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. A novel food 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. The EU Member States recently voted on a draft Implementing Regulation in which it is suggested to authorise whole, dried yellow mealworm (and derived products) for human consumption. What are the next steps following this vote and when can we expect the authorisation to be effective?

Following the vote by the EU Member States on the draft Implementing Regulation suggesting to authorise whole, dried yellow mealworm (and derived products) for human consumption, the European Commission will have to adopt the text formally, before it is published in the EU Official Journal. The completion of these next procedural steps and thus the entry into force can be expected by the end of June.

A prerequisite of the recent positive vote was the scientific opinion of the European Food Safety Authority's (EFSA) NDA Panel - published on 13 January 2021 - in which it was concluded that dried yellow mealworm is safe for human consumption under the levels and uses proposed by the applicant (the company SAS EAP Group Agronutris). This authorisation will, in the first instance, only benefit the applicant (SAS EAP Group Agronutris) as well as the companies using the applicant’s product in a derived food product (see answer to questions 10 and 11 for more details on this subject). It will be valid for the entire EU market which means that the product may be freely marketed across all EU Member States’ territory (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 draft Implementing Regulation 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?

Insect food products are assessed and then - potentially - authorised based on individual applications submitted by insect producers (e.g. in the above mentioned case, as previously indicated, the application leading to the draft Implementing Regulation was submitted by the company SAS EAP Group Agronutris) and covers ‘whole, dried yellow mealworm’ (Tenebrio molitor) intended to be consumed as whole insects or in the form of a powder to be incorporated into different food products.

So far, the European Commission has received more than 20 novel food applications for insect food products. Several species are covered, including Acheta domesticus (house cricket), Alphitobius diaperinus (lesser mealworm), Gryllodes sigillatus (banded crickets), Hermetia illucens (black soldier fly), Lucusta migratoria ( migratory locust), Tenebrio molitor (yellow mealworm) and Aphis mellifera male pupae (honey bee drone brood).

At the time of writing (end of April 2021), the status of the different applications submitted is as follows:

- One application has been assessed by EFSA and has subsequently led to a vote by the EU Member States (application by the company SAS EAP Group Agronutris). The authorisation procedure is expected to be completed by the end of June;
- Eight applications might currently be assessed by EFSA;
- The other applications - of which the majority has been submitted in time (i.e. before 1 January 2019) - are in the validity phase (or ‘suitably check phase’), meaning it is checked that the application is considered as complete and therefore ready to be assessed. EFSA is responsible for reviewing the applications in that regard. In case additional information is required, EFSA will contact the applicant and request the necessary document(s); however, the applicant must provide the requested document(s) within a timely manner, otherwise, the European Commission services may terminate the application in question (for details on the consequences of such a decision, please refer to question 11).

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 (operates 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) 178/2002) provides indications on those actors whom the legislator seeks responsible for submitting an application for authorisation, namely the first food business operator that places a novel food on the EU market (i.e. the first actor in the supply chain). 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.

However, three applications were submitted by a national association of insect producers (i.e. the Belgian Insect Industry Federation) and one by the Finnish Beekeepers’ association.

IPIFF has not filed any novel food application itself. IPIFF seeks, however, to support all ‘interested applicants’ by providing them with general scientific evidence (existing literature on toxicologic risk associated with insect food, information on history of insect production in Europe) and legal and administrative support in the preparation of their applications.

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

There are no direct costs linked to the submission of a novel food application to the European Commission. A novel food application for authorisation is submitted through a dedicated e-submission portal to the EC and shall consist of:

A. a cover letter;
B. a technical dossier (for more information on the content of the technical dossier, you may consult the IPIFF Briefing Paper on Novel Foods, chapter 4.5).
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 EFSA are laid down in Chapter III of Regulation (EU) 2015/2283. Several MS have admitted the commercialisation of these products on their national market, provided that they comply with general food safety standards. Other EU Member States have accepted their commercialisation under more restrictive conditions, while a few others denied it. The different national approaches are the result of uneven implementations of the ‘transitional measure’ laid down in article 35.2 of the new novel foods legislation (for further information, please refer to the IPIFF Contribution Paper on the application of the novel food transitional measure, 10 December 2020).

