,000 tonnes of insect-based products, including whole insects, insect ingredients and products with incorporated edible insects (pasta, snacks, bars, etc.).

Most of the iFBOs in Europe, which are largely comprised of start-ups and small companies,²¹ are only involved in the final processing of insects for food and producing final products (e.g., burgers, snacks, bars, biscuits, etc.), followed by those involved in all the stages of production, including insect farming.²² According to a recent study including the EU producers of edible insects for food,²³ the most common farmed species in the EU are the yellow mealworm (*Tenebrio molitor*), the house cricket (*Acheta domesticus*), the 'grasshopper' (*Locusta migratoria*), and the 'buffalo worm' (*Alphitobius diaperinus*). These four species were named by House²⁴ as the Big Four and have been selected based on their characteristics (e.g., high protein and fat content) and as the result of several technical and practical decisions (e.g., quite easy to rear) (Fig. 1).²⁵

¹⁶IPIFF (2020b). On this point, see also *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume.

¹⁷Sogari et al. (2018).

¹⁸The International Platform of Insects for Food and Feed (IPIFF) is a non-profit organisation which represents the interests of the insect production sector towards EU policymakers, European stakeholders, and citizens. Composed of 83 members, most of which are European insect producing companies, IPIFF promotes the use of insects and insect-derived products as top tier sources of nutrients for human consumption and animal feed (<https://ipiff.org/>).

¹⁹IPIFF (2020a).

²⁰Pippinato et al. (2020).

²¹Derrien and Boccuni (2018).

²²IPIFF (2020b).

²³Pippinato et al. (2020).

²⁴House (2018).

²⁵Pippinato et al. (2020).

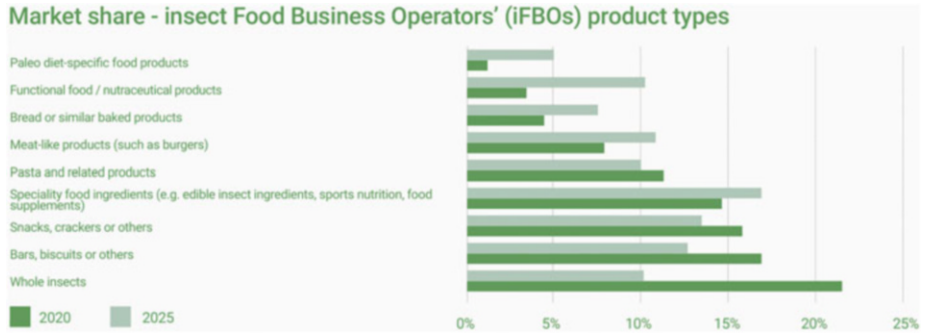


Fig. 1 Market share—insect Food Business Operators' (iFBOs) product types. Source: IPIFF 2020b, <https://ipiff.org/wp-content/uploads/2020/06/10-06-2020-IPIFF-edible-insects-market-factsheet.pdf>

2.2 EU Market of Insects As Feed

The sector for insects as feed for animal nutrition is much more advanced and mature compared to food applications.²⁶ This can be explained by several reasons, mainly attributable to a more liberal legal framework as well as an urgent call to address the environmental issues of animal farming.

In the context of the EU's deficiency in the supply of high protein animal feed ingredients (e.g., soya bean meals)²⁷ alongside the relative high dependency on imported animal feed, the use of insects as feed could represent a valid and sustainable solution. First, insects reared for food and feed production fall within the category of 'farmed animals' according to Regulation (EC) No 1069/2009.²⁸ Thus, insects are subject to EU rules which regulate the feeding of livestock, including the general principle enshrined in Article 4, para 1, lett. a) of Regulation (EC) 767/2009 whereby animals can be reared on substrates of vegetable origin or specifically allowed materials of animal origin such as fishmeal and hydrolysed proteins from non-ruminants.²⁹

²⁶Montanari et al. (2021a).

²⁷European Union (2021).

²⁸Regulation (EC) 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).

²⁹Lähteenmäki-Uutela et al. (2021) and Montanari et al. (2021a).

One of the first and most critical changes was EU Regulation 2017/893³⁰ which partially uplifted the ‘feed ban rules’ (Regulations (EC) 999/2001)³¹ regarding the use of insect-processed animal proteins (PAPs) for aquaculture animals.³² In terms of species, Regulation (EU) 2017/893 allows the feeding of seven insects: black soldier fly (*H. illucens*), common housefly (*Musca domestica*), yellow mealworm (*T. molitor*), lesser mealworm (*A. diaperinus*), house cricket (*A. domesticus*), banded cricket (*G. sigillatus*) and field cricket (*Gryllus assimilis*).

In 2021, a new Regulation on the use of insect processed animal proteins (PAPs) for animals entered into force (Commission Regulation 2021/1372)³³ allowing the use of PAPs in poultry and pig nutrition.³⁴ The production of insect PAPs for feed was several thousand tonnes in 2020, and by the year 2030 this sector is expected to reach a total turnover of circa two billion euros/year.³⁵ For instance, according to the IPIFF forecasts,³⁶ more than 10% of the fish consumed in the EU will be derived from fish farms that use insect protein in their aqua feed formulations. Currently, the aquafeed sector is the most relevant animal feed market for the producers of insects as feed.³⁷ However, according to these IPIFF forecasts, it is likely that in the coming years with the new Regulation 2021/1372 the quantities of insect meal sold for the poultry and pig markets will experience a strong increase, especially in the context of certain niche markets (e.g., free-range poultry, organic production, etc.). In terms of feed, the black soldier fly is currently the most farmed insect species.³⁸

The aim of this chapter is mainly to focus on the market, legislation, and consumer acceptance of the use of insects as feed and food; however, currently other insect applications are also possible, such as the use of frozen or dried insects as pet food (e.g., dogs and cats) (Figs. 2 and 3).³⁹

³⁰Regulation (EU) 2017/893 amending Annexes I and IV to Regulation (EC) No. 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein.

³¹Regulation (EC) 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

³²Lähtenmäki-Uutela et al. (2021) and Sogari et al. (2019a).

³³Regulation (EU) 2021/1372 of 17 August 2021 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals.

³⁴Mancini et al. (2022).

³⁵IPIFF (2021).

³⁶*Ibidem*.

³⁷*Ibidem*.

³⁸Montanari et al. (2021b).

³⁹IPIFF (2020b).

