

IPIFF Contribution Paper: Application of the novel food transitional measure

Introduction and background

Insects have been consumed traditionally by one-third of the world's population, predominantly in Latin America, Africa, and Asia. The production of insects and their derived products is a current practice in several regions of the world, most of them having rooted traditional history of their consumption and utilisation¹. As noticed in western countries (e.g. Europe and North America), there is growing interest in novel sources of nutrition in human food and animal feed - including insects². In terms of food safety and risks - as highlighted by the European Food Safety Agency (EFSA) in its conclusions - 'risks associated with insect consumption are comparable to other animal proteins materials, provided that insects are fed with 'European Union (EU) authorised feed' and appropriate production methods are being followed'³.

Under the former EU novel food legislation (Regulation, No 258/97 -hereinafter old NFR 97- that *applied until 31 December 2017*), there was **legal uncertainty** as to whether or not whole insects should be considered as a novel food in the scope of this regulation. Due to this uncertainty, it was not clear whether operators had to submit novel food applications for authorisations. In that context, several Member States (MS) have admitted the commercialisation of these products considering that they complied with general food safety standards, but resulted in creating divergent interpretations amongst the MS.

The Novel Foods Regulation (Regulation (EU) No 2015/2283 (hereinafter new NFR 2015), which entered into force on 1 January 2018), **included insects and their derived products as food** and thereby requires operators to submit a novel food application (i.e. centralised and generic pre-market authorisation that includes a safety assessment by EFSA)⁴. This inclusion resulted in **clarifying the legal status** of insects as a novel food. Under the new NFR 2015, over 20 'novel food' applications have been submitted while the first 'novel food' authorisations could intervene as from mid-2021⁵. Furthermore, the transitional measure (TM)⁶ provided in the new NFR 2015, allows products in line with its criteria to continue to remain on the market (supported by the respective national authority guidelines) until a final decision is made. The anticipated novel food authorisations would bring regulatory visibility, facilitating the creation of a level playing field on the European market for insects as food. Presently, insect as food business operators are bound by the **European Union (EU)**

¹ Edible insects: future prospects for food and feed security. [Van Huis, A., et al., 2013](#)

² Insects as food and feed, a new emerging agricultural sector: a review. [Van Huis, A., 2013](#)

³ European Food Safety Authority (EFSA), [Risk profile related to production and consumption of insects as food and feed](#)

⁴ IPIFF briefing paper on the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU - [August 2019](#).

⁵ IPIFF Press release - The European insect sector welcomes the CJEU ruling and looks ahead to the novel food authorisations- [October 2020](#).

⁶ The transitional measures provided under the new NFR 2015, allows edible insects and their preparations that have been legally marketed in the EU before this regulation to continue to be placed on the market. The transitional measures were intended to offer businesses time to comply with the new requirements.

food safety rules/legislation and are therefore required to comply with strict production standards defined at a European level. In particular, European food safety regulations - Regulation (EC) No 178/2002 ('General Food Law') or Regulation (EC) No 852/2004 (regulation from the 'hygiene package') require these producers to respect strict specifications both in terms of hygiene practices, product safety and traceability. Even after the entry into force of the new NFR 2015, the question if 'whole insects' fall under the scope of the old NFR 97 remained relevant, notably in light of the applicability of the transitional regime provided by the new NFR 2015.

Although the new NFR 2015 foresaw a TM, it was applied only in certain EU MS under the condition that operators complied with EU 'general food standards' and the criteria of the TM⁷. Certain MS⁸ have not applied the TM for insects as food products, on their understanding that the aforementioned products fell under the scope of the old NFR 97. This stance by the MS automatically disqualifies insect products in these MS to fulfil the criteria for benefiting from the transitional measures. Consequently, 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'. IPIFF foresees and continues to consider that MS should apply and give full effect to the TM⁹.