The transitional measure was introduced in the Regulation (EU) 2015/2283 to allow food business operators (including not only insect producers who had lawfully placed their products on their respective national market before 1 January 2018 to continue to do so, until a final decision on the novel foods applications) to take. This measure aims at giving food business operators more time to adapt to the new regulatory landscape (for more details, see answer to question 7 below).

To benefit from the transitional measure, the following criteria must be met:

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

If these criteria are met, the commercialisation of the respective 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 foods 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 75 members, most of which are European insect producing companies, IPIFF promotes the use of insects and insect-derived products as a 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?

Whether an insect food product has been ‘lawfully placed on the market’ depends on whether it has been classified as ‘novel food’ i.e. its ‘novel status’ according to the former novel foods regulation (Regulation (EC) 258/97) by the respective national authority or not. Regulation (EC) 258/97 was in force from 1 January 2000 until 31 December 2017 when it was replaced by Regulation (EU) 2015/2283 (Regulation (EU) 2015/2283). Under NFR 1997, a foodstuff was classified as ‘novel’ if it had not been consumed ‘to a significant degree’ in the EU before 15 May 1997 and if it fell under one of the categories listed in the Regulation. However, the EU Member States interpreted the regulation differently. They did not uniformly consider whole insects and their derived products as ‘novel’ food (i.e. food added to human food after 5 January 1997), and food ingredients isolated from animals. As a result, some Member States considered whole insects and their derived products as ‘novel’ pursuant to NFR 1997, others did not.

Those Member States which did consider whole insects and their derived products as ‘novel’ pursuant to Regulation (EU) 258/97, requested from the producers of these products – article 4 of the before-mentioned regulation – to submit a novel food application. If the foodstuff had been used as food or food ingredient before this date, and if it was to be used as food for the first time in the EU, it had to be submitted for authorisation in accordance with NFR 1997. 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 insect producers – active in those countries where the possibility to use the ‘transitional measure’ was denied – to adopt the insect food products were commercialised in the country before 1 January 2018). For this reason, IPIFF encourages insect producers/operators active in those EU Member States not benefiting from the transitional measure to give full effect to 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) 2015/2283 provided that the conditions for applying the transitional measure are met.

Indeed, the consequences of the ruling vary depending on the concrete situation of each operator (e.g. whether or not the product is regulated at the EU level). According to the Court’s ruling, the producer/exporter of dried insects active in the country before 1 January 2018 i.e. insect producers – active in those countries where the possibility to use the ‘transitional measure’ was denied – to adopt the insect food products were commercialised in the country before 1 January 2018. For this reason, IPIFF encourages insect producers/operators active in those EU Member States not benefiting from the transitional measure to give full effect to 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) 2015/2283.

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) 2015/2283 provided that the conditions for applying the transitional measure are met.

In summary 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

<table>
<thead>
<tr>
<th>Regulation (EC) No 258/97</th>
<th>Regulation (EU) No 2015/2283</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole insects</td>
<td><strong>Not in scope</strong></td>
</tr>
<tr>
<td>Parts of whole insects and ingredients isolated from insects (e.g. whole insects powder)</td>
<td><strong>Not in scope</strong></td>
</tr>
<tr>
<td>Ingredients other than (parts of) whole insects (e.g. insect extracts)</td>
<td>In scope</td>
</tr>
</tbody>
</table>

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 foods Regulation (EC) 258/97 (i.e. not covered under the category of food listed in article 2 of NFR 1997. Accordingly, the terms ‘foods ingredients isolated from animals’, identified in the scope of NFR 1997, do not include foods ingredients isolated from whole insects. The latter are products which are to be added to food as such for human consumption, and the Court considered that these products are not novel for the purposes of NFR 1997. The judgment created a jurisprudence applicable in all EU Member States, thus may have a significant impact for insect producers/operators active in those EU Member States not benefiting from the transitional measure (see answers to questions 6 and 7).

