

FREQUENTLY ASKED QUESTIONS

COMMERCIALISATION OF EDIBLE INSECTS IN THE EU

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.

For more information please consult the IPIFF INFO SHEET- HOW TO SUBMIT AN APPLICATION FOR AN EDIBLE INSECT NOVEL FOOD AUTHORISATION

2. If the Novel Foods application entered into force in 2018 why are there edible insects being commercialised before this date?

Several MS have tolerated 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 EU novel foods legislation. The transitional measure was introduced in the Regulation (EU) 2015/2283 to allow food business operators (including notably insect producers) who had lawfully placed their products on their respective national markets before 1 January 2018 to continue to do so, until a final decision on the application of the novel food (s) is taken. This measure aims at giving food business operators more time to adapt to the new regulatory landscape. To benefit from the transitional measure, the product was lawfully placed on the market by 1 January 2018. 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.

For more information please consult the IPIFF INFO SHEET ON THE APPLICATION OF THE TRANSITIONAL MEASURE



3. Which edible insects are authorised as Novel Food for human consumption in the EU and which are the authorised companies to commercialise them?

Presently (Q1 2023), 6 Novel Food authorisations have entered into force for edible insects, covering 4 different insect specie: (1) Agronutris's dried Yellow Mealworm *(Tenebrio molitor)*; (2) Protix's frozen, dried powder forms of Migratory Locust (*Locusta migratoria*); (3) Protix's frozen, dried, and powder forms of yellow mealworm (*Tenebrio molitor*); (4) Protix'srozen, dried, and powder formulations from house crikets (*Acheta domesticus*); (5) Cricket One.'s partially defatted powder forms of house cricket (*Acheta domesticus*) and (6) Ynsect's frozen, paste, dried, and powder formulations of Lesser mealworm (*Alphitobius diaperinus larvae*).

For more information, including access to each related European Food Safety authority's products safety opinion and each respective Commission Implementing Regulation, please consult the <u>INFO SHEET-THE</u> <u>COMMERCIALISATION OF EDIBLE INSECTS IN THE EU</u>

4. Can other companies besides those who have submitted a Novel Food application commercialise edible insects in the EU?

Presently all the authorised edible insects in the EU respect data-protected applications. Therefore, only authorised companies or those companies who have celebrated a commercial agreement with an authorised Novel Food application company, can commercialise them in the Internal Market.

For more information please consult the IPIFF <u>INFO SHEET TYPES OF NOVEL</u> <u>FOOD APPLICATION</u>

A business operator with a commercial agreement with an authorised applicant of a Novel Food product does not need to submit a different application to the European Commission. The business operator can commercialise the product in question, based on the terms defined in the agreement signed between both parties. Notwithstanding, the business operator continues to comply with all applicable national legislation where the product is to be commercialised (e.g. hygiene standards, safety, and security). EU national competent entities have the authority to verify its compliance and may request the business operator to present the commercial agreement in question. The European Commission Directorate-General on Health and Food Safety (DG SANTE) provides an open platform with data shared from all EU Member States' competent authorities, where all existing commercial agreements can be checked.

- For more information please consult the IPIFF INFO NOTE ON THE EXTENSION OF COMMERCIAL RIGHTS NOVEMBER 2022
- For information on the import, exports, and classification of edible insects as a traditional food from third countries, please consult the IPIFF INFO SHEET 03-EXPORTS-IMPORTS-INSECTS AS THIRD COUNTRY TRADITIONAL FOOD;



EDIBLE INSECTS AS ANY TYPE OF FOOD COMMERCIALISED IN THE EUROPEAN UNION MUST COMPLY TO ALL APPLICABLE FOOD RELATED LEGISLATION

5. What is the applicable legislation for edible insects for human consumption in the EU?

THE NOVEL FOOD REGULATION

REGULATION (EU) 2015/2283 OF 25 NOVEMBER 2015 of the European Parliament and of the Council 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 (latter referred as the 'Novel Food Regulation'). The Novel Food Regulation applies to certain categories of foods, including foods originating from plants, animals, microorganisms, cell cultures, or minerals (e.g., botanical extracts, insects, vitamins, minerals, food supplements, etc.) that were not used for human consumption to a significant degree within the EU before 15 May 1997, or resulting from production processes or practices not commonly used before that date (i.e., 'novel foods'). 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. 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.

