



# Regulation (EU) 2015/2283 on novel foods

Briefing paper on the provisions relevant  
to the commercialization of insect-based  
products intended for human consumption  
in the EU

V.2  
Brussels,  
August 2019



International Platform  
of Insects for Food and Feed

# Regulation (EU) 2015/2283 on novel foods

## Briefing paper on the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU

### Preliminary remarks on the objectives and proposed use of this document

This briefing paper sets out the **administrative steps** to be followed by insect producers intending to submit an application for **authorisation of an insect/insect product as novel food** within the European Union. It is intended to be used as a practical guide to the EU legislative texts that are applicable to their activities, namely Regulation (EU) 2015/2283 on novel foods and its implementing measures (see section I.1 for further information).

This briefing paper may also serve as guidance for other stakeholders, including all food business operators using insect products (i.e. by incorporating the insect raw material into food preparations) for final sale to consumers.

This briefing paper has been drafted by the **IPIFF Secretariat**, in collaboration with the Law Firm **Bird & Bird LLP**.

### DISCLAIMER

This briefing paper is a non-binding document that is intended to facilitate the interpretation and application of the legislation on novel foods and does not constitute legal or professional advice. It does not necessarily reflect the official position of the European institutions (e.g. European Commission) the European Food Safety Authority, nor of IPIFF or its members.

The binding interpretation of legislation is the exclusive competence of the competent national and European jurisdictions. The views expressed in this guidance document cannot prejudice the position that the authors of this briefing paper might take before the jurisdictions


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International Platform  
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# 1. Legislation and guidance documents cited in this briefing paper and abbreviations

## 1.1 Legislation and guidance documents

### **“Regulation (EU) 2015/2283”**

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 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.

**“Implementing Regulations” collectively refers to:**

### **“Implementing Regulation (EU) 2018/456”**

Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for 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.

### **“General Food Law”**

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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.

### **“Regulation (EC) No 882/2004”**

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

## “Regulation (EC) No 258/97”

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

## “EFSA Guidance on Applications for Authorisation”

Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283, adopted on 21 September 2016.

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

Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283, adopted on 22 September 2016.

## 1.2 Abbreviations

**EU:** European Union

**EC:** European Commission

**MS:** Member States

**DG SANTE:** The Directorate-General for Health and Food Safety

**EFSA:** European Food and Safety Authority

**EU:** European Union

**GMP:** Good Manufacturing Practices

**HACCP:** Hazard Analysis and Critical Control Point

**ISO:** International Organization for Standardization

**NFD:** Novel Food Dossier

**SCoPAFF:** Standing Committee on Plants, Animals, Food & Feed





## 2. Background on Regulation (EU) 2015/2283

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

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 **harmonized rules** for the placing on the market of these products in the EU.

With the recast of the legislation on novel foods, the EU legislator introduced, for the first time, a **centralised au-**

**thorisation procedure** that is managed by the European Commission and relies on the European Food Safety Authority (EFSA) as sole risk assessment body. Under Regulation (EC) No 258/97, the initial steps of the approval procedure were decentralised.

Under Regulation (EU) 2015/2283, **whole insects and their preparations** are considered as 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 EU Member States thereby generating a contrasted impact of the transitional provisions provided for under Regulation (EU) 2015/2283 (see below, Section 8).

Currently (1st August 2019) there are twenty applications submitted for authorisation of insects as novel food and five notification applications for insects as traditional food from third countries. Several species are covered including *Acheta domesticus* (house cricket), *Alphitobius diaperinus* (lesser mealworm), *Gryllodes sigillatus* (crickets), *Hermetia illucens* (black soldier fly), *Locusta migratoria* (migratory locust), *Tenebrio molitor* (mealworm) and *Apis mellifera* male pupae (honey bee drone brood). Their summaries have been published on the European Commission (EC) web portal under the section novel food:

[https://ec.europa.eu/food/safety/novel\\_food/authorisations/summary-applications-and-notifications\\_en](https://ec.europa.eu/food/safety/novel_food/authorisations/summary-applications-and-notifications_en).

Among the twenty applications for authorisation of insects as novel food, only eleven have their summaries published on the above-mentioned portal because these applications have cleared the European Commission 'validity check' (all requirements are submitted for an application for authorisation) on the application (see section below: Outline of novel food authorisation procedures).

### Regulation (EU) 2019/625 – Article 2 Definitions

'insects' means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Implementing Regulation (EU) 2017/2470;

Rest of the applications are incomplete and the respective applicants are requested for further data. Currently, the EC has requested EFSA for an opinion on the previously mentioned eleven applications out of which only three applications for authorisation of insects as novel food (lesser mealworm - *Alphitobius diaperinus* submitted by the company Proti-Farm and mealworm – *Tenebrio molitor*, cricket - *Gryllodes sigillatus* submitted by the company Micronutris) have been accepted for assessment by EFSA (the three applications were accepted for assessment by EFSA in July 2018). The reason for the other eight applications not being assessed by EFSA is due to the fact that they have not fulfilled the 'completeness/suitability check' put forth by EFSA (see section below: EFSA Administrative guidance on the submission of applications for authorisation of a novel food). Furthermore the extended timeline for an EFSA opinion on the three previously mentioned applications (timeframe for an opinion to be provided by EFSA on transmission of the dossier is 9 months) is due to 'stop the clock' procedures (see section below: Stop the clock) initiated during certain periods of the assessment. Anticipating the timeframe, the first authorisations for insects as novel food in the EU are expected in 2020.

### 3. How to use the briefing paper

In the present briefing paper:

- Elements included in **green frames** contain information on **legal provisions** extracted from the Novel Food Regulation and its Implementing Regulations.
- The above provisions are further **explained** throughout the present document, in order to **facilitate their implementation 'on the ground' by insect producers**.
- The content of this briefing paper is partially based on **official communication documents** (e.g. European Commission website, including press releases, EFSA guidance documents).
- In this updated version of the briefing paper the sections in 'red font' correspond to the updated text in the document.

## 4. EU regulatory requirements applicable to the placing of insects as food on the EU market

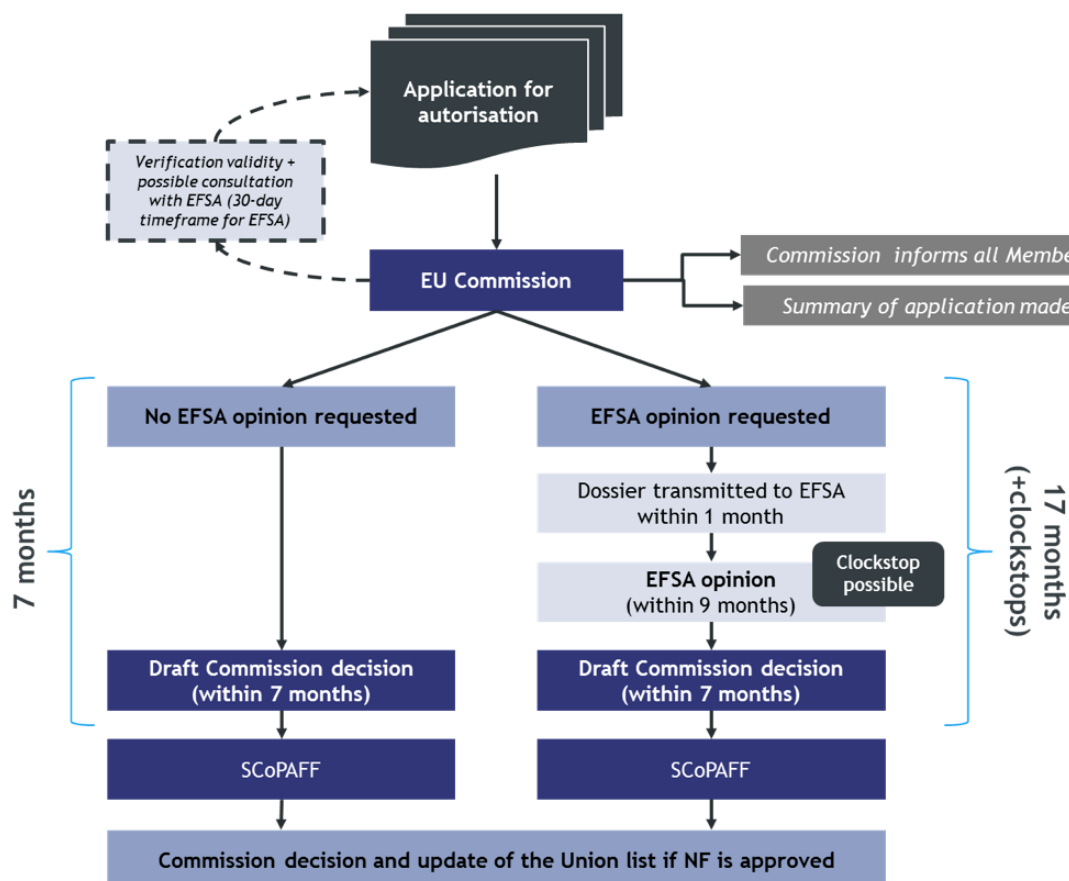
### 4.1. Outline of novel food authorisation procedures

