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IPIFF

Stakeholder Contribution Paper on the Romanian Authorities
Notification on the Order requiring economic operators to provide
consumers with clear and complete information on foods that
contain species of any insects authorised to be placed on the
market as novel foods

About IPIFF

The International Platform of Insects for Food and Feed (IPIFF) - the European insect sector umbrella association - is a non-profit organisation that represents the interests of actors active across the insect production value chain at the European level. Bringing together more than 75members - most of which are European insect-producing companies - it aims at contributing to sustainable, circular food and agricultural system by promoting the use of insects and insect-derived products, mainly for food and animal feed.

Introduction

The present document outlines the views of the EU insect producers, in response to the Order on behalf of Romanian authorities requiring economic operators to provide consumers with clear and complete information on foods that contain species of any insects authorised to be placed on the market as novel foods

The position of IPIFF, which reflects the views of the EU insect producers

IPIFF objects to the order's intentions on behalf of the Romanian authorities, taking into consideration the current EU legislation that safeguards the provision of complete information on foods that contain species of any insects authorised to be placed on the market as novel foods.

IPIFF further highlights that insect-based Novel Food producers display in a much visible form that their products are based on insects. on The concerned companies invested substantial resources in the development of the concerned applications responding to consumers' demand for the concerned products, notably owing to their nutritional value and sustainability-related aspects. Nevertheless, we believe that the measures foreseen by this order would lead to misleading and unfair business-to-consumer commercial practices.

Furthermore, IPIFF emphasises that insect-based Novel Food products, as any other food product, are subject to all EU food safety and labeling applicable legislation (e.g. 'General Food Law' Regulation; Food Hygiene legislation and 'Food Information Consumers' Regulation').

In addition, IPIFF highlights that insect-based Novel Food products must be in compliance with Regulation 2015/2283 on 'Novel Food' (provisions on safety and labeling) and related authorisation procedures, which involves a safety Opinion on each product by the European Food Safety Authority, followed by a favourable vote by the EU Member States on a product-

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specific Commission Implementing Regulation which define the terms and conditions for their commercialisation in the EU (including safety and labeling).

IPIFF stresses that the measures foreseen by this order, including the placement of such products in separate stands, are misleading to the consumer.

Moreover, IPIFF considers such a measure to materially distort the consumer's economic behaviour. In practice, such a legislative initiative **will lead to unfair commercial practices** that in consequence will impair the consumer's ability to make an informed decision. Therefore, in accordance with Directive 2005/29/EC on Unfair Business-to-consumer commercial practices in the internal market, the Romanian authorities by pursuing its legislative intentions will disrupt the internal market by influencing consumers' free choice while subjecting a specific sector to unfair commercial practices to its disadvantage.

Lastly, the EU Regulation on the Provision of Food Information Consumers is currently being revised with the aim to set a more harmonised EU-level food labeling legislation, bringing more clarity, better information, and recognition by the EU consumer to trustworthy food labels. In this context, we believe that this initiative by the Romanian authorities is 'counterproductive' and, misleading to the consumer.

Along the same line, IPIFF recalls that the Unfair business-to-consumer commercial practices Directive is a fully harmonised legal instrument at the EU level. Should the Romanian authorities' initiative go through, this could lead to commercial practices that stand against the principle set out in Directive 2005/29/EC.

Furthermore, IPIFF considers such intention contradicts the EU 'General Food Law' and 'Food Information Consumers' Regulations and even questions the safety assessment reliability conducted by the European Food Safety Authority and as well of the principles and provisions established by Regulation 2015/2283 on 'Novel Foods'.

Grounds for the Objection

IPIFF emphasises that insect-based Novel Food products are subject, as any other food product, to all EU food safety and food labeling applicable legislation.

Rue Joseph Stevens, 7, 13th floor, 1000 Brussels



Justification

'General Food Law' Regulation

Insect-based Novel Food products are subjected as any other food product to the EU "General Food Law" Regulation (EC) NO 178/2002 of 28 January 2002 of the European Parliament and of the Council 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.

'General food hygiene Regulation'

As any food product lawfully placed in the EU market, insect-based Novel Food Products producers are obliged to comply with the EU General Food Hygiene Requirements, Regulation (EC) No 852/2004 lays down general rules for food business operators on the hygiene of foodstuffs taking into account the principle that it is necessary to ensure food safety throughout the food chain, starting with primary production.