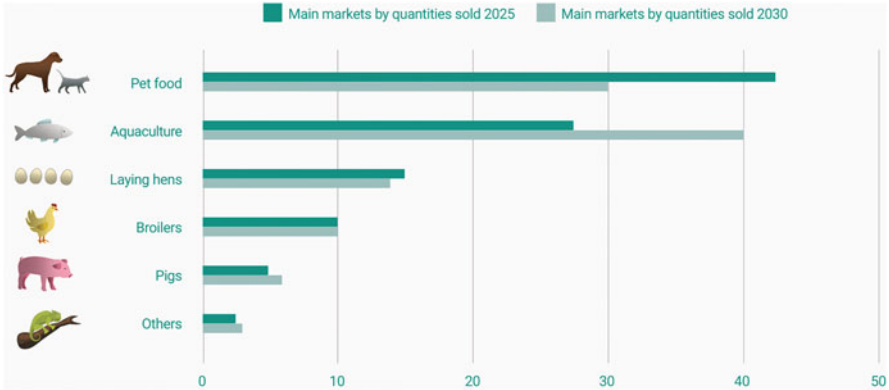


Fig. 2 European market of insects as feed. Source: IPIFF 2021, https://ipiff.org/wp-content/uploads/2021/04/Apr-27-2021-IPIFF_The-European-market-of-insects-as-feed.pdf

Insects as feed- Regulation (EU No 68/2013 on the Catalogue of feed materials and in accordance with Regulation (EC) No 999/2001 and Regulation (EC) No 1069/2009	Ruminant animals	Aquaculture	Poultry	Pigs	Pets	Fur and other animals (e.g. zoo)	Technical uses (e.g. cosmetic industry, bio-based fuels, production of other bio-based materials such as bioplastics)
Insect proteins (under entry 9.4.1. 'Processed animal protein')	⊗	⊙**	⊙**	⊙**	⊙	⊙	⊙
Insect fats (under entry 9.2.1 'animal fat')	⊙	⊙	⊙	⊙	⊙	⊙	⊙
Whole insects (untreated) (under entry 9.16.2. 'terrestrial invertebrates, dead')	⊗	⊗	⊗	⊗	⊗	⊙*	⊙
Whole insects (treated- e.g. freeze-drying) (under entry 9.16.2. 'terrestrial invertebrates, dead')	⊗	⊗	⊗	⊗	⊙*	⊙*	⊙
Live insects (under entry 9.16.1 'terrestrial invertebrates, live')	⊗	⊙*	⊙*	⊙*	⊙*	⊙*	⊙
Hydrolysed insect proteins (under entry 9.6.1. 'Hydrolysed animal proteins')	⊙	⊙	⊙	⊙	⊙	⊙	⊙

Fig. 3 EU Regulatory possibilities for insects’ use in animal feed. Source: IPIFF 2022 (p. 25), <https://ipiff.org/wp-content/uploads/2019/12/IPIFF-Guide-on-Good-Hygiene-Practices.pdf>

3 Consumer Acceptance of Edible Insects As Feed

3.1 Insects As Feed, Making Their Way

With a dramatically growing world population, the need to meet increasing nutritional needs is a topic of interest to policymakers and academics alike. In order to accommodate the expanding needs of animal-sourced food, the EU relies on imports

of protein-rich animal feeds, especially soybean. Soybeans account for two-thirds of the world's total protein feed production.⁴⁰ Their dietary value is unsurpassed by any other plant protein source and is the standard to which other protein sources are compared.⁴¹ Although soybean cultivation has an exceptional protein yield per hectare, its production is often associated with environmentally harmful practices,⁴² its predominant use as feed is economically inefficient compared to direct human consumption. Considering the EU's Farm to Fork strategy (F2F) where domestic protein feed production is encouraged, import dependence is overcome, and demand for land in deforestation-prone regions is reduced, various alternative protein feeds have been investigated, including insects. Insect species currently farmed and involved in commercial development share short life cycles, have high feed conversion rates, and can grow at high densities on low-value wastes.⁴³ In addition, insect amino acid profiles are suitable for monogastric animals and fish, different from soybean meals, which often require supplementation when used in feed for monogastric animals.⁴⁴ Lastly, insects can be reared easily at an economically and environmentally sustainable cost.⁴⁵

In contrast to the many studies that make up the literature on the acceptability of insects as food, the number of studies related to consumer preference for insects as feed is distinctly limited. This is probably because the feed used for breeding is not clearly shown on the label, and therefore consumers cannot identify the type of feed when purchasing products. Yet, many companies could use new label information as a tool to differentiate from competitors, making the product stand out. The European Union approved the use of insects in aquaculture with Commission Regulation (EU) 2017/893,⁴⁶ consequently most studies on consumer preferences have focused on insect-fed fish. Nevertheless, some pioneering studies have investigated consumer preferences regarding other types of meat raised with insects, specifically pork and chicken, in the light of possible changes in European Union legislation which has recently allowed their use through Commission Regulation (EU) 2021/1372. One of the key topics related to introducing a process innovation, such as the use of alternative feeds for insect-based animal husbandry, is consumer acceptance, and what communication and positioning drivers might be used to facilitate success. Considering that both (direct entomophagy) and the use of insects as feed (indirect entomophagy) are traditions and uses far removed from the European citizen, the

⁴⁰Oil World (2015).

⁴¹Cromwell (1999).

⁴²Nordborg et al. (2014).

⁴³Nordborg et al. (2014).

⁴⁴Parolini et al. (2020).

⁴⁵On this point, see also *Food (In)Security: The Role of Novel Foods on Sustainability* by S. Sforza in this volume.

⁴⁶Regulation (EU) 2017/893 amending Annexes I and IV to Regulation (EC) No. 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein.

number of studies assessing consumer acceptability of entomophagy practices is flourishing in this geographic area. Section 3.2 illustrates this with respect to indirect entomophagy while Sect. 4.1 does so with respect to direct entomophagy.

3.2 *Emerging Consumer Studies on Insects As Feed*

In order to investigate consumer and market reactions and acceptance, which are crucial in determining the success of the use of insect-based feeds for different species, the EU-funded research project PROteINSECT questioned over 2400 respondents worldwide about their preferences towards the use of insects as feed. More than 70% of participants found insects as feed for farmed animals to be acceptable and stated that they would eat pork, poultry, and fish reared in this way. Respondents also manifested their willingness to receive more information on the topic, while perceiving insects as feed as no to low risk for human health.⁴⁷ A substantial lack of knowledge on feed and its environmental impact in general, and insect feed in particular, has been also outlined by Weinrich and Busch⁴⁸ and Popoff et al.⁴⁹ In the former study, a survey of 618 German consumers revealed that, despite little general knowledge of the subject, a better perceived environmental impact of feeding insects might lead to an improved attitude towards market introduction of poultry products fed with insects.⁵⁰ In addition to lack of awareness, Popoff et al. evidenced other factors involved in the decision-making process, independently of the type of feed used. Most respondents (75%) stated that the use of insect feed would not influence their willingness to purchase, and only 10% expressed opposition to eating Scottish salmon reared with insects.