Regulation (EU) 2015/2283 sets out the requirements for the placing of 'novel food' products on the EU market: notably these requirements concern the content of the application for authorisation which applicants must conform with (see section 5) and the procedural steps to be followed by the EC, the EU Member States and the EFSA in the authorisation process. The different steps of the authorisation procedure are laid down in **chapter III of Regulation (EU) 2015/2283**.

A distinction must be drawn between the 'standard' authorisation procedure and the specific rules applying to traditional products from third countries (the so-called 'Notification procedure').

**Note:** the present chapter provides a general description of the authorisation procedure applying to traditional food from a third country, but it does not address in detail the aspects related to the preparation of notification dossiers.

#### 'Standard' procedure for novel food authorisation



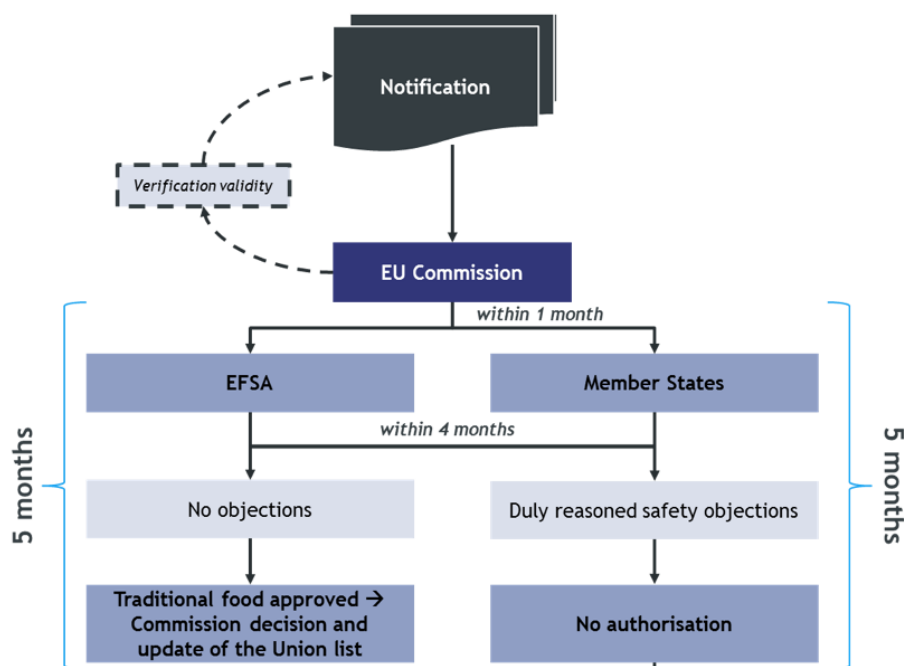


## Notification of a traditional food from a third country (and where, applicable, authorisation procedure)

Articles 14 et seq. of Regulation (EU) 2015/2283 introduce a simplified and 'fast track route' to lawfully place novel foods on the EU market for which an history of consumption can be demonstrated in a non-EU country (third country). This procedure is called 'notification of a traditional food from a third country' (hereafter referred to as 'the Notification Procedure').

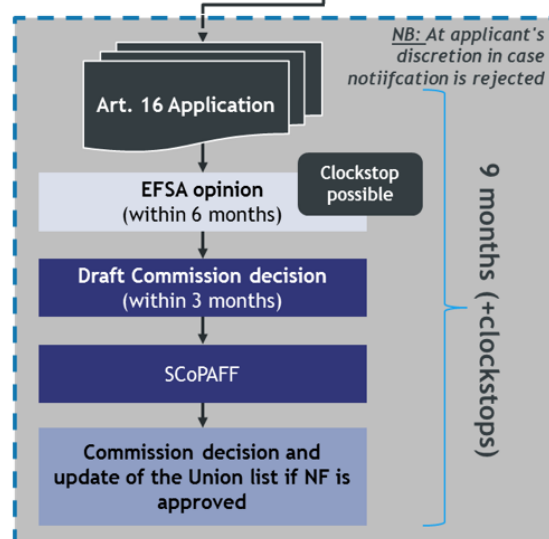
Under the Notification Procedure, a traditional food may be allowed to be placed on the European Union market after only four months from the date of submission of a valid and complete notification by the European Commission to the Member States and EFSA, provided that no safety concerns ('duly reasoned safety objections') are raised by any Member State or EFSA during that period. In case such objections are raised, an authorisation procedure similar to the 'standard' procedure, but with shorter timeframes, is open to the entity that had unsuccessfully filed a notification. An overview of the procedural rules applicable to the Notification Procedure is provided below.

Novel Food applications for authorisation and notification concerning traditional products from third country must be submitted to the European Commission services, through the **e-submission system**, which is available on the DG SANTE website (European Commission) through the following link: [https://ec.europa.eu/food/safety/novel\\_food/e-submission\\_en](https://ec.europa.eu/food/safety/novel_food/e-submission_en). Practical guidance on how to submit an application is provided in the **e-submission user guide**, which is available through the following link: [https://ec.europa.eu/food/sites/food/files/safety/docs/fs\\_novel-food\\_e-submission-system\\_user-guide.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/fs_novel-food_e-submission-system_user-guide.pdf).



### 'Stop-the-clock'

When EFSA is conducting its risk opinion during an authorisation or notification procedure of a novel food application, EFSA may ask for additional information in order to complete its evaluation. When this happens, the clock on the regulatory timetable for the risk assessment is stopped until the new data is supplied. This mechanism aims to ensure that applications are assessed on a case-by-case basis in the most time-efficient way. However, this mechanism does not pre-judge on 'quality of the dossier' submitted, but rather aims to collect additional evidence or documentation for EFSA to develop its opinion. The three applications 'in the pipeline' (mentioned in section 2: Background on regulation (EU) 2015/2283) have been subject to 'stop the clock' mechanism and explains the delay in EFSA's opinion corresponding to the pre-mentioned timeframe of 9 months.