'Food Information Consumers' Regulation'

Insect-based Novel Food products, as any other food product lawfully placed in the EU market, must comply with Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC Regulation) entered into application on 13 December 2014. The obligation to provide nutrition information applies since 13 December 2016.

IPIFF emphasises that Regulation (EC) No 178/2002 on 'General Food Law' aims at ensuring a high level of protection of human health and consumers' interest in relation to food while ensuring the effective functioning of the internal market. It is the foundation of the Union Food Law. It establishes, amongst others, common principles of (Union and national) food law as well as responsibilities of food and feed business operators at all stages of production, processing, and distribution of food and feed. In that respect, it establishes the protection of consumers' interests as a general principle of food law (183).

Accordingly, 'Food Law' aims at the protection of the interests of consumers and must provide a basis for consumers to make informed choices in relation to the foods they consume. In particular, it must aim at the prevention of:

- (a) fraudulent or deceptive practices;
- (b) the adulteration of food; and
- (c) any other practices which may mislead the consumer.

It also provides for a general obligation for the labeling, advertising, and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged, the setting in which they are displaced, and the information which is made available about them through whatever medium.

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Only safe food and feed products may be placed on the Union market. Finally, food and feed business operators at all stages of production, processing, and distribution within the businesses under their control are required to ensure that foods or feeds satisfy all requirements of the 'Food Law', which are relevant to their activities and must verify that such requirements are met.

Furthermore, Regulation (EU) No 1169/2011 on the provision of food information to consumers (the FIC Regulation) lays down general labeling rules and requirements, including the mandatory provision of a complete list of ingredients, the quantity of certain ingredients or categories of ingredients, allergen information, a nutrition declaration, etc.

This enables consumers to be fully informed of the composition of the food products and prevents misleading food information. Food information must be clear, accurate, and easy to understand for the consumer. For that purpose, the FIC Regulation lays down specific requirements for the presentation of mandatory information, including minimum font size. The 'EU food law' puts in place a comprehensive legal framework aimed at ensuring not only a high level of protection of the health of consumers and their social and economic interests but also the free movement of safe food in the EU Single Market.

IPIFF further recalls that in addition to all food safety and food labeling EU applicable legislation, insect-based Novel Food Products must be compliant with the provisions set out in Regulation on 'Novel Foods', Regulation (EU) 2015/2283.

Regulation (EU) 2015/2283 of 25 November 2015 2015 (latter referred to as the 'Novel Food' Regulation

The Novel Food Regulation sets out harmonised rules for the placing on the market of the aforementioned products in the European Union (EU). With the recast of the EU legislation on novel foods, the EU legislator introduced, for the first time, a centralised authorisation procedure that is managed by the European Commission and relies on the European Food Safety Authority (EFSA) as the sole risk assessment body. Under Regulation (EC) No 258/97, the initial steps of the approval procedure were 'decentralised' indeed. Under Regulation (EU) 2015/2283, whole insects and their parts, including their derived preparations or ingredients are considered novel food and must thus be authorised under the new EU novel food system with the view to be lawfully marketed within the EU.

IPIFF stresses that specific provisions are set out in the 'Novel Food' Regulation concerning the labeling of Novel Food Products, to which insect-based Novel Food products must also be in compliance besides those defined in Regulation (EU) No 1169/2011 on the provision of food information to consumers:

Chapter I (33)- Novel foods are subject to the general labeling requirements laid down in Regulation (EU) No 1169/2011 and other relevant labeling requirements in Union food law. In certain cases, it may be necessary to provide additional labeling information, in particular regarding the description of the food, its source, its composition or its conditions of intended use to ensure that consumers are sufficiently informed of the nature and safety of the novel food, particularly with regard to vulnerable groups of the population.

Rue Joseph Stevens, 7, 13th floor, 1000 Brussels



IPIFF further recalls that additional labeling information is provided by each product specific Positive Opinion by the European Food Safety Authority (product characteristics; nutritional elements; labeling requirements) and as well in each product-specific Commission Implementing Regulation, which defines the terms and conditions applying to each product commercialisation in the EU.

Chapter II Article 6 (2)- Only novel foods authorised and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.

Chapter II Article 7 on General conditions for inclusion of novel foods in the Union list. The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

- (a) the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;
- (b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
- (c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Chapter II Article 9- The entry for a novel food in the Union list provided for in paragraph 2 shall include the specification of the novel food and, where appropriate:

- (a) the conditions under which the novel food may be used, including in particular any requirements necessary to avoid possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;
- (b) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;
- (c) post-market monitoring requirements in accordance with Article 24.

