Insects as Novel Foods in the European Union
Frequently Asked Questions

1. **Can edible insects be lawfully placed on the European Union (EU) market today?**

   Yes, whole edible insects and their derived ingredients can be lawfully placed on the EU market - but require pre-market authorisations. The market authorisation is granted following the submission of an application to the European Commission (EC), the safety evaluation of the novel food by the European Food Safety Authority (EFSA) and a favourable vote given by the EU Member States (MS). Edible insects are regulated under the 'new' EU novel foods legislation – Regulation (EU) 2015/2283 which applies from 1 January 2018.

2. **When could we expect the first authorisations for insects as a novel food?**

   On 24 November 2020, the NDA Panel of the **European Food Safety Authority** (EFSA) concluded that **dried yellow mealworm is safe for human consumption** - under the levels and uses proposed by the applicant (the company EAP Group Agronutris). Published on 13 January 2021, the EFSA scientific opinion represents an important milestone towards the EU authorisation of insects as food. Following this step, the EFSA opinion is sent to the European Commission which proposes the EU authorisation of the novel food and the formulations covered by the respective opinion – a proposed Implementing Regulation which must obtain the approval of the Member States of the European Union (by qualified majority).

   The vote of the EU Member States could take place in **mid-2021**, leading to the authorisation of the species/product - and the formulations covered by the abovementioned opinion - on the entire EU market (for more information on this process, please consult the IPIFF Briefing paper on the commercialisation of edible insects, Chapter 4.1).

3. **Why does this opinion cover 'dried yellow mealworm' only ? Are there other applications for insects as novel food which have been submitted to the European Commission since the new novel foods legislation entered into force?**

   EFSA's assessments are conducted based on individual applications submitted by insect producers (e.g. in this case, the application was submitted by the company EAP Group Agronutris and concerned 'dried yellow mealworm' (*Tenebrio molitor*) and intended to be consumed as whole insects or in form of a powder).

   Currently (January 2021) there over **twenty applications** submitted for the authorisation of insects as a novel food. Several species are covered, including *Acheta domesticus* (house cricket), *Alphitobius diaperinus* (lesser mealworm), *Gryllodes sigillatus* (banded crickets), *Hermetia illucens* (black soldier fly), *Locusta migratoria* (migratory locust), *Tenebrio molitor* (yellow mealworm) and *Apis mellifera* male pupae (honeybee drone brood).

4. **Who are the actors that have submitted such applications? Has IPIFF submitted an application?**

   The actors who have submitted these applications are mostly insect primary producers/insect breeders (usually micro-, medium-sized or small enterprises) who sell insects as 'ingredient' to a subsequent processor (operators involved in the preparation of insect-based ingredients or end-consumer products) and/or directly to consumers through an intermediary or distributor. The definition of 'placing on the market' in the 'General Food Law' (i.e. Regulation (EC) No 178/2002), provides 'indications' on those actors (on whom the responsibility for submitting an application for authorisation mainly lies, namely the first food business operator that places a novel food on the EU market). Consequently, the main responsibility of submitting applications will generally lie on the insect primary producers (breeders), as they determine the composition / intrinsic characteristics of the product that forms the subject-matter of the application.

   No, IPIFF has not filed any novel food application.

   However, several applications were submitted by a national association of insect producers (i.e. the Belgian Insect Industry Federation).

5. **How much does it cost to submit an application and how complex is the process to obtain an authorisation?**

   There are **no costs for submitting a novel food application** to the European Commission (EC). A novel food application for authorisation is submitted through a dedicated e-submission portal. An application shall be submitted electronically to the EC and shall consist:

   (a) a cover letter;

   (b) a technical dossier;

   (c) a summary of the dossier.

   After the receipt of the application, the procedural steps to be followed by the EC, the EU Member States and the EFSA are laid down in Chapter III of Regulation (EU) 2015/2283. An authorisation process takes (on average) about 17 months, excluding possible 'clock stops'[1].

1 When EFSA is conducting its risk opinion during an authorisation or notification procedure of a novel food application, it may ask for additional information in order to complete its evaluation. When this happens, the clock of the regulatory timetable for the risk assessment is stopped until the requested data is sent.