## 4.2. Material scope of Regulation (EU) 2015/2283 and applicability to insect products

### Categories of food covered under the definition of 'novel food' in Regulation (EU) 2015/2283 vs. in Regulation (EC) No 258/97

Regulation (EU) 2015/2283 clarified the concept of 'novel food', i.e. Regulation (EC) No 258/97 mentioned a category that referred to "food ingredients isolated from animals" whereas Regulation (EU) 2015/2283 provides a broader description and more precise of the above-mentioned category by referring to "food consisting of, isolated from or produced from animals or their parts" in Article 3(2)(a) of Regulation (EU) 2015/2283. Indeed, the narrow definition of 'novel food' provided in Regulation 258/97 may have led **to diverging opinions among national competent authorities as to the qualification of whole insects as novel foods**: several authorities and stakeholders argued that foods or food ingredients consisting of whole insects did not constitute 'novel food' under the Regulation (EC) No 258/97 (see section 8 below).

By including both whole animals and their parts within the category of products under the scope of the new novel food authorisation system, the legislator clarified that **this category therefore encompasses insects and insect-derived products**.

#### Regulation (EU) 2015/2283 - Article 3(2)(a)

"**'novel food'** means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:

[...]

(v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union; [...]"

The legislator even included a **specific reference to whole insects and their parts in Recital 8** of Regulation (EU) 2015/2283, that now places the qualification of whole insects as novel foods beyond question.

#### Regulation (EU) 2015/2283 - Recital 8

"The scope of this Regulation should, in principle, remain the same as the scope of Regulation (EC) No 258/97. However, on the basis of scientific and technological developments that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods. Those categories **should cover whole insects and their parts.**"

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

	Regulation (EC) No 258/97	Regulation (EU) 2015/2283
Whole insects	✗ Not in scope*	✓ In scope
Parts of whole insects and ingredients processed from whole insects (e.g. whole insects flour)	✗ 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

### Is there evidence supporting a significant consumption of insects within the European Union before 15 May 1997?

The category of novel foods defined under Article 3(2) (a)(v) excludes “animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union”.

Furthermore, a given food or ingredient only qualifies as ‘novel food’ under the condition that it “was not used for human consumption to a significant degree within the Union before 15 May 1997”.

The qualification as ‘novel food’ is therefore **not ‘automatic’**, but results from the **absence of tangible information to substantiate ‘relevant’ consumption levels in Europe** before that date.

Yet, none of the surveys so far conducted by EU Member States competent authorities<sup>1</sup> concluded to the existence of such history of consumption in relation to insects. There is also no history of traditional breeding practices for insects that would have been used in the EU before 15 May 1997.

While operators are still in time to submit information to substantiate ‘history of consumption in Europe before 1997’, to the best knowledge of the authors of this document, no tangible information has been identified that would enable to substantiate such consumption levels. It is therefore very unlikely that European insect producers can benefit from an exemption to the application of the EU novel foods legislation to their products (i.e. exemption based on a demonstrated significant consumption or traditional breeding within the Union before 15 May 1997).

<sup>1</sup> See Surveys conducted by Belgium (Federal Agency for the Safety of the Food Chain) and the UK (Food Standards Agency) authorities in 2014 and 2015.

## 4.3. May insects qualify as ‘traditional food from a third country’?

The Notification Procedure (see section 1 above for more details) constitutes an opportunity for the authorisation of insects and insect ingredients produced outside the EU, **in third countries/regions in which insects form part of the traditional diets of local populations.**

However, Regulation (EU) 2015/2283 imposes strict conditions for producers to benefit from such regime. The concerned products must indeed, as per Article 3 of Regulation (EU) 2015/2283, meet the following cumulative conditions:

- be derived from **primary production**, i.e. the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. Primary production also includes hunting and fishing and the harvesting of wild products.
- have a **history of safe use in a third country**, i.e. the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country.

Insect producers seeking a novel food authorisation through the Notification Procedure must also demonstrate **25 years of uninterrupted consumption**, to be substantiated by **both anecdotal** and documented evidence. Operators have however freedom to select the forms of materials to substantiate such a claim. Notably, the EFSA Guidance on Applications and Notifications of Traditional Food indicates that scientific publications, scientific expert opinions, monographs, information from national or international organisations, government documentation, figures on cultivation harvesting, and from sales and trade are ‘acceptable references’ to substanti-

ate such consumption. It also indicates that supporting documentation on the experience of the continued food use should provide a description of the extent of use of the traditional food, the population group for which the traditional food has been a part of their diet, information on its preparation and handling, its role in the diet, information on precautions. It recommends the performance of a comprehensive literature review of human studies related to the consumption of the traditional food.

**Insect Food business operators established within the EU may use the Notification Procedure** for authorising their products as ‘novel food’ under Regulation (EU) 2015/2283. However, where primary production takes place in the EU, it may be difficult, in practice, for the applicant to demonstrate that the traditional product that it notifies under the Notification Procedure is similar, for example in terms of preparation mode or processing methods used, to a product that is traditionally consumed in a third country.

Besides this, while all types of products are in principle eligible for the Notification Procedure, whole insects (including those subjected to limited/simple processing steps such as dehydration) are more likely to be notified than more significantly processed products. Indeed, it is less likely that a history of safe use may be established for highly processed product derived from insects (incl. insect meal products) given that the commonly known and documented traditional uses of insects generally entail minimal and/or basic processing steps.

## 4.4. Operators' responsibilities for submitting an application for authorisation or initiating a notification under Regulation 2015/2283

### Which operator(s) within the production chain is (are) responsible for submitting a novel food application for authorisation or initiating a Notification Procedure?

It is prohibited for any food business operator to place a novel food on the market if that novel food is not duly authorised or notified in accordance with Regulation (EU) 2015/2283. So in other words, the responsibility for submitting a novel food application or initiating a Notification Procedure primarily lies on actors 'placing the novel food on the market'.

#### General Food Law - Article 3(8)

"'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves."

The definition of placing on the market' provides indications on those actors on whom the responsibility for submitting an application for authorisation (or initiating a notification procedure) mainly lies.

The first food business operator that places a novel food on the EU market is required to initiate the appropriate steps towards approval of that product, irrespective of whether the product is intended to be reused, incorporated into a final product or further processed by a subsequent food business operator further down the supply chain. In that regard, **primary producers will play a key role and will in most cases act as initial applicants.** Consequently, the main responsibility for submitting an

application will generally lie on the following actors:

- **Insect primary producers/** insect breeders who sell insects as raw material **to a subsequent producer**, who further processes and/or incorporates the material into a final product (later referred as the 'insect product user');
- **insect primary producers** who sell insects directly to consumers or through an intermediary or **distributor**.

**The central role of insect primary producers** in the approval process derives from the fact that such operators **control the farming and main production operations**, from the sourcing of the substrates fed to the insects up to the first processing activities. These operators thus determine the composition/ intrinsic characteristics of the product that forms the subject-matter of the application or notification (see section 6 below for more details).

### Is the responsibility for submitting a novel food application for authorisation or initiating a Notification Procedure limited to operators 'placing the product on the market'?

Article 3(2)(d) of Regulation (EU) 2015/2283 defines the term 'applicant': according to this provision, the initiative for initiating the process of authorisation of a novel food also belongs to the European Commission (as per Article 10(1) of Regulation (EU) 2015/2283). This right of initiative of the Commission is not expressly provided for in respect of the Notification Procedure (see Article 14 of Regulation (EU) 2015/2283) however.

### Regulation (EU) 2015/2283 – Article 3 - Definitions

“[...]2. [...] (d) ‘the applicant’ means the Member State, the third country or the interested party, which may represent several interested parties and has submitted to the Commission an application in accordance with Article 10 or 16 or a notification in accordance with Article 14; [...]”

### Regulation (EU) 2015/2283 – Article 10 - Procedure for authorising the placing on the market within the Union of a novel food and updating the Union list

“1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 shall start either on the Commission’s initiative or following an application to the Commission by an applicant [...]”

### Regulation (EU) 2015/2283 – Article 14 - Notification of a traditional food from a third country

“Instead of following the procedure referred to in Article 10, an applicant, who intends to place on the market within the Union a traditional food from a third country, may opt to submit a notification of that intention to the Commission [...]”