Through the use of informed and uninformed choice experiments, Bazoche and Poret⁵¹ examined consumer preferences toward fillets of smoked trout raised with or without insects. Although a small proportion of participants (15.3%) showed distaste for this type of insect-reared fish, 60% of the sample agreed it “followed the natural order of things.” This study, conducted in France, also shows that providing information to consumers about the environmental impact differences between the conventional use of fishmeal and insects significantly influences consumer choice. Furthermore, it has been highlighted how important it is to position the product adequately within the market. Regardless of the experimental condition, when the price of conventional trout was higher than trout reared with insects, the former was preferred. Conversely, 73% of consumers in the informed condition chose insect-reared trout if the price was lower than conventionally reared trout. Similarly,

⁴⁷ PROteINSECT (2016).

⁴⁸ Weinrich and Busch (2021).

⁴⁹ Popoff et al. (2017).

⁵⁰ Weinrich and Busch (2021).

⁵¹ Bazoche and Poret (2020).

Ankamah-Yeboah et al.⁵² showed that German consumers were likely to purchase insect-farmed fish if the price was affordable. Using an online questionnaire, it was found that although most of the sample was indifferent towards the type of feed used, 23% showed an unfavourable attitude towards the use of insects in aquaculture.

At the same time, some results indicate that consumption would rise if price were reduced, or convenience aspects were improved. In accordance with previous results, Altmann et al.⁵³ found that a sub-set of their sample will not accept chicken-breast produced with insect-meals unless at largely discounted prices. Ferrer Llagostera et al.⁵⁴ found that in Spain there is a higher willingness to pay (WTP) for fish fed with insect protein or vegetable matter over those fed with conventional fish meal (11.89 and 17.20 euros/kg respectively), nevertheless, the taste expectation for fish reared with insects is still low. In a similar fashion, Giotis and Drichoutis⁵⁵ estimated Greek consumers' willingness to pay for a gilt head bream fed with insects. Their results show that 84% of the respondents were willing to accept insects as animal feed and 55.5% of the sample would pay a premium. Differently from the previous studies, in a study involving 565 Italian consumers investigating the role of information on consumers' attitudes and intention to eat insect-fed ducks, Menozzi et al.⁵⁶ found that most of the respondents would pay the same average price for both a duck fed with insect meal and a conventionally fed duck. Thus, it can be concluded that results are quite mixed. Alternative feeds such as insect meals can be used as long as prices remain lower than or similar to conventional products. However, Ankamah-Yeboah et al.⁵⁷ also found a negative interaction effect between a certified production method and using insect protein as feed, which suggests that the type of feed does not affect the WTP if the product lacks a trusted certification. Interestingly, in a study by Spartano and Grasso⁵⁸ it was found that in a sample of United Kingdom (UK) consumers, those who had a previous tasting experience of edible insects as food have higher WTP for eggs from insect-fed hen than those who did not. Similarly, Sogari et al.⁵⁹ also found that other variables such as interest in environmental issues and positive attitude towards animal welfare influence WTP for meat products from animals fed with insects.

The studies reported so far seem to agree that the attitudes of European consumers towards the use of insects as feed are generally positive and acceptance is high, as has also been pointed out by Mancuso et al.,⁶⁰ who evidenced that 90% of all consumers interviewed had a positive attitude towards insects as feed. However,

⁵²Ankamah-Yeboah et al. (2018).

⁵³Altmann et al. (2022).

⁵⁴Ferrer Llagostera et al. (2019).

⁵⁵Giotis and Drichoutis (2021).

⁵⁶Menozzi et al. (2021).

⁵⁷Ankamah-Yeboah et al. (2018).

⁵⁸Spartano and Grasso (2021).

⁵⁹Sogari et al. (2022).

⁶⁰Mancuso et al. (2016).

Mancuso et al. work also highlighted the existence of a behavioural gap, i.e., despite the generally positive attitude reported by most respondents, not all (25%) are actually ready to buy farmed fish fed on insect meal, and an even steeper share (53%) of hesitant Italian consumers can emerge in the research, as seen in Laureati et al.⁶¹ Among the socio-demographic factors that impact the willingness to consume insect-fed animals, Szendrő et al.⁶² determined that age, gender, and income have a significant effect, in accordance with Baldi et al.⁶³ where it was found that men and younger consumers tend to be more prone to accept the product. Similar results have been previously highlighted by Laureati et al.⁶⁴ where it was observed that age, gender, food neophobia, and cultural background affected Italian consumers' willingness to accept insect-fed animal products.

Following the results of the studies focusing on consumer preferences towards insect-fed fish or livestock, it could be argued that consumer acceptance will not hinder this newly developed business,⁶⁵ but there are multiple factors that should be considered. These include pricing, previous knowledge and information provided, socio-demographic characteristics, and the taste of the meat or fish derived from insect-fed animals.

4 Consumer Acceptance of Edible Insects As Food

4.1 A 'Mini-Compilation'

Consumer acceptance of insect-based foods poses a great challenge in societies unaccustomed to consume insects as food (i.e., entomophagy). This lack of an entomophagous tradition directly informs one of the main issues underlying Westerners' reluctance to accept insects for human consumption and adopt edible insects into their diets. Broad scholarly consensus exists about unfamiliarity with entomophagy being a primary reason for low acceptance rates generally found in contemporary consumer studies on eating insects in Western countries. The topic of consuming edible insects is radically different for Western consumers in non-entomophagous societies than for those hundreds of millions of people worldwide who are traditionally familiar with regularly eating insects.⁶⁶

⁶¹Laureati et al. (2016).

⁶²Szendrő et al. (2020).

⁶³Baldi et al. (2021).

⁶⁴Laureati et al. (2016).

⁶⁵Sogari et al. (2019a).

⁶⁶Payne et al. (2019) and van Huis et al. (2022).

This section is devoted to giving a concise overview of research in the field of direct entomophagy primarily based on recently published review studies.⁶⁷ The focus of this ‘mini-compilation’ is on the main benefits that are highlighted when it comes to the consumption of edible insects as well as on major hurdles that will have to be overcome before the practice of eating insects becomes a normal and integrated part of the Western diet. By summarizing and synthesizing some of the main findings in this body of literature, we aim to provide an up-to-date picture of the state of play in consumer research on eating insects.