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) 2015/2283 provided that the conditions for applying the transitional measure are met.

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 law (Regulation (EC) No 2002 (General Food Law) on food safety) and the European ‘hygiene package’) require these producers to respect very specific strictifications both in terms of hygiene practices and traceability. Likewise, the Regulation (EU) 1169/2011 on provision of food information to consumers, should be adhered by insects as food business operators.

10. If an authorisation is granted for an insect food product (e.g. whole insects or insect-derived products), may other operators producing the same authorised insect food product still sell it on the market? What are the implications of the following additional agreement granted to SAS EAP Group Agronutris to authorised producers of dried yellow mealworm?

The implications of an authorisation granted for an insect food product depends on whether the authorisation is based on protected data or not. Under the new novel foods legislation (Regulation (EU) 2015/2283), applicants may request that the data included in the application shall not be used for the benefit of a subsequent application during a period of five years. Thus, in case an application in which data protection is requested, is authorised, the original applicant has de facto the exclusive right to commercialise the respective insect food product for five years. In the case of SAS EAP Group Agronutris’ application covering dried yellow mealworm, data protection was requested and has been granted. As a result, as soon as the authorisation is granted, the producer/exporter will have the exclusive right to commercialise the product in question on the EU market for a period of five years, unless decided otherwise by the company (see below for more details).

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 the data;
- The novel food could not have been assessed by EFSAM and authorised by the Commission without the submission of this data protection request

The decision on whether data protection is granted or not, lies with the European Commission.

In the case of the above-mentioned application submitted by the company SAS EAP Group Agronutris, EFSAM mentioned in its opinion that it considered the data as provided essential for the safety assessment. As a result, it could be expected that data protection would then be granted.

In addition to SAS EAP Group Agronutris, several other companies have submitted applications in which data protection is applied. Some companies have not requested data protection, while other companies have requested data protection in applications in which in question data protection is not possible. In such a scenario, the company (or organisation) may request from the producers of these products - article 4 of the before-mentioned regulation - to submit a novel food application. In such a scenario, the products referred to are consequently not eligible for the transitional measures for the ‘novel foods regulation’ (for more information on the different interpretations and positions adopted by the different EU Member States concerning whole insects and their preparations, refer to the graphical illustration (i.e. map of Europe) included in this document).

11. To what extent do authorised novel foods products impact the application of the transitional measure?

As highlighted in answer to question 6, insect food products can benefit from the transitional measure under article 35.2 of Regulation (EC) 258/97 if the product was legally placed on the market before 1 January 2018 and if an application for a new food product was submitted by 1 January 2018. However, as a result of the CJEU ruling, the transitional measure ceases to be applicable for a specific insect food product, once a decision on the application covering this food product has been taken by the European Commission. The decision will have consequences for the other producers of the same food product who have benefited from the transitional measure until then.

Several different scenarios can be envisaged. In case:

A. the food product is authorised and the authorisation is ‘generic’ (meaning data protection was either requested in the application or it was requested, but was not granted), the novel food product covered in question may consequently be placed on the market by any operator, provided that the specifications and conditions of use laid down in the authorisation are complied with;

B. the novel food product is authorised and data protection is granted, the implications for the other producers of the same product, depend on whether other outstanding NF application(s) covering the same product are submitted; and

C. the novel food is not authorised by the European Commission (e.g. if the applicant did not provide the requested clarifications during the time given period), the implications are the same as described under B.

In the case of dried yellow mealworm, there are at least two outstanding applications covering the same insect food product, although both these applications concern insect food products in those EU Member States which apply the transitional measure. This possibility lasts until a final decision is taken on these outstanding applications (Please note that this information only reflects an interpretation made by the IPFF Secretariat, based on information collected from public authorities, such as EFSA and/or informal discussions).

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

Yes - in addition to 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 III to Commission Implementing Regulation (EU) 2017/1895, which apply the transitional measure). This possibility lasts until a final decision is taken on these outstanding applications (Please note that this information only reflects an interpretation made by the IPFF Secretariat, based on information collected from public authorities, such as EFSA and/or informal discussions).