The regulation thus identifies two main categories of potential applicants, namely “institutional” applicants (EU countries, non-EU countries and the Commission) and “non-institutional” applicants (food business operators). It is however expected in practice that most applications and notifications will be performed by or on behalf of food business operators, who intend to place the novel food on the EU market.

### REMARKS CONCERNING “INSTITUTIONAL” APPLICANTS

- The definition under Article 3(2)(d) of Regulation (EU) 2015/2283 entails that **EU Member States authorities** may assist companies that are active in the production of a same species, so as to prepare and submit an application on their behalf. This type of approach could be envisaged for example where insect products originating from several different insect producers are concerned, provided that these products originate from the same insect species and have similar intrinsic characteristics. This approach would then lead to a joint application.
- In practice, this option of a joint application led by an authority however seems more relevant in the case of a **third country** seeking authorisation **through the notification procedure** (as per Article 14 of Regulation (EU) 2015/2283). Indeed, national authorities in those countries where insects are traditionally consumed (e.g. South East Asia, African countries, Mexico) are sometimes ‘better placed’ than operators themselves – who very often are ‘micro scale’ farmers – to gather, collect, aggregate and analyse the data required for the compilation of the notification dossier.



- The **European Commission** has a right of initiative for the authorisation and update of authorisation of novel foods. For example, the Commission may deem it appropriate to amend a specific authorisation in consideration of public safety concerns. In such cases it is entitled to initiate a process towards amendments to the list of authorised Novel Food products. It is worth mentioning that in this process and in all procedures led and managed by the European Commission under Regulation (EU) 2015/2283, the Commission is assisted by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF).

## REMARKS CONCERNING 'NON-INSTITUTIONAL' APPLICANTS

- Any legal or natural person may be an applicant under Regulation (EU) 2015/2283. In particular, the regulation does not require that an applicant is established in the EU to the purpose of seeking an authorisation or submitting a notification. In practice, applicants may be food business operators, consultants, counsels, industry associations or any other natural or legal person.
- Applications can be filed by single applicants, or jointly by several applicants, e.g. a **joint application** could be submitted on behalf of **several producers** that are active in the production of the same product. The text of Regulation (EU) 2015/2283 leaves **freedom for operators on how to organize their collaboration**. In practice, any form of 'horizontal' structure gathering several insect primary producers of the same species or 'vertical' forms of collaboration, congregating actors at different stages of the production chain (e.g. primary producers, processors and retailers) is possible, and the choice of the **legal form to use** (e.g. joint venture, consortia, non-profit organisation or registered company) is also left to the interested parties' discretion. It is also advisable to restrict the ambit of the application to one single insect species. Furthermore, one of the practical

challenges that these actors will need to address is the precise characterisation of the product(s) that form(s) the subject-matter of their application. A particular attention will need to be reserved in that context to the production conditions and production processes used, as recorded in the product specifications. At the same time, these operators will need to demonstrate that their products have '**similar characteristics**' and/or are produced under '**similar conditions**' (see below, section 6 sub section 'principle of generic authorisation' for further details). Other points of attention for operators intending to proceed with a joint application include –without limitation– the cost and profit sharing, confidentiality, regulatory data protection and antitrust compliance.

## 4.5. Content of the application for authorisation (‘standard’ procedure)

**Note:** the present briefing paper but does not cover aspects related to the preparation of notification dossiers for traditional food from third country.

### Overall structure of the dossier and administrative requirements

While article 10(2) of Regulation (EU) 2015/2283 sets out the main components of an application for authorisation, Implementing Regulation (EU) 2017/2469 (more specifically, Articles 3 and 4 thereof) singles out more precisely the main elements to be included in the application.

#### Implementing Regulation (EU) 2017/2469 - Article 3 - Structure, content and presentation of an application

1. An application shall be submitted electronically to the Commission and shall consist of the following:

- (a) a **cover letter**;
- (b) a **technical dossier**;
- (c) a **summary of the dossier**.

2. The cover letter referred to in paragraph 1(a) shall be drafted in accordance with the template provided in Annex I.

3. The technical dossier referred to in paragraph 1(b) shall contain:

- (a) the administrative data as provided for in Article 4;
- (b) the scientific data as provided for in Article 5.

Implementing Regulation (EU) 2017/2469 - Article 4 – administrative data requirements

In addition to the information set out in Article 10(2) of Regulation (EU) 2015/2283, the application shall include the following administrative data:

- (a) the name(s) of the manufacturer(s) of the novel food, if different than the applicant's, address and contact details;
- (b) the name, address and contact details of the person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission;
- (c) the date of submission of the dossier;
- (d) a table of contents of the dossier;
- (e) a detailed list of documents annexed to the dossier, including references to titles, volumes and pages;
- (f) a list of the parts of the dossier to be treated as confidential and verifiable justification in accordance with Article 23 of Regulation (EU) 2015/2283 and the rules set out in Annex II to this Regulation. Where the production process contains confidential data, a non-confidential summary of the production process shall be provided;
- (g) information and explanations substantiating the existence of the applicant's right of reference to the proprietary scientific evidence or scientific data in accordance with Article 26 of Regulation (EU) 2015/2283. That information shall be included in a separate folder.

## Scientific data requirements

Implementing Regulation (EU) 2017/2469 defines the scientific data requirements to be included in the application for authorisation.

### Implementing Regulation (EU) 2017/2469 - Article 5 – Scientific data requirements

1. The dossier submitted in support of an application for the authorisation of a novel food shall enable a **comprehensive risk** assessment of the novel food.

(...)

3. The applicant shall provide a copy of **the documentation on the procedure and strategy followed when gathering the data**.

4. The applicant shall provide **a description of the safety evaluation strategy** and the corresponding toxicological testing strategy and shall justify the inclusion or exclusion of specific studies or information.

5. The applicant shall provide on request the raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, to support their application. This information includes data used to generate the conclusions of the individual studies and results of examinations.

6. Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups.

7. For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration. Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC or, if they are carried out outside the territory of the Union, they shall follow the OECD Principles of Good Laboratory Practice. The applicant shall provide evidence of compliance with those requirements and shall justify any deviation from the standard protocols.

8. The applicant shall propose an **overall conclusion on the safety of the proposed uses of the novel food**. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

## Provision of evidence substantiating the absence of safety risks

### Regulation (EU) 2015/2283 - Article 10(2), (c) and (e)

“2. The application for an authorisation shall include:

[...]

(c) the description of the production process(es);

[...]

(e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;”

The production process(es) used to produce the novel food also have to be described.

In the case of insect products, all **measures implemented for production control and quality and safety assurance** should be described (e.g. HACCP, GMP, ISO): notably, a production flow chart may be provided, including quality and safety control checks. Adherence to **recognized professional guides of good hygiene practices** are also a critical element to substantiate product food safety.

The Scientific Opinion that EFSA published on 8 October 2015 on the risk profile related to production and consumption of insects as food and feed<sup>2</sup> identified the production conditions, including inputs during production, as main determinant of potential hazards (e.g. biological and chemical contaminants) for the use and consumption of insects.

An express reference to this Scientific Opinion is made in the EFSA Guidance on Applications for Authorisation, in the following terms (see Section 2.10.7.1 of the Guidance):

*“The EFSA Scientific Committee has identified potential hazards related to the use of farmed insects as food (EFSA Scientific Committee, 2015). These should be considered in applications for novel foods which consist of, are isolated from, or are produced from farmed insects, taking into account the species and substrate to be used, as well as methods for farming and processing. Insects collected from the wild may bear additional biological and chemical hazards which should be considered and addressed.”*

For more information in this regard, reference is made to the ‘IPIFF report on approaches to addressing data requirements for insects as novel food’ (published on 24 May 2018)<sup>3</sup>.