To begin with, a salient feature of this research domain is its vibrancy, reflected in a significant growth in recent years in the number of entomophagy studies published in peer-reviewed journals.⁶⁸ In contrast to the current high and warm scholarly interest in insects as food is the low and cool overall receptiveness of today’s Western consumers towards the acceptance and adoption of edible insects. Entomophagy studies have highlighted multiple obstacles preventing Western consumers from engaging in the practice of eating insects. Various factors are reported to influence consumer unwillingness to eat insects and insect-based foods. Studies consistently show that two major barriers to preventing the acceptance of insects as food in Western diets are food neophobia (fear of trying new foods) and disgust.⁶⁹ Both aversions decrease the probability of accepting entomophagy. Disgust is an immediate emotional reaction of revulsion, and as such a core barrier. Food neophobia rejects, avoids and is biased negative about (the taste, price, or other product features of) unfamiliar foods.

Although two different notions, both are likely to be cognate, and appear to be aversive responses reflecting other negative consumer perceptions and reserves. Put differently, disgust and food neophobia seem to be fuelled by negative attitudes to entomophagy as well as fuelling other aversions simultaneously. Such obstacles to consuming edible insects are food safety/health risk concerns,⁷⁰ low perceived sensory appeal, cultural inappropriateness (‘edibility’), or unwillingness to eat any animal-derived food—whether or not this is supplemented with concerns regarding the animal welfare of commercially farmed insects.⁷¹

The consumption of edible insects is particularly subjected to these negative associations because of its unfamiliarity. As indicated above, unfamiliarity with

⁶⁷ Ardoin and Prinyawiwatkul (2021), Dagevos (2021), de Carvalho et al. (2020), Kauppi et al. (2019), Kröger et al. (2022), Mancini et al. (2019), Sogari et al. (2019c) and Wendin and Nyberg (2021).

⁶⁸ For further details, see Mancini et al. (2019), pp. 663–669; Kröger et al. (2022), pp. 5–6; Sogari et al. (2019b), p. 172; Sogari et al. (2019c), pp. 32–33.

⁶⁹ Ardoin and Prinyawiwatkul (2021), de Carvalho et al. (2020), Kröger et al. (2022), Onwezen et al. (2021), Sogari et al. (2019c) and Wendin and Nyberg (2021).

⁷⁰ On this specific point, see *Why “New” Foods Are Safe and How They Can Be Assessed* by C. Dall’Asta and *The Safety Assessment of Insects and Products Thereof as Novel Foods in the European Union* by G. Precup, E. Ververis, D. Azzollini, F. Rivero-Pino, P. Zakidou, A. Germini, all in this volume.

⁷¹ Lambert et al. (2021).

entomophagy is considered a key barrier to achieving consumer acceptance for edible insects. Dagevos⁷² demonstrated how widely this point has been discussed in the literature. It does not seem a stretch to assume that many of the reasons for rejecting insects as food or food source are rooted in this lack of familiarity with edible insects in the Western diet. From this perspective, there is reason to believe that consumer reluctance or rejection eventually comes down to the fact that insects are not traditional foods and remain unfamiliar to date.

The opposite holds true, however, for the animal proteins (Western) consumers are used to eating abundantly: meat, dairy, eggs or fish. Contemporary food consumer attachment to meat is a particularly relevant issue in the context of entomophagy acceptance and adoption. Insect foods are often positioned as a non-conventional source of animal protein; as a meat alternative,⁷³ insect foods have to compete with the central position of meat on our plates and in our dominant eating regime. Since the early work of Verbeke,⁷⁴ the relationship between meat eating and eating insects has been given attention in several studies. Over time, findings have evolved somewhat.⁷⁵ Verbeke found that devoted meat lovers were very unlikely to belong to the early adopters of eating insects because they indicated little to no interest in consuming insects. This improbability still stands, and it has been corroborated that having strong attitudes towards meat may be associated with weak consumer willingness to try and buy insect food products.⁷⁶ More recently, complementary findings were reported by Sogari et al.⁷⁷ who did not find a specific link between meat consumption frequency and openness to insect-eating. In a similar vein, a study of Kornher et al.⁷⁸ showed that respondents who report infrequent and low consumption of meat products were more ready to adopt insect consumption. This suggests that entomophagy acceptance and adoption look more promising from the perspective of meat reducers (flexitarians) than that of convinced meat eaters whose meat attachment is high and inclination to substitute meat for insects correspondingly low. This aversive position may be supported by scepticism about the necessity for reducing meat intake and/or by beliefs that insect products will never resemble meat in taste, texture, and appearance.

On the other hand, in efforts to overcome widespread Western reluctance to adopting and accepting insects as food or a food source, the practice of entomophagy has some strong trumps. Consuming edible insects has environmental and human health benefits. The environmental footprint of 'miniature livestock' is significantly lower than conventional livestock farming. Farming edible insects is lower in greenhouse gas emissions, freshwater utilization, and land use. The efficient

⁷²Dagevos (2021).

⁷³de Carvalho et al. (2020), Guiné et al. (2022) and Sogari et al. (2019c).

⁷⁴Verbeke (2015).

⁷⁵See also Kröger et al. (2022), p. 12.

⁷⁶E.g. Van Thielen et al. (2019).

⁷⁷Sogari et al. (2019b).

⁷⁸Kornher et al. (2019).

conversion of feed into valuable proteins also make insects sustainable protein producers. Important nutritional properties of insects are beneficial to human health and food security as a rich source of protein, fibre, fatty acids, minerals and vitamins. Also, the aforementioned recent review studies pay close attention to the environmental, health and food security advantages of insects as food or food source.

This last point brings us to another potential driver of consumer willingness to eat insects. In addition to the introduction of insects into the food system through insects as feed (indirect entomophagy), consuming edible insects can be seen in two forms of direct entomophagy. Eating insects directly can take place not only through the consumption of whole insects, but also by consuming food products in which insects are indistinguishable. Such foods contain no visually identifiable insect ingredients, for instance in the form of insect flour or insect-based proteins. Based on several consumer studies demonstrating that consumer willingness to engage with insect consumption increases when insects are processed ‘in disguise’ in food products, it has been suggested that disguising insects in such familiar products as bread and biscuits, or sauces and soups, is a crucial facilitator to improving consumer receptiveness towards edible insects. This form of direct entomophagy has recently been termed ‘entomophagy by stealth’,⁷⁹ and is believed to help raise familiarity and willingness to engage with eating insects.⁸⁰

4.2 New Instruments to Measure Consumer Perceptions and Acceptance

To assess consumer responses to insects as food and feed, a few new instruments have been recently introduced: Moruzzo et al.⁸¹ developed the Insect Phobia Scale (IPS), La Barbera et al.⁸² composed the Entomophagy Attitude Questionnaire (EAQ), and Guiné et al.⁸³ compiled a questionnaire containing seven subscales including a variety of items.

