

## **INFO SHEET**

### ***EU APPLICABLE LEGISLATION FOR THE COMMERCIALISATION OF EDIBLE INSECTS***

#### **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’).

#### **SINCE WHEN DOES IT APPLY?**

- 🌐 Regulation (EU) 2015/2283 has become applicable on 1 January 2018. It repeals and replaces Regulation (EC) No 258/97, which has been in force until 31 December 2017.

#### **WHAT IS IT?**

- 🌐 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.
- ✚ 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.
- ✚ The qualification of whole insects as novel foods was legally uncertain under Regulation (EC) No 258/97, and this has led to diverging approaches among the EU Member States, thereby generating a contrasting impact on the possibility for insect producers to continue marketing these products under the transitional provisions provided for under this Regulation. *Please check [the IPIFF Fact Sheet on the Implementation of the Novel Food Transitional Measure on Edible Insects](#).*

## RELATED LEGISLATION

### ✚ [“IMPLEMENTING REGULATION \(EU\) 2018/456”](#)

Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the **procedural steps of the consultation process for the determination of novel food status** in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

### ✚ [“IMPLEMENTING REGULATION \(EU\) 2017/2470”](#)

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 **establishing the Union list of novel foods** in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

🚩 **[“IMPLEMENTING REGULATION \(EU\) 2017/2469”](#)**

Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 **laying down administrative and scientific requirements for applications** referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

🚩 **[“IMPLEMENTING REGULATION \(EU\) 2017/2468”](#)**

Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 **laying down administrative and scientific requirements concerning traditional foods from third countries** in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

## NOVEL FOOD AUTHORISATIONS ARE PRODUCT-SPECIFIC

🚩 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 Member States.

## THE AUTHORISATION OF THE CONCERNED INSECT PRODUCTS ARE DEFINED THROUGH 'INDIVIDUAL REGULATIONS ADOPTED BY THE EUROPEAN COMMISSION'

### [COMMISSION IMPLEMENTING REGULATION \(EU\) 2021/882 OF 1ST OF JUNE 2021](#)

authorising the placing on the market of dried yellow mealworm (*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. The former 'positive' opinion on behalf of the European Food Safety Authority (EFSA) was published on the 21st of January 2021.

### [COMMISSION IMPLEMENTING REGULATION \(EU\) 2021/1975 OF 12TH OF NOVEMBER 2021](#)

authorising the placing on the market of frozen, dried, and powder forms of migratory locust (*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. The respective 'positive' opinion from the EFSA was published on the 2nd of July 2021.

### [COMMISSION IMPLEMENTING REGULATION \(EU\) 2022/169 OF THE 8TH OF 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 European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470. The associated 'positive' opinion was published by the EFSA on the 25th of August 2021.

### [COMMISSION IMPLEMENTING REGULATION \(EU\) 2022/188 OF 10 FEBRUARY 2022](#)

authorising the placing on the market of frozen, dried, and powder forms of house cricket (*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. The respective 'positive' opinion from EFSA was published on the 17th of August 2021.

## **“REGULATION (EC) NO 258/97” - THE FORMER NOVEL FOODS REGULATION**

- 🚩 [REGULATION \(EC\) NO 258/97 OF 27 JANUARY 1997](#) of the European Parliament and of the Council 1997 concerning novel foods and novel food ingredients. This regulation was replaced by Regulation (EU) 2015/2283 on Novel Foods. [Please consult the Fact Sheet on the implementation of the Novel Food Transitional Measure on Edible Insects.](#)

## **“TRANSPARENCY REGULATION”**

- 🚩 [REGULATION \(EU\) 2019/1381 OF 20 JUNE 2019](#) of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

## **THE MAIN ELEMENTS OF THE REGULATION AIM AT:**

- 🚩 **INCREASING THE INDEPENDENCE OF STUDIES:** Potential applicants are required to notify all studies they undertake for authorisation purposes when commissioned, by the European Food Safety Authority; this provision provides additional guarantees that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies. The Authority also provides general advice to applicants, in particular SMEs, prior to the submission of the dossier, upon request. The Commission also has the possibility in exceptional circumstances of serious controversies or conflicting results to ask the Authority to commission additional studies for verification purposes. Finally, the Commission will be performing a series of fact-finding missions to assess the compliance of laboratories/studies with standards until March 2025.

- ✚ **STRENGTHENING THE GOVERNANCE AND THE SCIENTIFIC COOPERATION:** As of 1 July 2022, Member States, the European Parliament, the Commission as well as food chain and civil society interests are involved in the governance of the Authority by being duly represented in its Management Board. Member States are expected to foster the Authority's scientific capacity and engage the best independent experts in its work.
- ✚ **DEVELOPING COMPREHENSIVE RISK COMMUNICATION:** A general plan for risk communication will be adopted to ensure a coherent risk communication strategy throughout the risk analysis process, combined with open dialogue amongst all interested parties.

The main implications of this legislation for the insect sector are translated into, for example, the obligation for insect producers to provide additional studies when required. Also to note that applications submitted before the entry into force of the mentioned Regulation were not covered by these rules.

## “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.

## WHAT IS THE PURPOSE OF THIS REGULATION?

- ✚ 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.

- It also sets up an independent agency responsible for scientific advice and support, the European Food Safety Authority (EFSA). Moreover, it creates the main procedures and tools for the management of emergencies and crises as well as the [RAPID ALERT SYSTEM FOR FOOD AND FEED](#). The General Food Law Regulation ensures a high level of protection of human life and consumers' interests in relation to food while ensuring the effective functioning of the internal market.

## **“OFFICIAL CONTROLS REGULATION”**

- [REGULATION \(EU\) 2017/625 OF 15 MARCH 2017](#) 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.

### **WHAT IS THE PURPOSE OF THIS REGULATION?**

- 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.

## **GUIDANCE DOCUMENTS**

### **“EFSA Guidance on Applications for Authorisation”**

- Provides guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1), published on 26 March 2021.

### “EFSA Guidance on Applications and Notifications of Traditional Food”

- ✚ Provides guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (Revision 1), published on 26 March 2021.

For more in-depth information on all applicable legislation and procedures please consult the [IPIFF Briefing Paper- Regulation 2015/2283 on novel foods-](#) *“On the provisions relevant to the commercialisation of insect-based products intended for human consumption in the EU”*