On 1 October 2020, the Court of Justice of the European Union (CJEU) ruled¹⁰ that 'whole insects' as food **do not fall** under the scope of the old NFR 97. This judgment creates a jurisprudence applicable in every EU MS, thus can have a significant impact for insect producers/operators active in EU MS not benefiting from the TM. In light of the ruling, and with the legal clarity on the scope of insects as food the respective MS should give full effect to the TM foreseen in the new NFR 2015.¹¹

The objectives of this Contribution Paper

This paper aims to outline the views of the IPIFF organisation with regard to the implementation of the TM notably in light of the 'new regulatory landscape' and further **explore the possibilities for EU competent authorities to implement this TM¹²**. **'We encourage national competent authorities to explore avenues for implementing the 'novel food' TM, thereby giving full effect to the CJEU ruling and ensuring a level playing field between insect producers across the EU.** To this end, this document looks into the conditions associated with the use of the TM under the new NFR 2015:

⁷ Chapter 4.8. Transitional measures and pg. 37 on EU Member States' approaches on the novel status of 'whole insects and their preparations' IPIFF briefing paper on the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU - [IPIFF, August 2019](#);

⁸ Bulgaria, Croatia, Republic of Cyprus, Estonia, France, Germany (certain states), Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, and Spain.

⁹ IPIFF position paper - Implementation of EU Regulation 2015/2283 on 'novel foods': '*IPIFF fears, however, that due to 'restrictive interpretations' of this provision by several EU national authorities (i.e. several Member States are prone to consider that these products are currently not 'lawfully placed on the market'), the transitional period of 2 years will be applied by a few countries only. These diverging interpretations will furthermore create unfair competition between insect producers across the EU because of these 'differentiated treatments'*' - [IPIFF, November 2016](#).

¹⁰ The ruling of the Court of Justice of the European Union in case [C-526/19](#).

¹¹ IPIFF legal briefing note: Impact of the CJEU judgement on the novel food status of edible insects in the EU - [October 2020](#).

¹² This document complements the IPIFF position paper on *the Implementation of EU Regulation 2015/2283 on 'novel foods'*- [November 2016](#).

- defining the material scope of the old NFR 97 in the case of insect products;
- determining whether the product was legally placed on the market before 2018;
- application for novel food authorisation was submitted before 1 January 2019' under the new NFR 2015.

IPIFF welcomes the developments towards the application of the transitional measures

- I. For IPIFF, the CJEU ruling is fundamental as it **puts an end to the uncertainty** regarding the material scope of application of the old NFR 97 - thus, having a considerable impact¹³ with regard to the possibilities of placing insect products on the market of certain MS under the TM of the new NFR 2015. This ruling would be applicable to two categories of products:
 1. **Whole insects:** the CJEU ruling explicitly states that that 'whole insects' do not fall under the scope of the old NFR 97. It stems from the CJEU ruling that the terms 'foods ingredients isolated from animals', identified in the scope of the old NFR 97, do not include foods intended to be consumed in by itself.
 2. **Whole insect powders:** based on the reasoning of the Court, we may reasonably consider that both whole insects and 'foods made of whole' insects (such as powders made of whole insects - not subject to additional treatment such as protein extracts) do not fall within the scope of the old NFR 97 ('foods ingredients isolated from animals'). Although there is no clear-cut answer on this made by the Court, the fact that the CJEU did not exclude the possibility to market these products is consistent with the position adopted by national competent authorities which have considered that operators producing powders made of insects should benefit from the TM as well¹⁴.
- II. **IPIFF urges EU MS** (i.e. countries which did not implement the TM so far) to **examine the application of the TM for insects as food** foreseen in the new 'novel food' Regulation. Application of the TM, when previously denied due to the uncertainty on the scope of insects as food (i.e. if under the scope of the old NFR 97) will thereby give full effect to the CJEU ruling from 1 October 2020. To benefit from the TM, the products can continue to be placed on the market subject to the following criteria:

¹³ Sweden did not apply the TM provided under the new NFR 2015 for insect as food products, as it considered the aforementioned products under the old NFR. Following the CJEU ruling on the scope of whole insects to be not considered under the old NFR, Sweden in October 2020 applied the TM for insects as food products ([link](#)).

¹⁴ E.g. Finnish food safety authority EVIRA guide (2018): 'All operators may sell and market these insect species and products produced from them as foodstuffs'.

It is also important to note that the question referred to the CJEU only concerned the subject of 'whole insects' and not any other product such as whole insect powders. Thus, we intend to highlight that this judgment should also not be overinterpreted by MS in order to define the scope of 'whole powdered insects'. E.g. Subsequent to the ruling of the CJEU on the scope of insects as food under the old NFR 97, the Austrian authorities that applied TM for whole insects and their products (such as insect powder), demanded operators in Austria to remove insect powders or products with their integration (insect bars, pasta, etc) off the market. Thus, only allowing 'whole insect' products (whole products such as appetizers, etc) on the market. This action may be resultant to an overinterpretation of the CJEU ruling which only addressed 'whole insects'.