COMMISSION IMPLEMENTING REGULATIONS

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 Member States.

GENERAL FOOD LAW

<u>REGULATION (EC) NO 178/2002 OF 28 JANUARY 2002</u> 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. The General Food Law Regulation is the foundation of food and feed law. It sets out an overarching and coherent framework for the development of food and feed legislation both at Union and national levels. To this end, it lays down general principles, requirements and procedures that underpin decision-making in matters of food and feed safety, covering all stages of food and feed production and distribution.



THE OFFICIAL CONTROLS REGULATION

<u>REGULATION (EU) 2017/625 OF 15 MARCH 2017</u> of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, and plant protection products. The regulation establishes common rules for EU official controls to ensure that agri-food chain legislation for the protection of human health, animal health and welfare, and plant health, is correctly applied and enforced. The regulation introduces a better harmonised and coherent approach to official controls and enforcement measures along the agri-food chain and strengthens the principle of risk-based controls.

EU FOOD LABELLING LEGISLTATION APPLIES TO EDIBLE INSECTS

6. What are the labelling rules edible insects must comply with in the EU?

<u>REGULATION (EU) NO 1169/2011</u> of the European Parliament and of the Council of 25 October 2011 on the provision of Food Information to Consumers (FIC) codifies and modifies the provisions on food labelling applicable in the Union at the time. One of the main objectives of the FIC Regulation is to allow consumers to make informed choices and to make safe use of food, while at the same time ensuring the free movement of legally produced and marketed food in the EU. The FIC Regulation is applicable to all foods intended for the final consumer since 13 December 2014. Edible insect-based food products intended for final consumers are subject to all provisions of the FIC Regulation. Moreover, each authorised edible insect Novel Food product respective Commission Implementing Regulation establishes additional specific labelling requirements. All food products containing edible insects as ingredients must state such on its label.

SAFE HYGIENE PRACTICES

The prime objective of the European insect production sector is to produce safe products suitable for both human consumption and animal feed. Against this background, in November 2016, the IPIFF members decided to launch a Task Force on 'Good Hygiene Principles' aimed at preparing and developing a <u>Guide on Good Hygiene Practices (GHP)</u> for insect production (hereafter referred to as 'the Guide'), which is currently under discussion within the European Commission comitology work in view of being adopted as an official guide for Good Hygiene Practices for insect production in the EU.

EDIBLE INSECTS COMMERCIALISED IN THE EU ARE SAFE FOR CONSUMPTION

7. Are there any safety concerns related to the consumption of edible insects?

All edible insects available in the EU market are safe for consumers. 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).



8. Do edible insect food products provoke any type of allergic reaction?

The EU rules on food labelling identify a list of 14 allergens that need to be labelled (e.g. eggs, milk, fish, crustaceans etc...). This is to allow people living with food allergies to be informed on whether products contain ingredients they are sensitive to. EFSA concluded that the consumption of the so far evaluated insect proteins which lead to their respective authorisation may potentially lead to allergic reactions, where it may be the case for those with pre-existing allergies to crustaceans, dust mites and in some cases molluscs. Additionally, allergens from the feed (e.g. gluten) may end up in the insect that is consumed. Therefore, the authorisation of this novel food clarifies this issue and lays down specific labelling requirements regarding allergenicity'.

For more information please consult the Commission Implementing Regulations for each authorised edible insect products as Novel food: <u>INFO</u> <u>SHEET 02-APPLICABLE LEGISLATION FOR EDIBLE INSECTS IN THE EU</u>