These recently developed scales to measure consumer perceptions, awareness, and acceptance represent a next step into consumer-oriented entomophagy studies and are, therefore, worth mentioning with respect to current and future research. By briefly introducing these three different scales and the items included we can see which factors are taken into account and which of the issues mentioned in the previous subsection are conspicuous by their absence.

⁷⁹Dagevos (2021), p. 253.

⁸⁰Ardoin and Prinyawiwatkul (2021), Dagevos (2021), de Carvalho et al. (2020), Kröger et al. (2022), Onwezen et al. (2021), Sogari et al. (2019c) and Wendin and Nyberg (2021).

⁸¹Moruzzo et al. (2021a).

⁸²La Barbera et al. (2020, 2021).

⁸³Guiné et al. (2022).

Table 1 Insect Phobia Scale (IPS)

Items
1. The idea of eating insects causes me disgust/repulsion
2. Insect consumption is not socially acceptable
3. I'm afraid insect-based foods have an unpleasant taste
4. I'm afraid insect-based foods have an unpleasant consistency
5. I think insect-based foods have poor hygiene
6. I think that eating insects is not suitable for our diet

The IPS by Moruzzo et al.⁸⁴ is the scale with the smallest scope. To come to a more specific scale than the traditional and more general Food Neophobia Scale,⁸⁵ the IPS focused on a variety of factors that obstruct the consumption of edible insects. A total of six statements referring to the acceptance/rejection of consuming insect-based foods were collected (Table 1).

The IPS clearly outlines common negative associations with eating insects. As such, the IPS-statements belong to the body of entomophagy literature that concentrates on addressing obstacles regarding consumer acceptance of including edible insects in the diet.

A broader perspective is obtained in the EAQ by La Barbera et al.⁸⁶ Next to statements about consumer hesitation due to disgust and perceived risks (negative associations) of eating insects, this instrument also includes items about intentions and readiness to eat insects (positive associations). The wording of the items in the EAQ remain more indefinite about how (un)processed insect foods and dishes are found to be in comparison to the IPS-items, which refer more explicitly to insects 'in disguise' (3–5), whereas items in the EAQ, in turn, refer more explicitly to insects as feed (indirect entomophagy) next to insects as food. Also, statements are included referring to practical situations of availability (12–14) and setting (4–5, 7). An impression of the EAQ is given in the following Table 2.

The perspective is further broadened by Guiné et al.⁸⁷ In their objective to develop and validate a questionnaire designed to assess consumer perceptions and knowledge regarding the consumption of edible insects, Guiné et al. include a wide variety of items ranging from sustainability and economic dimensions, and nutrition and health aspects to cultural and gastronomic perspectives. This has resulted in one of the most comprehensive questionnaires in the entomophagy research domain generated so far. This questionnaire is composed of no less than 64 items, grouped into seven subscales. A selection of its constituting items is presented in Table 3.

Even this selection of about a third of the items included clearly shows that the questionnaire by Guiné et al. addresses many of the issues raised in the literature as

⁸⁴Moruzzo et al. (2021a).

⁸⁵Pliner and Hobden (1992).

⁸⁶La Barbera et al. (2020, 2021).

⁸⁷Guiné et al. (2022).

Table 2 Entomophagy attitude questionnaire

Items
1. I would be disgusted to eat any dish with insects ^a
2. Thinking about the flavour that a bug might have sickens me ^a
3. If I ate a dish and then came to know that there were insects among the ingredients, I would be disgusted ^a
4. I would avoid eating a dish with insects among the ingredients, even if it was cooked by a famous chef ^a
5. I would be bothered by finding dishes cooked with insects on a restaurant menu ^a
6. I'd be curious to taste a dish with insects, if cooked well ^a
7. In special circumstances, I might try to eat a dish of insects ^a
8. At a dinner with friends I would try new foods prepared with insect flour ^a
9. I think it is fine to give insect-based feed to fish that are farmed for human consumption
10. In your opinion, does eating insects pose a risk to human health?
11. How serious do you think the risks of eating insects could be for human health?
12. Using insects as feed is a good way of producing meat ^a
13. I am ready to eat meat [beef, chicken, pork, fish] from animals raised on insect feed as soon as it is available on the market
14. I am ready to try edible insect foods as soon as they are available on the market
15. I think it is fine to give insect-based feed to fish that are farmed for human consumption ^a

^aItems that constitute the final version of EAQ

described in the previous Subsection. Strikingly, and in contrast to EAQ and particularly IPS, the questionnaire by Guiné et al. paid very little attention to negative perceptions: responses of disgust or food neophobia to ‘creeping and crawling creatures’ as food are entirely absent. Only the statement about obstacles to consumer acceptance of edible insects in Western countries refers—though in an unspecified way—to negative attitudes. However important it is to bring the benefits of the inclusion of insects in the Western diet to the fore, it is unrealistic to ignore consumer responses of reluctance and rejection to putting insects in their mouths. As Dagevos⁸⁸ aptly stated: insects are hard to swallow for many present-day Westerners. Consequently, widespread consumer acceptance and adoption of insect foods in Western diets may be expected to be a slow, difficult, and challenging process.

5 Discussion and Conclusions

5.1 Legislation, Information, and Temptation

In this chapter, we sought to outline the state of the art regarding legislation, consumer perceptions, and attitudes towards both insects as feed (indirect

⁸⁸Dagevos (2021), p. 258.

Table 3 Knowledge and perceptions about edible insects

<i>Culture and Tradition</i>
1. Entomophagy is a dietary practice that consists in the consumption of insects by humans
2. Consuming insects is characteristic of developing countries
3. There are obstacles to consumers' acceptance of edible insects in Western countries
<i>Gastronomic Innovation and Gourmet Kitchen</i>
4. Some gourmet restaurants use edible insects in their culinary preparations
5. Chefs contribute to the popularization of insects into gastronomy in Western countries
6. Culinary education favours overall liking for innovative insect-based products
<i>Environment and Sustainability</i>
7. Insects are a more sustainable alternative when compared with other sources of animal protein
8. Insects efficiently convert organic matter into protein
9. Insects are a possibility for responding to the growing world demand for protein
<i>Economic and Social Aspects</i>
10. Insect production can contribute to increase the income of families in low-income areas
11. Insects provide protein foods at cheap prices
12. In some countries insect farming is becoming a key factor in the fight against rural poverty
<i>Commercialization and Marketing</i>
13. The level of knowledge influences the willingness to purchase insect food
14. Price is among the motivations to consume insect foods
15. The consumption of insects and derived foods depends on availability
<i>Nutritional Aspects</i>
16. Insects are a good source of energy
17. Insects have high protein content
18. Insects contain group B vitamins
<i>Health Effects</i>
19. There are appropriate regulations to guarantee the food safety of edible insects
20. Industrially processed insect products are hygienic and safe
21. Insects contain bioactive compounds beneficial to human health

These 21 items have been selected by the authors to provide an overview of the scale. For the full version of the questionnaire (64 items) see the study by Guiné et al. (2022)

entomophagy) and insects as food (direct entomophagy). In addition to the necessary condition of legal approved introduction to the European food market—as discussed in Sect. 2 and more extensively in the second, third, and sixth chapters of this volume—at least two problems should be solved to tackle the unfamiliarity towards these products. First, increasing the amount of information provided to consumers about these foods. and second, offering more appealing products. Both these conditions are both important if we are to create a more enabling environment for (in)direct entomophagy.