## Conditions of intended uses, product specifications and labelling requirements

Besides the ‘scientific demonstration’ (see above), the novel food specifications or ‘conditions of intended use’ constitute another key element to be included in the application for authorisation. These specifications **form a crucial component of the subsequent novel food authorisation** and are specified in the **Union list of novel foods**.

Article 10(2)(g) of Regulation (EU) 2015/2283 sets out these elements.

### Regulation (EU) 2015/2283 - Article 10(2)(g)

“2. The application for an authorisation shall include:

[...]

g) a proposal for the **conditions of intended use** and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.”

<sup>2</sup> Available at <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4257/epdf>

<sup>3</sup> A summary of the abovementioned report is made available on the IPIFF website. For more information you may contact the IPIFF Secretariat.

Careful consideration should be given by the applicant to the framing of **the conditions of intended uses** in order to ensure that they are representative enough of the product to be placed on the European Union market and that they cover **all intended uses** of the product for which an authorisation is sought by the applicant.

Any authorisation results in the inclusion of the authorised product in the Union list of novel foods, along with relevant **product specifications** that are listed in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470.

Based on the compositional data relating to the novel food, the specifications may notably include a description of the novel food and set out limits for relevant parameters. In the case of insect products, these specifications are likely to include:

- the **concentrations of the main constituents** in products (compositional requirements);
- **microbiological criteria (most likely in range values)**;
- **limits for impurities and degradation products** (e.g. residues levels from chemical and biological contaminants that may originate from the substrate used or manufacturing practices) that may be present in the final product<sup>4</sup>.

These may also **include a precise description of good farming/production and hygiene practices to be followed by producers** if the risk assessment concludes that these are necessary to achieve a high level of food safety for the final product.

Compliance with the above conditions may notably be verified by **Member States authorities in the context of official controls** in relation to the applicant's product, but also in relation to products marketed by other operators relying on the same authorisation.

## Description of the food categories for which a novel food authorisation is sought

It is important to note that any applicant is required, both in the ordinary authorisation route and the Notification Procedure, to indicate the food categories for which the use is requested (hereafter, the "food uses"), along with a proposal for the conditions of intended use of the novel food (See Articles 10(2)(g) and 14(f) of Regulation (EU) 2015/2283 and Annex I of Implementing Regulation (EU) 2017/2469 and Annexes I and II of Implementing Regulation (EU) 2017/2468). As regards the requested food uses, it is recommended to make use of the EFSA Food Classification system FoodEx2.

Any novel food authorisation or notification will be valid only for the food uses requested by the applicant. This means that food uses which are **not** listed in the approved application or notification will not be covered by this application or notification. **In case an operator seeks to commercialise a product for a food use that is not covered it will need to obtain an extension of the existing authorisation** (see section 6 below for more details). In practice, **joint applications** (as outlined above, section 4) submitted on behalf of producers that are vertically integrated into a same structure (i.e. at different stages of production) are likely to offer valuable opportunities to tackle such situations, as insect users may anticipate and bring in food uses envisioned by insect users directly into the first, joint application.

## EFSA Administrative guidance on the submission of applications for authorisation of a novel food

The document provides administrative guidance on the submission of applications for authorisation of a novel food in the European Union. It consists of:

- **Completeness checklist** – which refers to the data requirements for the application. The applicant should use the checklist to verify the completeness of the data for risk assessment in the technical dossier. It should be filled in and submitted using a common

<sup>4</sup> "IPIFF report on approaches to addressing data requirements for insects as novel food" (published on 24 May 2018), p 7.



word processing format (e.g. MS Word). EFSA will use the completeness checklist provided by the applicant in its technical dossier to check the completeness of the data.

- **Summary tables:** The applicants are encouraged to use the summary tables in order to summarise the results of the scientific studies provided in the technical dossier. These tables represent an example for the presentation of scientific data. The adherence to the common format will facilitate EFSA to carry out the risk assessment.

EFSA strongly recommends the use of the completeness checklist and summary tables when preparing an application for novel food and to upload the two documents as other relevant information through the EC e-submission system.

The Document can be accessed through this link: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1381>

## TECHNICAL REPORT



APPROVED: 07 February 2018  
doi:10.2903/sp.efsa.2018.EN-1381

### Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283

European Food Safety Authority

#### Abstract

This document provides guidance on the submission of applications for authorisation of a novel food in the European Union within the scope of Article 10 of Regulation (EU) 2015/2283 and according to Commission Implementing Regulation (EU) 2017/2469. The guidance is currently composed of a completeness checklist which reflects the data requirements for applications on novel foods, as outlined in the EFSA 'Guidance on the preparation and presentation of an authorisation of a novel food in the context of Regulation (EU) 2015/2283' and four tables on the scientific studies provided in the technical dossier. EFSA recommends applicants to use the completeness checklist and the summary tables during the preparation of a technical dossier on novel foods to ensure that the criteria for the completeness of the data for risk assessment are met. The information contained in this document only applies to applications submitted under Article 10 of Regulation (EU) 2015/2283.

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**Key words:** Application, submission, completeness check, novel foods, Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2469

**Requestor:** European Food Safety Authority

**Question number:** EFSA-Q-2017-00291

**Correspondence:** [APDESK.applications@efsa.europa.eu](mailto:APDESK.applications@efsa.europa.eu)

### Implementing Regulation (EU) 2017/2469 – Article 2

“‘application’ means a stand-alone dossier containing the information and the scientific data submitted for the authorization of a novel food pursuant to Article 10(1) of Regulation (EU) 2015/2283.”

### Implementing Regulation (EU) 2017/2468 – Article 2

“(a) ‘notification’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 14 of Regulation (EU) 2015/2283.

(b) ‘application’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 16 of Regulation (EU) 2015/2283.”

### Stand-alone evaluation vs. grouped authorisation

Article 2 of Implementing Regulation (EU) 2017/2468 and Article 2 of Implementing Regulation (EU) 2017/2469 define the concepts of ‘notification’ and of ‘application’.

The fact that an application or, where relevant, a notification constitutes a stand-alone dossier, means that each scientific evaluation conducted by EFSA is specific to the concerned product, based on the information and scientific data provided in the corresponding dossier submitted in support of the notification or the application for authorisation.

This article finds its relevance if two or more applications covering the same insect species are being examined at the same time. In that case, each application will **be eval-**



**uated individually and separate decisions to authorise the product** as novel food shall be taken based on the information and scientific evidence provided in each application.

However, **cross-references** between applications may be considered when evaluating information and evidence that are equally relevant to all products being evaluated (generic published study substantiating the safety of insects for human consumption - e.g. nutri-

tional information history of safe use, allergenicity). Such cross-references will however be possible only where the concerned information does not benefit from regulatory data protection.

Furthermore, all products authorised and covering the same insect species may be recorded **into one single entry within the Union list of novel foods**. This entry would in such cases encompass **common specifications** applicable to all respective products authorised.

## 4.6. Extension of an existing novel food authorisation or notification

### Principle of extension of a novel food authorisation

An extension of an existing novel food authorisation or notification may be necessary where:

- certain food uses (see section 5 above) are not covered by an initial authorisation or notification;
- activities performed by users of insects down the supply chain (e.g. processors, who may be the direct supplier or the users or another part) may lead to substantial changes in the intrinsic characteristics of the final product, leading to modify the specifications of the product);
- an insect primary producer produces an insect species which has been previously authorised (as novel food) but using production methods that may impact its intrinsic characteristics and resulting specifications, and therefore (or otherwise) affect the results of the existing risk/safety assessment.
- **in case of ceasing 'protected data' to a subsequent producer in the framework of a contractual agreement with the initial applicant who has gained an authorisation.**

In most cases however, it is expected that operators down the supply chain will be able to rely on existing authorisations.