6. **If insects are not yet authorised on the entire EU market, why can we still find them in certain EU Member States (MS)?**

   In that context, several MS have admitted the commercialisation of these products on their national market, considering that they complied with general food safety standards. Several other EU Member States accepted its commercialisation under more restrictive conditions, while a few others denied it. This resulted in **creating divergent interpretations amongst the MS** (for further information, please read the IPIFF Contribution Paper on the application of the novel food transitional measure 10-12-2020).

   To offer time to businesses involved in the placing on the market of edible insects, the new novel foods regulation includes a 'transitional measure' (article 35.2). To benefit from the transitional measure, the insect food products (whole insects or food products derived from whole insects) that were marketed in one EU Member State before the end of 2017 (i.e. 31 December 2017) can continue to be placed on the market subject to the following criteria:

   - the products were lawfully placed on the market by 1 January 2018;
   - an application (data protected/non-data protected) for these foods was submitted by 1 January 2019.

   If these criteria are met, the commercialisation of this product on the territory of this EU Member State may continue until a final decision on the EU authorisation of this product is taken (i.e. the EU novel food authorisation).

The approach of the Member States on the implementation of the 'EU novel food transitional measure for whole insects and their preparations'

- EU countries in which national authorities have agreed to grant the novel food transitional measure to whole insects and/or their derived products;
- EU countries in which national authorities did apply the novel food transitional measure, but imposed specific conditions (e.g. the transitional measure only applies to whole insects and not to powder derived from it, the implementation of the transitional measure is limited to certain administrative regions);
- EU countries in which national authorities took the position to deny the implementation of the transitional measure (or applied it restrictively) and whose position may possibly evolve, following the Court of Justice of the European Union ruling (see question 8 for further details);
- **EU Member States whose position is unknown to the authors** at the time of drafting this document;
- **Non-EU countries** from which **insects as food may not be placed on the EU market;**
- Insect food products originating from these non-EU Member States may be placed on the market of those EU Member States which apply the transitional measure under national legislation. Once a novel food authorisation has been granted for a specific product, it can be exported to the EU.

The International Platform of Insects for Food and Feed (IPIFF) is a nonprofit organisation which represents the interests of the insect production sector towards EU policymakers, European stakeholders and citizens. Composed of 74 members, most of which are European insect producing companies, IPIFF promotes the use of insects and insect-derived products as top tier source of nutrients for human consumption and animal feed.

7. **How can it be determined whether insects and their preparations were lawfully placed on the market before 1 January 2018?**

The 'lawful placing on the market' of insects and their preparations was essentially based on their classification or not as 'novel food' (i.e. their 'novel' status) under the old novel foods regulation. Thus, if the MS regarded edible insects as 'novel' under 'old novel food regulation', then the product was not (and still is not) 'lawfully placed on the market'. The reasoning entails that the concerned product should have been authorised (i.e. an application be submitted through the novel food authorisation procedure) in accordance with the requirements of the 'old novel foods regulation' to be considered as 'lawfully placed on the market'. Thus, such a product would not qualify for the application of the transitional measures under the 'new novel foods regulation'. In practice, no novel food authorisation has been granted for any insect product under the 'old novel food regulation'.

An overview of the different interpretations and positions adopted by the different EU Member States concerning whole insects and their preparations can be found in the IPIFF Briefing paper on the commercialisation of edible insects the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU (see page 37).

8. **What is new since the CJEU ruling from 1 October 2020? Does it impact the 'transitional measure'?**

On 1 October 2020, the Court of Justice of the European Union (CJEU) ruled that 'whole insects' as food do not fall under the scope of the old Novel Food Regulation (EC) No 258/97. This judgment created a jurisprudence applicable in every EU Member State, thus may have a significant impact for insect producers/operators active in those EU Member States not benefiting from the transitional measure (see above).

Summary overview of the respective scopes of Regulation (EC) No 258/97 and Regulation (EU) 2015/2283 with respect of whole insects, parts of whole insects and insect-based preparations

	Regulation (EC) No 258/97	Regulation (EU) No 2015/2283
Whole insects	✗ Not in scope * **	✓ In scope
Parts of whole insects and ingredients processed from whole insects (e.g. whole insects powder)	✗ Not in scope * **	✓ In scope
Ingredients other than (parts of) whole insects (e.g. insect extracts)	✓ In scope	✓ In scope

*Diverging national interpretations - some Member States did consider these categories of products as novel food under Regulation (EC) No 258/97.
** According to the CJEU ruling from the 1 October 2020, 'whole insects' were not covered by the Regulation (EC) No 258/97. From this ruling, 'whole insects' could be interpreted as covering the ingredients processed from whole insects.