Limited information about insects as food, food source, or feed is the first main issue. Secondly, an actual lack of appealing and readily available insect foods perpetuates unfamiliarity. From behavioural theory it is known that consumer choice is influenced by motivation, opportunity, and capability. The availability of information impacts the first factor, motivation. The availability of appropriate and

convenient products facilitates the latter factors, opportunity and capability. Lack of familiarity as a main cause of Westerners' non-acceptance of eating insects can be confronted by increasing information from a trusted source about the nutritional and environmental benefits and food safety guarantees of consuming edible insects and insect-based foods.⁸⁹ A higher awareness of the benefits of eating insects may be associated with an increased likelihood of food consumers beginning and continuing to eat insects and becoming—slowly but gradually—more convinced entomophagists.

Information also has an important role to play with respect to insects as feed. Considering that the market for new insect-fed meat products is set to emerge rapidly in Europe, policymakers, manufacturers and distributors will face new challenges related to label regulation and ingredient declaration.⁹⁰ As confirmed by most consumer studies, the success of such insect-fed products depends on providing adequate information to consumers through marketing campaigns at the point of sale and public communication.⁹¹ It has been suggested that Western consumers are likely to welcome insects as a feed, even if they are unlikely to notice the change.⁹² However, currently consumer interest in insects as feedstuff has not received broad media attention, with the result that awareness of the potential benefits of this alternative protein source is still low.⁹³

At a more practice-oriented level, increased availability and accessibility of desirable insect-based food products may also be associated with opposing unfamiliarity and negative consumer associations with eating insects. More and more positive exposure is vital to encouraging consumer willingness to try and buy insect foods, and eventually, to achieve a persistent consumer acceptance. In line with this is the finding that previous experience with eating insects appeared as a primary facilitator of consumer receptiveness to edible insects and insect-based food products.⁹⁴ In other words, increased exposure to insect-based foods and repeated insect-eating experiences increases familiarity that, in turn, increases entomophagy acceptance and decreases reluctance towards insects as food. Providing information on the merits of eating insects as well as putting palatable and desirable insect-based products on the supermarket shelves and on the menus of restaurants are key factors likely to overpower the disgust and fear of edible insects that prevail in current food consumer perceptions, as Sect. 3.1 clearly addressed, and tempt consumers to entomophagy. In the words of Ardoin and Prinyawiwatkul,⁹⁵ “as [insect-based] products become more appealing, existing negative emotions may diminish over time.”

⁸⁹Kröger et al. (2022) and Menozzi et al. (2017).

⁹⁰Sogari et al. (2022).

⁹¹Menozzi et al. (2021) and Spartano and Grasso (2021).

⁹²Altmann et al. (2022).

⁹³Sogari et al. (2022).

⁹⁴Dagevos (2021), Kauppi et al. (2019), Kröger et al. (2022) and Mancini et al. (2019).

⁹⁵Ardoin and Prinyawiwatkul (2021), p. 4954.

Future research should continue to examine both drivers and inhibitors of consumer acceptance of insects as food or food source separately, as well as the interrelationship between consumer readiness and reluctance to consume edible insects. The same holds for possible relationships between the use of insects as feed and its influence on consumer acceptance of insects as food—and possibly also vice versa. In this respect, future studies should also further apply the recently developed instruments in consumer-oriented research in both indirect and direct entomophagy. Finally, future studies should investigate psycho-attitudinal, behavioural, and experiential variables that will depend, at least in part, on future feed declaration regulations and expected label information.

5.2 *Final Considerations*

The pioneering industry of insects as feed and food could offer promising solutions to address major challenges to our global food system, including a growing population, limited natural resources and food waste mitigation. In this respect, this sector may be considered ‘strategic’ by national and international authorities from both SDG and CE perspectives as well as from the point of view of the current European policy reform (e.g., F2F) targeted at more sustainable and circular food supply chains.

Today the insect sector is still at an early stage, and its effect on the frequency and volume of consumption is almost negligible.⁹⁶ However, it is likely that in the coming years, the current legislative framework on Novel Foods and recent authorization approvals from the European Commission will play a constructive role in shaping the market⁹⁷ and facilitating access to such products. As a result, we might witness an increase in consumption, especially of products containing hidden insects: entomophagy by stealth seems the most promising way to move forward when it comes to direct entomophagy.⁹⁸

In addition, and turning to indirect entomophagy, safety laws related to animals farming and feeds are also a very central issue for the development of the insect sector.⁹⁹ The recent EU authorizations for using insects as feed in the poultry and pig sector are expected to open new avenues for insect producers, and to significantly impact the food supply chain for meat and animal-based products. According to recent studies, European consumers seem to be more open to accepting the use of insects as feed to produce meat and animal-based products (e.g., eggs) rather than embarking upon direct entomophagy.¹⁰⁰

⁹⁶Montanari et al. (2021b), Pippinato et al. (2020) and van Huis et al. (2022).

⁹⁷Mancini et al. (2022).

⁹⁸Dagevos (2021) and Pippinato et al. (2020).

⁹⁹Lähteenmäki-Uutela et al. (2021).

¹⁰⁰Mancini et al. (2022) and Spartano and Grasso (2021).

Acknowledgements All the authors would like to thank that the School of Advanced Studies on Food and Nutrition of the University of Parma and the Editors for providing the opportunity to share the latest advancements on this topic in this Volume.

With respect to the contribution to this chapter by Dagevos and Taufik, funding was provided by the Dutch Ministry of Agriculture, Nature, and Food Quality through the Knowledgebase Program 34: Circular and Climate Neutral [KB-34-006-001], Project ‘The Role of Insects in New Production Cycles’.