Furthermore, each insect-based Novel Food product to be authorised in the EU must be granted a 'Positive' Safety Opinion by European Food Safety Authority (EFSA), determining its use levels and processing conditions for safe use for human consumption. EFSA Safety Opinions describe the nutritional characteristics of each insect-based Novel Food Product and how it should be labeled, according to applying legislation.

EFSA Safety Opinions are the result of an individual safety assessment conducted on each applicant's insect-based Novel food product. These assessments examine the product's stability, toxicology, and allergenicity. Therefore, for each one of the six (6) authorised edible insect-based Novel Food Products, there is six (6) individual corresponding EFSA Safety Opinions, published in the EFSA Journal:

Rue Joseph Stevens, 7, 13th floor, 1000 Brussels



- 1. The EFSA Opinion on the Safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283. Adopted on 24 November 2020. Published on 13 January 2021;
- The EFSA Opinion on the Safety of frozen and dried formulations from migratory locust (*Locusta migratoria*) as a Novel food pursuant to Regulation (EU) 2015/2283.
 Adopted on 25 May 2021. Published on 2 July 2021;
- 3. The EFSA 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. Adopted on 7 July 2021. Published on 25 August 2021;
- 4. The EFSA 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. Adopted on 7 July 2021. Published on 17 August 2021;
- 5. The EFSA Opinion on the Safety of partially defatted house cricket (*Acheta domesticus*) powder as a novel food pursuant to Regulation (EU) 2015/2283. Adopted on 23 March 2022. Published on 13 May 2022;
- 6. The EFSA Opinion on the Safety of frozen and freeze-dried formulations of the lesser mealworm (*Alphitobius diaperinus* larva) as a Novel food pursuant to Regulation (EU) 2015/2283. Adopted on 26 April 2022. Published on 4 July 2022.

IPIFF reiterates that each insect-based Novel Food product defines additional individual requirements concerning the commercialisation of each one of the authorised products in the Internal Market, including for its labeling.

Insect food products are assessed and then, potentially, authorised based on the applications submitted by insect producers (or other stakeholders) that concern a specific product made from insects. For each authorised edible insect food product that formed the basis of a novel food application, the European Commission adopts and publishes an Implementing Regulation that authorises its commercialisation.

Such a regulatory act shall be based on a 'positive' opinion adopted by the European Food Safety Authority (EFSA) regarding the safety of its product and following a qualified majority from the representatives of the EU Member States.

For all the six (6) authorised edible insect-based Novel Food Products, six (6) Commission Implementing Regulations are published in the Official Journal of the EU:

- 1. 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;
- 2. 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;
- 3. Commission Implementing Regulation (EU) 2022/169 of 8 February 2022 authorising the placing on the market of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) as a novel food under Regulation (EU) 2015/2283 of the

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- European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470;
- 4. 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;
- 5. Commission Implementing Regulation (EU) 2023/5 of 3 January 2023 authorising the placing on the market of *Acheta domesticus* (house cricket) partially defatted powder as a novel food and amending Implementing Regulation (EU) 2017/2470;
- 6. Commission Implementing Regulation (EU) 2023/58 of 5 January 2023 authorising the placing on the market of the frozen, paste, dried, and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470.

Conclusion & Main Statement

IPIFF objects to the proposed order on behalf of the Romanian authorities, and highlights that insect-based Novel Food producers proudly display in a much visible form that their products are based on insects.

IPIFF considers that the order promoted by the Romanian authorities is unsubstantiated, recalling that insect-based Novel Food products, as any other food product, are subject to all EU food safety and labeling applicable legislation (e.g. 'General Food Law' Regulation; 'Food Information to the Consumer Regulation'), and in addition with Regulation 2015/2283 on 'Novel Food' (provisions on safety and labeling).

Therefore, Novel Food products are the most regulated type of food in terms of the protection of the consumer, both regarding its safety and its labeling. Moreover, IPIFF considers such a measure to materially distort the consumer's economic behaviour. In practice, such a legislative initiative will lead to unfair commercial practices that in consequence will impair the consumer's ability to make an informed decision.

Lastly, considering that such intention distorts the objectives of a more harmonised EU-level food labeling legislation with the aim of bringing more clarity, better information, and recognition by the EU consumer to trustworthy food labels.