In light of the ruling, and with the legal clarity on the scope of insects as food, the respective Member States should give full effect to the transitional measure foreseen in article 35.2 of the new novel foods Regulation (EU) No 2015/2283.

Yet, the consequences of the ruling vary depending on the concrete situation of each operator (e.g. whether or not the insect food products were commercialised in the country before 1 January 2018). In that context, IPIFF encourages insect producers - active in those countries where the possibility to use the 'transitional measure' was denied - to adopt a concerted approach towards their competent authorities. Notably, these companies should clarify with the corresponding authorities whether and how this ruling may apply to their particular situation.

9. **Are producers of insects that have been able to market their products under the novel food transitional measures exempt from any food safety obligation?**

No. In line with the European legislation, producers of insects and their preparations are considered food producers 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 very strict **specifications both in terms of hygiene practices and traceability**. Furthermore, food labelling criteria under the Regulation (EU) No 1169/2011 on provision of food information to consumers, should be adhered by insects as food business operators.

2 As of January 2021, the authorities from Vietnam provided sufficient safety and hygiene guarantees on the insect production and control and will be added to the list. However, imports of insects from Vietnam will only be allowed in the EU once the amending Regulation comes into force

10. **If the authorisation is granted to an insect as novel food application, would that mean that any operator producing the same authorised edible insect has the possibility to market the product?**

The final decision on the latter lies with the European Commission (EC) when proposing – to the EU MS which must agree (via 'qualified majority') with the EC proposal for grating data protection - to authorise the product as novel food.

However, these features and improvements in the Regulation also include a possibility for 'Promotion of innovation' by granting an **individual authorisation for five years** based on protected data, after which the authorisation becomes generic. Data protection is granted based on the data being newly developed scientific evidence and proprietary. That means that an applicant may be **granted an individual authorisation for placing on the market an insect-based novel food for a period of five years** after which the authorisation will apply to all the operators. The final decision on the latter lies with the European Commission (EC) when proposing - to the EU MS - to authorise the product as novel food. To this end, the EC assesses the justification submitted and decides as to whether or not the applicant fulfils the requirement for benefiting from data protection. Pursuant to article 26 (2) of Regulation (EU) 2015/2283, **three cumulative conditions** must be met to be eligible for data protection:

- The data must consist of newly developed scientific evidence or scientific data that the applicant has designated as proprietary upon the first application;
- At the time the first application was made, the initial applicant had an exclusive right of reference to data;
- The novel food could not have been assessed by the EFSA and authorised by the Commission without the submission of the concerned data by the initial applicant.

11. **Can an authorisation based on protected proprietary data be extended to a third party?**

Yes, if the initial applicant agrees with (a) subsequent applicant(s) on the use of the data that benefits from 'data protection', the latter must file a separate authorisation application to the EC accompanied by the agreement made by the two parties to benefit on placing the said product on the market (ceasing 'protected data' to a subsequent producer in the framework of a contractual agreement).

12. **Can non-EU insect food business operators place edible insects on the EU market?**

Yes - in addition to the authorisation as a novel food, insects intended for human consumption farmed and exported from Canada, South Korea, Switzerland, Thailand and Vietnam (i.e. countries listed in Annex IIIa to Commission Implementing Regulation (EU) 2019/626 and in the IPIFF information note available on the IPIFF website) may be placed on the EU market. The European Commission intends to expand this list, provided that sufficient data and information about insect production activities is presented (e.g. sufficient safety and hygiene guarantees). Applications from other countries are currently being examined[2].

13. **What is the status of Great Britain with regards to the import of insects as food into the EU?**

As from 1 January 2021, Great Britain (GB) has the status of a 'third country' and would need to follow the same authorisation process as indicated in the Regulation (EU) 2019/626.
British insect food business operators who would like to access the EU market should contact their respective national competent authority.

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