References

- Altmann BA, Anders S, Risius A, Mörlein D (2022) Information effects on consumer preferences for alternative animal feedstuffs. *Food Policy* 106:102192
- Ankamah-Yeboah I, Jacobsen JB, Olsen SB (2018) Innovating out of the fishmeal trap: the role of insect-based fish feed in consumers’ preferences for fish attributes. *Br Food J* 120:2395–2410
- Ardoin R, Prinyawiwatkul W (2021) Consumer perceptions of insect consumption: a review of Western Research since 2015. *Int J Food Sci Technol* 56:4942–4958
- Baldi L, Mancuso T, Peri M, Gasco L, Trentinaglia MT (2021) Consumer attitude and acceptance toward fish fed with insects: a focus on the new generations. *J Insects Food Feed*:1–16
- Bazoche P, Poret S (2020) Acceptability of insects in animal feed: a survey of French consumers. *J Consum Behav* 20:251–270
- Cromwell GL (1999) Soybean meal - the “Gold Standard”. *The Farmer’s Pride*, KPPA News, 1120
- Dagevos H (2021) A literature review of consumer research on edible insects: recent evidence and new vistas from 2019 studies. *J Insects Food Feed* 7:249–259
- de Carvalho NM, Madureira AR, Pintado ME (2020) The potential of insects as food sources. A review. *Crit Rev Food Sci Nutr* 60:3642–3652
- Derrien C, Bocconi A (2018) Current status of the insect producing industry in Europe. In: Halloran A, Flore R, Vantomme P, Roos N (eds) *Edible insects in sustainable food systems*. Springer, Cham, pp 471–479
- European Union (2021) EU Feed Protein Balance Sheet (forecast), https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/eu-feed-protein-balance-sheet_2020-2021_en.pdf. Accessed 15 Feb 2022
- Ferrer Llagostera P, Kallas Z, Reig L, Amores de Gea D (2019) The use of insect meal as a sustainable feeding alternative in aquaculture: current situation, Spanish Consumers’ perceptions and willingness to pay. *J Clean Prod* 229:10–21
- Giotis T, Drichoutis AC (2021) Consumer acceptance and willingness to pay for direct and indirect entomophagy. *Q Open* 1:qoab015
- Guiné RPF, Florença SG, Costa CA, Correia PMR, Ferreira M, Duarte J, Cardoso AP, Campos S, Anjos O (2022) Development of a questionnaire to assess knowledge and perceptions about edible insects. *Insects* 13:47
- House J (2018) Insects are not ‘the New Sushi’: theories of practice and the acceptance of novel foods. *Soc Cult Geogr* 20(9):1285–1306
- IPIFF (2020a) Edible insects on the European Market, <https://ipiff.org/wp-content/uploads/2020/06/10-06-2020-IPIFF-edible-insects-market-factsheet.pdf>. Accessed 15 Feb 2022
- IPIFF (2020b) The insect sector milestones towards sustainable food supply chains, <https://ipiff.org/wp-content/uploads/2020/05/IPIFF-RegulatoryBrochure-update07-2020-1.pdf>. Accessed 15 Feb 2022
- IPIFF (2021) An overview of the European Market of insects as feed, https://ipiff.org/wp-content/uploads/2021/04/Apr-27-2021-IPIFF_The-European-market-of-insects-as-feed.pdf. Accessed 15 Feb 2022

- IPIFF (2022) Guide on good hygiene practices for European Union (EU) producers of insects as food and feed. <https://ipiff.org/wp-content/uploads/2019/12/IPIFF-Guide-on-Good-Hygiene-Practices.pdf>. Accessed 15 Feb 2022
- Kauppi S-M, Pettersen IN, Boks C (2019) Consumer acceptance of edible insects and design interventions as adoption strategy. *Int J Food Design* 4:39–62
- Kornher L, Schellhorn M, Vetter S (2019, 1878) Disgusting or innovative-consumer willingness to pay for insect based burger patties in Germany. *Sustainability* 11(7)
- Kröger T, Dupont J, Büsing L, Fiebelkorn F (2022) Acceptance of insect-based food products in Western societies: a systematic review. *Front Nutr* 8:759885
- La Barbera F, Verneau F, Videbæk PN, Amato M, Grunert KG (2020) A self-report measure of attitudes toward the eating of insects: construction and validation of the entomophagy attitude questionnaire. *Food Qual Prefer* 79:103757
- La Barbera F, Verneau F, Amato M, Grunert KG, Schnettler B (2021) Acceptance of insect-based food in Chile: evidence from a survey using the entomophagy attitude questionnaire (EAQ). *Food Qual Prefer* 93:104269
- Lähteenmäki-Uutela A, Marimuthu SB, Meijer N (2021) Regulations on insects as food and feed: a global comparison. *J Insects Food Feed* 7:849–856
- Lambert H, Elwin A, D’Cruze N (2021) Wouldn’t hurt a fly? A review of insect cognition and sentience in relation to their use as food and feed. *Appl Anim Behav Sci* 243:105432
- Laureati M, Proserpio C, Jucker C, Savoldelli S (2016) New sustainable protein sources: consumers’ willingness to adopt insects as feed and food. *Italian J Food Sci* 28:652–668
- Lotta F (2019) Insects as food: the legal framework. In: Sogari G, Mora C, Menozzi D (eds) *Edible insects food sector methods, current applications and perspectives*. Springer, Cham, pp 105–118
- Mancini S, Moruzzo R, Riccioli F, Paci G (2019) European consumers’ readiness to adopt insects as food. *A Review. Food Res Int* 122:661–678
- Mancini S, Sogari G, Espinosa Diaz S, Menozzi D, Paci G, Moruzzo R (2022) Exploring the future of edible insects in Europe. *Foods* 11(3):445
- Mancuso T, Baldi L, Gasco L (2016) An empirical study on consumer acceptance of farmed fish fed on insect meals: the Italian case. *Aquac Int* 24:1489–1507
- Menozzi D, Sogari G, Veneziani M, Simoni E, Mora C (2017) Explaining the intention to consume an insect-based product: a cross-cultural comparison. In: Seyal AH, Al E (eds) *Theory planned behaviour: new research*. Nova Science Publishers, New-York, pp 1–15
- Menozzi D, Sogari G, Mora C, Gariglio M, Gasco L, Schiavone A (2021) Insects as feed for farmed poultry: are Italian consumers ready to embrace this innovation? *Insects* 12(5):435
- Montanari F, Pinto de Moura A, Miguel Cunha L (2021a) The EU regulatory framework for insects as food and feed and its current constraints. In: Montanari F, Pinto de Moura A, Cunha LM (eds) *Production and commercialization of insects as food and feed; identification of the main constraints in the European Union*. Springer, Cham, pp 41–78
- Montanari F, Pinto de Moura A, Miguel Cunha L (2021b) The global market of insects as food and feed. In: Montanari F, Pinto de Moura A, Cunha LM (eds) *Production and commercialization of insects as food and feed; identification of the main constraints in the European Union*. Springer, Cham, pp 19–27
- Moruzzo R, Mancini S, Boncinelli F, Riccioli F (2021a) Exploring the acceptance of entomophagy: a survey of Italian consumers. *Insects* 12(2):123
- Moruzzo R, Mancini S, Guidi A (2021b) Edible insects and sustainable development goals. *Insects* 12(6):557
- Nordborg M, Cederberg C, Berndes G (2014) Modeling potential freshwater ecotoxicity impacts due to pesticide use in biofuel feedstock production: the cases of maize, rapeseed, salix, soybean, sugar cane, and wheat. *Environ Sci Technol* 48:11379–11388
- Oil World (2015) *Oil World Annual 2015*. ISTA Mielke GmbH, Hamburg
- Onwezen MC, Bouwman EP, Reinders MJ, Dagevos H (2021) A systematic review on consumer acceptance of alternative proteins: pulses, algae, insects, plant-based meat alternatives, and cultured meat. *Appetite* 159:105058