**In principle, the extension would have to follow the same procedural path as the initial authorisation.** However, pursuant to Article 3(4) of Implementing Regulation (EU) 2017/2469, where the applicant submits an application to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food, **it may not be necessary for the applicant to provide all the supporting scientific data where the applicant provides verifiable justification explaining that the proposed changes do not affect the results of the risk assessment.** Similar rule applies in respect of amendments to notifications or authorisations of traditional foods from third countries (See Articles 3(4) and 4(4) of Implementing Regulation (EU) 2017/2468).

The party applying for an extension of the authorisation (e.g. for additional food uses) may be the **initial applicant** or **another operator**. In the latter case, for novel foods other than traditional foods from third countries, due account will need to be taken with the remaining period of data protection that may cover parts of the initial dossier (see also Section 7 below).

<sup>5</sup> See DG SANTE (European Commission) web page on the novel food legislation [https://ec.europa.eu/food/safety/novel\\_food/legislation\\_en](https://ec.europa.eu/food/safety/novel_food/legislation_en)

## Principle of generic authorisation and exceptions

Under Regulation (EU) 2015/2283, all **authorisations become 'generic'** (as opposed to the applicant-specific authorisation system on which Regulation (EC) No 258/97 was based). This means that food business operators will be entitled to lawfully place any novel food product that has been included in the Union list of novel foods pursuant to Regulation (EU) 2015/2283, as long as the authorised conditions of use, labelling requirements (Please refer to IPIFF Food Information to Consumer guidance document for insect-based products), and specifications are complied with<sup>5</sup>.

Translating this principle to the particular situation of **insects means that insect producers will be entitled to place insect-based food products on the EU market without having to prepare and submit a new novel food application or notification** (i.e. 'an extension of a novel food authorisation' as described in the above sub section) where the concerned products are made of/originate from a **previously authorised insect species** and the concerned products are covered by the existing authorisation or notification. This principle would however only apply in case **the corresponding dossier does not benefit from regulatory data protection**.

A contrario, it also means that such producers will have to submit a new application in case the intrinsic characteristics of a product that these operators intend to place on the market are 'significantly distinct' from the products included in the Union list of novel foods **or in case of ceasing 'protected data' to a subsequent producer in the framework of a contractual agreement with the initial applicant who has gained an authorisation**.

Unlike the rules under Regulation (EC) No 258/97, there is no requirement under Regulation (EU) 2015/2283 to notify or demonstrate the **substantial equivalence** of a given product to a product that has been previously authorised for the purpose of placing that product on the

market. On the other hand, only products meeting the applicable specifications, conditions of use, labelling requirements and post-market monitoring requirements as included and specified in the Union list of novel foods will be allowed on the market.

## Duty for operators to check that their product corresponds to the specifications provided for under the Union list of novel foods

Food business operators that intend to place insect products on the market need to ascertain that their products meet the conditions defined under the Union list of novel foods. This is part of their general obligation under Article 14 of the General Food Law.

The list below is a non-exhaustive list of elements that food business operators should consider to ascertain whether the conditions defined under the Union list of novel foods are met, and consequently decide whether extending an application or notification is necessary for the purpose of lawfully placing their product on the EU market.

- Do the (types of) **substrates** used by the producer **differ substantially** from a previously authorised product<sup>6</sup> (e.g. use of different arable crops or vegetable species) to the extent that these **modify significantly the nutritional composition** of the final product?
- Does the product contain significantly **higher levels of contaminants** (e.g. residues of pesticides, pathogenic bacteria heavy metals, mycotoxins transmitted via the substrate), and do the levels differ to the extent that these **may have an impact on the safety of the product for human consumption?**
- Do the **manufacturing processes used** impact on the **'key characteristics'** of the final product, notably **on its nutritional composition** (e.g. dried insect, insect meal, full fat meal and defatted meal are different products even when they are produced from the same insect species) or on its **food safety?**

<sup>6</sup> Insects may be produced in the EU exclusively with substrates eligible as feed materials for farmed animals (products of non-animal origin or the following products of animal origin: fishmeal, blood products from non-ruminant, di and tricalcium phosphate of animal origin, hydrolysed proteins from non-ruminant, hydrolysed proteins from hides and skins of ruminant, gelatine and collagen from non-ruminants, eggs and egg products, milk, milk based-products, milk-derived products and colostrum, honey and rendered fat)

In case the answer provided to any of these 3 questions is affirmative, it is likely that the concerned food business operator will have to prepare and submit a new application in which this operator will need to provide evidence that the intrinsic characteristics of the concerned product – which were therefore previously assessed – do not alter the food safety of the final product. It should be borne in mind that the use of different manufacturing processes does not constitute, as such, a sufficient criterion to require the preparation of a new application. Due account must indeed be taken with the novel food approved uses and specifications as set out in the Union list as a result of the initial approval process. Different processes may result in products with specifications that meet those approved by the Commission. The concerned food business operators remain in any event responsible for ensuring compliance of their products with the requirements (see also sub-section below).

A useful tool that should be used in case of doubt is the procedure for determination of novel food status, as provided by Article 4 of Regulation (EU) 2015/2283 and as further ruled under Implementing Regulation (EU) 2018/456.

Considering the above, the conditions of intended use provided in the initial application are not only an important component of the authorisation and of subsequent controls for the novel food (see Section 6 above, sub-section ‘conditions of intended uses, product specifications and labelling requirements’), they are also crucial elements to determine the latitude for subsequent operators to benefit from a previously authorised application.

### Consequences and control measures by Member States authorities

**A food business operator claiming that his/her product should benefit from a previous authorisation may place it on the European market freely**, under the condition that this food business operator complies with conditions of intended use and labelling requirements

applying the authorised novel food, as specified in the Union list of novel foods.

A pre-authorisation is thus not required under Regulation (EU) 2015/2283. However, the food business operator will have to demonstrate the compliance of the concerned products in **the context of official controls** –i.e. pursuant to Regulation (EC) No 882/2004.

Different means can be used to demonstrate compliance, such as e.g.:

- **Sampling results** substantiating conformity with maximum limits for impurities and degradation products as defined in the relevant specifications;
- **Check of measures implemented for production control and quality and safety assurance** (HACCP, ISO standards, adherence to professional guide of good hygiene standards) to demonstrate conformity with the levels of food hygiene standards that allow meeting the specifications defined in the Union list as part of the approval of the application or notification.
- **Monitoring the nutritional characteristics of the products** (e.g. as resulting from manufacturing processes used) to ensure that these do not differ from the criteria defined in the Union list.

**Non-compliance with the specifications or conditions of intended use** of a previously authorised product would result in the concerned product being non-compliant with the requirements under both Regulation (EU) 2015/2283 and the General Food Law obligations. Such **infringements** are sanctioned by measures enacted at **Member State level**, namely penalties implemented pursuant to Article 29 of Regulation (EU) 2015/2283 and/or sanctions implemented pursuant to Article 55 of Regulation (EC) No 882/2004).