- the products were lawfully placed on the market by 1 January 2018
- an application¹⁵ for these foods was submitted by 1 January 2019

Once the insects as novel food applications for authorisation have been assessed, a position on whether they can be placed on the market will be known. The TM measures will continue in those countries applying it, until a decision has been taken on the authorisation of the respective novel food product¹⁶.

Lawfully placed on the market: IPIFF considers that the operators that were already active on the EU market before 1 January 2018 and were prevented from pursuing their activities due to a national interpretation (i.e. insects as food are in the scope of the old NFR 97) contrary to the CJEU's ruling should be taken into account. Such operators should not be given an unfair disadvantage due to the positions taken by their respective MS. Considering the provisions of the TM under the new NFR, until a decision of novel food authorisation would be made, these operators would have **lawfully placed their products on the market**¹⁷ complying with applicable legislative requirements encompassing both at EU (e.g. such as the General Food Law, food hygiene, etc.) and individual country level if specific provisions apply nationally¹⁸. Operators in the following situations should be encompassed whilst examining the application of the TM¹⁹:

- The company placed the products on the market and were later **subject to a prohibition or suspension to benefit from the TM** at national level²⁰;
- The company placed the products on the market but **removed them voluntarily following a general prohibition** taken on products to benefit from the TM at national level²¹.

Submission of application for authorisation: To benefit from the TM under the new NFR 2015 **an application for authorisation** should also have been legally submitted to the European Commission **for the same concerned species**, before **1 January 2019**. The TM would therefore apply operators in the following scenarios:

- The **operator itself** has introduced an application for authorisation (or a notification) as per the new NFR 2015;

¹⁵ Any form of application whether data protection has been requested by an applicant or not.

¹⁶ This information has been notified and discussed by the European Commission with the respective Member States at the Working Group on 'novel food' held on 2-3 July 2019. Furthermore, according to IPIFF's knowledge, if the authorisation is data protected, the TM will continue until the expiration of the data protection period of 5 years after which the authorisation becomes generic. At that phase, the transitional measure (for the respective species) ends.

¹⁷ The concept of 'lawfully placed on the market' should be read in the light of Article 35.2. of the new NFR, broadly phrasing. In the absence of a definition for 'geographical perimeter' associated with the concept of 'market', several national competent authorities have admitted the 'lawful commercialization of insects' in cases where a similar product (i.e. similar insect species and similar characteristics) would have been marketed in another country of the EU before 1 January 2018.

¹⁸ The EC (2013) 592 guidance document provides a lot of indications on the type of documents that can be used to prove that a product is lawfully marketed such as '*product invoice, product label, catalogue with evidence of a date, sale or tax records, registrations, licenses, notifications to/from the authorities, certifications, extracts from public records*'.

¹⁹ IPIFF Legal analysis identifies the following scenarios in regard to operators not benefiting from the TM

²⁰ E.g. Insects as food business operators in France were demanded to take down their products off the market subsequent to the stance of the national authorities. This led to the legal case of an operator vs the French national authority. The matter was taken up to the CJEU resulting in the ruling on the scope of insects as food not falling under the old NFR 97.

²¹ E.g. Insects as food business operators in Portugal voluntarily took down their products from the market subsequent to the stance of the national authorities.

- The operator is supplied by a company that submitted such application or;
- The operator produces a product for which an application for authorisation has been submitted by 'another party/operator'. In such a case, the operators will have to be able to demonstrate that both products are the result of the same production process and have the same detailed composition/meet the same specifications (product form - whole powder, paste; proposed uses- cereals, bars, pasta, bread, etc) as defined in the application for novel food authorisation.

Several national competent authorities have indeed broadly interpreted/implemented these aforementioned criteria for the TM (e.g. Netherlands, Czech Republic, etc). We believe that such positions were justified considering that the characteristics of the products and its application which formed part of these applications remain similar from products produced amongst all the operators claiming the benefit of the TM. Finally, there is no exception for insect-based food products in terms of applying EU food safety, labelling and hygiene regulations. The application of the TM concord with the current EU regulatory framework applicable to all food business operators.