- Parolini M, Ganzaroli A, Bacenetti J (2020) Earthworm as an alternative protein source in poultry and fish farming: current applications and future perspectives. *Sci Total Environ* 734:139460
- Payne C, Caparros Megido R, Dobermann D, Frédéric F, Shockley M, Sogari G (2019) Insects as food in the global North – the evolution of the entomophagy movement. In: Sogari G, Mora C, Menozzi D (eds) *Edible insects food sector methods, current applications and perspectives*. Springer, Cham, pp 11–26
- Pippinato L, Gasco L, Di Vita G, Mancuso T (2020) Current scenario in the European edible-insect industry: a preliminary study. *J Insects Food Feed* 6:371–381
- Placentino U, Sogari G, Viscecchia R, De Devitiis B, Monacis L (2021) The new challenge of sports nutrition: accepting insect food as dietary supplements in professional athletes. *Foods* 10(5):1117
- Pliner P, Hobden K (1992) Development of a scale to measure the trait of food neophobia in humans. *Appetite* 19:105–120
- Popoff M, MacLeod M, Leschen W (2017) Attitudes towards the use of insect-derived materials in Scottish Salmon Feeds. *J Insects Food Feed* 3:131–138
- PROteinSECT (2016) Final report summary–PROTEINSECT (Enabling the exploitation of insects as a sustainable source of protein for animal feed and human nutrition), <https://cordis.europa.eu/project/id/312084/reporting/it>. Accessed 15 Feb 2022
- Sogari G, Menozzi D, Mora C (2018) Sensory-liking expectations and perceptions of processed and unprocessed insect products. *Int J Food Syst Dynam* 9:314–320
- Sogari G, Amato M, Biasato I, Chiesa S, Gasco L (2019a) The potential role of insects as feed: a multi-perspective review. *Animals* 9(4):119
- Sogari G, Liu A, Li J (2019b) Understanding edible insects as food in Western and Eastern Societies. In: Bogueva D, Marinova D, Raphaely T, Schmidinger K (eds) *Environmental, health, and business opportunities in the new meat alternatives market*. IGI Global, Hershey, pp 166–181
- Sogari G, Menozzi D, Hartmann C, Mora C (2019c) How to measure consumers acceptance towards edible insects? – A scoping review about methodological approaches. In: Sogari G, Mora C, Menozzi D (eds) *Edible insects in the food sector*. Springer, Cham, pp 27–44
- Sogari G, Menozzi D, Mora C, Gariglio M, Gasco L, Schiavone A (2022) How information affects consumers' purchase intention and willingness to pay for poultry farmed with insect-based meal and live insects. *J Insects Food Feed* 8:197–206
- Spartano S, Grasso S (2021) UK consumers' willingness to try and pay for eggs from insect-fed hens. *Future Foods* 3:100026
- Szendró K, Nagy MZ, Tóth K (2020) Consumer acceptance of meat from animals reared on insect meal as feed. *Animals* 10:1312
- van Huis A, Van Itterbeeck J, Klunder H, Mertens E, Halloran A, Muir G, Vantomme P (2013) Edible insects: future prospects for food and feed security. *FAO Forestry Paper no. 171*, <http://www.fao.org/docrep/018/i3253e/i3253e.pdf>. Accessed 15 Feb 2022
- van Huis A, Halloran A, Van Itterbeeck J, Klunder H, Vantomme P (2022) How many people on our planet eat insects: 2 billion? *J Insects Food Feed* 8:1–4
- Van Thielen L, Vermuyten S, Storms B, Rumpold B, Van Campenhout L (2019) Consumer acceptance of foods containing edible insects in Belgium two years after their introduction to the market. *J Insects Food Feed* 5:35–44
- Verbeke W (2015) Profiling consumers who are ready to adopt insects as a meat substitute in a Western Society. *Food Qual Prefer* 39:147–155
- Weinrich R, Busch G (2021) Consumer knowledge about protein sources and consumers' openness to feeding micro-algae and insects to pigs and poultry. *Future Foods* 4:100100
- Wendin KME, Nyberg ME (2021) Factors influencing consumer perception and acceptability of insect-based foods. *Curr Opin Food Sci* 40:67–71

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



Correction to: The Safety Assessment of Insects and Products There of As Novel Foods in the European Union



Gabriela Precup, Ermolaos Ververis, Domenico Azzollini,
Fernando Rivero-Pino, Panagiota Zakidou, and Andrea Germini

Correction to:
Chapter 7 in: L. Scaffardi, G. Formici (eds.),
Novel Foods and Edible Insects in the European Union,
https://doi.org/10.1007/978-3-031-13494-4_7

The book was inadvertently published with an incorrect affiliation. Ermolaos Ververis is affiliated to National and Kapodistrian University of Athens (NKUA), Department of Hygiene, Epidemiology and Medical Statistics, School of Medicine, Athens, Greece and EFSA, Nutrition and Food Innovation Unit, Novel Foods Team, Parma, Italy.

The FM & chapter has now been corrected and approved by the author.

Open Access This chapter is licensed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.



The updated original version of this chapter can be found at
https://doi.org/10.1007/978-3-031-13494-4_7

© The Author(s) 2022
L. Scaffardi, G. Formici (eds.), *Novel Foods and Edible Insects in the European Union*, https://doi.org/10.1007/978-3-031-13494-4_9