## LIST OF NATIONAL COMPETENT AUTHORITIES RESPONSIBLE FOR THE IMPLEMENTATION OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/456

### AUSTRIA

Bundesministerium für Arbeit, Soziales, Gesundheit und  
Konsumentenschutz  
Sektion IX, Gruppe B - Veterinärmedizin und Veterinär-  
wesen, Lebensmittelsicherheit  
Radetzkystrasse 2  
A-1030 Wien  
[https://www.verbrauchergesundheit.gv.at/Lebensmittel/  
neuartige\\_lm/neuarti\\_gelm.html](https://www.verbrauchergesundheit.gv.at/Lebensmittel/neuartige_lm/neuarti_gelm.html)  
[novelfood@sozialministerium.at](mailto:novelfood@sozialministerium.at)

### BELGIUM

Federal Public Service of Health, Food Chain Safety and  
Environment Service of Food, Feed and Other Consump-  
tion Products  
Place Victor Horta 40/10  
Eurostation II  
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stuffs/novelfoods/](http://www.health.belgium.be/eportal/foodsafety/food-<br/>stuffs/novelfoods/)

### BULGARIA

Ministry of Health  
5, Sveta Nedelya sq 1000 Sofia

### CROATIA

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10 000 Zagreb, Croatia  
[hrana@miz.hr](mailto:hrana@miz.hr) [www.zdravstvo.gov.hr](http://www.zdravstvo.gov.hr)

### CZECH REPUBLIC

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110 00 Prague 1  
Czech Republic  
[novelfoods@mze.cz](mailto:novelfoods@mze.cz)

### CYPRUS

Medical and Public Health Services Ministry of Health,  
Prodromou 1  
1449, Nicosia  
Cyprus  
[healthservices@mphs.moh.gov.cy](mailto:healthservices@mphs.moh.gov.cy)

### DENMARK

Fødevareministeriet Fødevarestyrelsen Stationsparken  
31-33  
2600 Glostrup [Novelfood@fvst.dk](mailto:Novelfood@fvst.dk)  
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### ESTONIA

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11415 Tallinn [vet@vet.agri.ee](mailto:vet@vet.agri.ee)  
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### CROATIA

Ministry of Health Ksaver 200a  
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[hrana@miz.hr](mailto:hrana@miz.hr) [www.zdravstvo.gov.hr](http://www.zdravstvo.gov.hr)

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## GERMANY

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Postfach 11 02 60  
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[novel.food@bvl.bund.de](mailto:novel.food@bvl.bund.de)

## GREECE

Independent Authority for Public Revenue  
Directorate General of GENERAL CHEMICAL STATE  
LABORATORY Directorate of Alcohol and Foodstuffs  
An. Tsoha 16,  
GR-11521 Athens  
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## ICELAND

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## ITALY

Ministry of Health  
Off. 4 of the Directorate General Hygiene, Food Safety  
and Nutrition Via Giorgio Ribotta 5  
I-00144 Roma  
[http://www.salute.gov.it/portale/ministro/p4\\_8\\_0.jsp?lingua=italiano&label=servizionline&idMat=APINF&idAmb=Nf&idSrv=NfAC&flag=P](http://www.salute.gov.it/portale/ministro/p4_8_0.jsp?lingua=italiano&label=servizionline&idMat=APINF&idAmb=Nf&idSrv=NfAC&flag=P)  
[dgsan@postacert.sanita.it](mailto:dgsan@postacert.sanita.it)  
Tel : 01 44 97 31 51  
[v.digiorgi@sanita.it](mailto:v.digiorgi@sanita.it)  
(until further notice, the request needs to be done with the template available on the website and needs to be indicated as a subject the following: I5IH5- RNFS- name of the substance for which the request is done)

## LATVIA

Food and Veterinary Service  
Peldu street 30  
Riga, LV-1050  
[www.pvd.gov.lv](http://www.pvd.gov.lv)  
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Ministry of Health of the Republic of Lithuania  
Vilniaus str. 33  
LT-01506 Vilnius  
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## LUXEMBOURG

Ministère de la Santé  
Direction de la Santé  
Division de la sécurité alimentaire  
Villa Louvigny Allée Marconi  
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## MALTA

Food Safety Commission  
Continental Business Centre Cutrico Buildings  
Old Railway Track Santa Venera SVR9018 MALTA

## THE NETHERLANDS

Ministry of Health, Welfare, and Sport PO Box 20350  
2500 EJ The Hague  
The Netherlands  
Consultation requests should be sent electronically to the novel food assessment body:  
Medicines Evaluation Board (CBG-MEB)  
Novel Food Unit  
P.O. Box 8275  
3503 RG Utrecht  
[novelfoods@cbg-meb.nl](mailto:novelfoods@cbg-meb.nl)  
<https://english.cbg-meb.nl/topics/nv-determination-of-novel-food-status>

## POLAND

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## ROMANIA

Ministry of Health  
General Directorate of Healthcare and Public Health  
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[www.ms.ro](http://www.ms.ro)  
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## 4.7 Data protection and confidentiality

### Confidentiality

Article 23 of Regulation (EU) 2015/2283 provides for confidentiality rules in respect of applications for updates of the Union list, i.e. for application for authorisation or notification dossiers.

#### Regulation (EU) 2015/2283 - Article 23

“1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may harm their competitive position.

2. For the purposes of paragraph 1, applicants shall indicate which parts of the information provided they wish to be treated as confidential and provide all the necessary details to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.

3. After being informed of the Commission’s position on the request, applicants may withdraw their application within three weeks, during which the confidentiality of the information provided shall be observed.

4. After expiry of the period referred to in paragraph 3, if an applicant has not withdrawn the application and in case of disagreement the Commission shall decide which parts of the information are to remain confidential and, in case a decision has been taken, notify the Member States and the applicant accordingly.

However, confidentiality shall not apply to the following information:

- (a) the name and address of the applicant;
- (b) the name and description of the novel food;
- (c) the proposed conditions of use of the novel food;
- (d) a summary of the studies submitted by the applicant;

(e) the results of the studies carried out to demonstrate the safety of the food;

(f) where appropriate, the analysis method(s);

(g) any prohibition or restriction imposed in respect of the food by a third country.

5. The Commission, the Member States and the Authority shall take necessary measures to ensure appropriate confidentiality of the information as referred to in paragraph 4 and received by them under this Regulation, except for information which is required to be made public in order to protect human health.

6. Where an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and the Authority shall not disclose confidential information, including the information whose confidentiality is the subject of disagreement between the Commission and the applicant.

7. The application of paragraphs 1 to 6 shall not affect the exchange of information concerning the application between the Commission, the Member States and the Authority.

8. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).”

All parts of an application or notification that the applicant deems confidential must be marked as such. For each information requested to be considered as confidential, the applicant must provide a justification. These elements constitute a specific annex of the dossier, that is updated each time an applicant submits a request for information to be treated as confidential.

Importantly, where the production process contains confidential data, a non-confidential summary of the **production process** must be provided by the applicant.

When an applicant requests the confidential treatment of certain parts of the dossier, the Commission assesses the justification submitted and takes a decision as to whether or not the Commission accepts to treat the concerned information confidentially. In case the Commission disagrees, in whole or in part, with the confidential character of certain information, the applicant has the possibility to withdraw the pending application within three weeks. Pending this, the confidentiality of the information provided will be maintained. If after that period the concerned applicant has not withdrawn the application, and in case of disagreement, the Commission is competent to decide which parts of the information are to remain confidential and, in case a decision has been taken, notifies the Member States and the applicant accordingly. In case an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and the Authority have a duty not to disclose confidential information, including the information whose confidentiality is or was the subject of disagreement between the Commission and the applicant.

In all cases, certain parts of the dossier will not be considered as confidential, namely those listed under paragraph 4 of Article 23 of Regulation (EU) 2015/2283 (see above).

## Data protection

In the context of an application for authorisation of a novel food other than a traditional food for a third country, applicants may apply for a five-year period of regulatory data protection.

### Regulation (EU) 2015/2283 – Article 26

“1. On request by the applicant, and where supported by appropriate and verifiable information included in the application provided for in Article 10(1), newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.

2. The data protection shall be granted by the Commission under Article 27(1) where the following conditions are met:

- (a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;
- (b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and
- (c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.”

