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

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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 pandemic[1] 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

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

[2] Migali and Natale (2021).

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

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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 livestock[5] 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

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

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

[6] Melgar-Lalanne and Hernandez-Alvarex (2019); see also Van Huis and Ooninex (2017) and Halloran et al. (2018).

[7] FAO (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).

[8] Wageningen 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).

[9] According 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).

[10] For 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 safety[11] 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 identity[12] 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

[11] On 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.

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

[13] Melgar-Lalanne and Hernandez-Alvarex (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.

[14] EFSA (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

[15] 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*.

[16] The 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 sector[20]—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 landscape[24] 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' Europe[25] 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,

[23] This 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.

[24] The 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.

[25] La 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 identity[26]—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 2008[33] 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

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

[27] We 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.

[28] For 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.

[29] The 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).

[30] Brookes (2007).

[31] Hyde (2017).

[32] Lahteenmaki-Uutela (2007, 2020).

[33] Brookes (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 Countries[34] or foods deriving from animal clones[35]—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

[34] 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, but also Formici (2020a).

[35] Scaffardi (2020) and Coppens (2013).

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

[37] For a vast analysis of the current Regulation see Pisanello and Caruso (2018), Scaffardi (2020), Montanari et al. (2021) and Lahteenmaki-Uutela 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.

[38] IPIFF (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 prefectoral 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 considerations[40] 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*

[39] The 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).

[40] Opinion 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

[44] IPIFF (2020a, b).

[45] This 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.

[46] IPIFF (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 procedure[48] 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

[47] Moreover, 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.

[48] On 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.

[49] IPIFF (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

[56] FAO (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).

[57] Regulation (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) 2017/893[58]—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 prohibitions[59] 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 fish[60] (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 852/2004/EC and 183/2005/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.

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

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

[60] This 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

[61] This 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).

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

[63] It 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 information[64] 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]

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[64] On 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.

[65] Lanni (2020), p. 78.

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