The period of data protection that can be granted has a duration of **five years** and is not renewable. Only the data that meets the three cumulative conditions listed under paragraph 2 of Article 26 can be eligible for data protection, i.e.:

1. the data must consist of newly developed scientific evidence or scientific data that the applicant has designated as proprietary upon the first application; and
2. at the time the first application was made, the initial applicant had an exclusive right of reference to data; and
3. 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.<sup>7</sup>

It is the competence and responsibility of the European Commission to decide on the grant of data protection. With respect to the handling and use of proprietary data by EFSA, where evidence for the safety of a novel food includes a request for the protection of proprietary data, the EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) considers in its opinion whether the safety of the novel food could have been assessed without the data claimed as proprietary by the applicant or not: this element is indeed crucial in the context of the Commission's decision-making relating to the grant of data protection or not.

In practice, where data benefits regulatory data protection, other applicants will not be entitled to refer to these data for the purpose of obtaining a novel food authorisation. **The applicant that has obtained an authorisation on the basis of protected proprietary data indeed benefits from a market exclusivity** in respect of those data and of the product to the extent the protected data is relied upon for the sake of placing the product on the market. In cases where data protection is granted, the Union list specifies it, and indicates that during the period of data protection the novel food is authorised for

placing on the market within the Union only by the initial applicant, unless a subsequent applicant obtains authorisation for the novel food without reference to the protected data or with the agreement of the initial applicant.

It is thus important to note that the **grant of data protection does not prevent other applicants to submit their own data** (i.e. data that is not covered by the protection), nor to reference to the non-protected parts of dossiers that have previously been approved. No provision under the Novel Food regulation prevents a reference to be made to the parts of the dossier that are not covered by data protection. Article 26(2) in fine expressly provides for the possibility for the initial applicant to agree with (a) subsequent applicant(s) on the use of the data that benefits data protection. The terms under which such agreement is reached are however not further defined by the regulation and are left to the discretion of the concerned applicants. This can notably be done by means of a letter of access. **However, 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– see Chapter 4.6 for more details).** Alternatively, if the initial applicant does not agree to a reference being made to the data benefitting from data protection, the subsequent applicants may submit an own set of data to “fill the gap” of the data that is protected. They will however not be eligible for a separate data protection period for these data, as the data protection mechanism only benefits the initial applicant.

As indicated above, **no data protection can be applied for in respect of the notification of a traditional food from a third country** (as per Article 26(3) of Regulation (EU) 2015/2283).

<sup>7</sup> These criteria are identical to the criteria laid down in respect of the protection of data submitted to the purpose of obtaining approval of a health claim.

## 4.8. Transitional measures

### Objectives and measures provided as transitional provisions under the Article 35(2) of Regulation (EU) 2015/2283

Article 35(2) of Regulation (EU) 2015/2283 provides for transitional measures that aim to ensure that products that were lawfully commercialized in a Member State of the EU before Regulation (EU) 2015/2283 became applicable (i.e. before 1<sup>st</sup> January 2018) may remain on the market of this particular Member State for a given period of time, subject to certain conditions.

Transitional measures are usually intended to avoid situations where a product that is lawfully on the market becomes unlawful and needs as a consequence to be withdrawn or suspended from the market as a result of the entry into force of a new legislation. Avoiding such situations is in the interest of all stakeholders, including industry (legal certainty), authorities (reduce administrative burden) and consumers (confidence that products on the market are safe).

Regulation (EU) 2015/2283 provides for such measures for products that did not fall under the scope of application of Regulation (EC) No 258/97 and that do fall under the scope of application of Regulation (EU) 2015/2283. This may well be the case for whole insects and products made of/from whole insects (see Section 2 above and below).

Article 35(2) of Regulation (EU) 2015/2283 defines the criteria that must be met in order for food business operators to benefit from the transition measures and sets out its implementation modalities.

### Regulation (EU) 2015/2283 - Article 35(2) – Transitional measures

“Foods not falling within the scope of Regulation (EC) No 258/97, **which are lawfully placed on the market by 1 January 2018** and which fall within the scope of this Regulation may **continue to be placed on the market** until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of this Regulation following an application for authorisation of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of this Regulation respectively, **but no later than 2 January 2020.**”

The application of the above transitional measure is of particular relevance for insect producers, since it guarantees **that operators are not compelled to discontinue the production and/or marketing of their products** whilst they prepare and submit their application for authorisation or notification in accordance with Regulation (EU) 2015/2283<sup>8</sup>. These operators are allowed to continue placing their products on the market **until a final decision has been adopted in respect of their application or notification**, i.e. until the European Commission adopts a decision – see Section 1 above).

<sup>8</sup> See IPIFF position paper - implementation of EU Regulation 2015/2283 on 'novel foods' (19 November 2016)

While Article 35(2) provides that the transition period may benefit to operators who submit an application for authorisation or a notification for their lawfully marketed product until 2 January 2020, the same article however empowered the European Commission to set a shorter deadline. Such shorter deadline was in fact defined by the Commission through Implementing Regulation (EU) 2017/2469, that was adopted on 20 December 2017 following unanimous approval by Member States)<sup>9</sup>. Implementing Regulation (EU) 2017/2469 sets **1<sup>st</sup> January 2019 as final deadline for the submission of applications** eligible for the benefit of the transitional period. Article 11 of Implementing Regulation (EU) 2017/2468 sets an identical deadline in respect of traditional foods from third countries.

#### Implementing Regulation (EU) 2017/2469 - Article 8(5) – Transitional measures

“The deadline for the submission of the applications referred to in Article 35(2) of Regulation (EU) 2015/2283 shall be **1st January 2019.**”

#### Implementing Regulation (EU) 2017/2468 - Article 11 – Transitional measures

“The notifications as referred to in Article 35(2) of Regulation (EU) 2015/2283 shall be submitted to the Commission not later than 1 January 2019.”

The European Commission considers that the application of such deadline to the case of insects is adequate to ensure “timely certainty about the legality of products on the EU market (both for consumers and food business operators)”<sup>10</sup>.

**Taking into account the timeframes imposed under Regulation (EU) 2015/2283, the expected timeframe for the**

**adoption of a final decision on an application for authorisation is estimated between 18 months and 24 months (in the absence of repeated ‘stop the clock’). Since first decisions are not expected before 1 January 2020, (see Chapter 2 ‘background information on Regulation 2015/2283), insect food operators who became eligible for the transitional measure at national level (see table in section: EU Member States’ approaches on the novel status of ‘whole insects and their preparations’) **should continue to benefit from it after 2020** in those countries applying it, until a decision has been taken **provided that an application for authorisation as novel food has been submitted before 1 January 2019.** (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). If a data protected application is authorised, another insect operator producing the same product/species can continue to benefit from the transitional measure as this authorisation is company specific. If a non-data protected application is authorised, all operators from the EU would benefit from it, therefore putting an end to the transitional measure for the said product.**

#### Eligibility of insect products for the transitional measure provided for under Regulation (EU) 2015/2283

- Article 35(2) of Regulation (EU) 2015/2283 provides that the **first eligibility criterion** for the benefit of the transitional measures is that **the concerned foods did not fall within the scope of Regulation (EC) No 258/97**. As explained above (see Section 2), it is arguable that whole insects and their preparations did not fall within the scope of Regulation (EC) No 258/97, given that the latter applied – in respect of animal-derived foods and food ingredients- solely to “food ingredients isolated from animals”, thereby excluding from its scope of application whole animals – such as whole insects. An interpretation according to which whole insects were not falling within the scope of Regulation (EC) No 258/97 can thus reasonably be followed.

<sup>9</sup> See conclusions from the PAFF Committee meeting on 17 November 2017

<sup>10</sup> See letter from the Commissioner for health and food safety Vytenis Andriukaitis to IPIFF (8 December 2017)



- The **second eligibility criterion** for the benefit of the transitional measures is that the products were **lawfully placed on the market by 1 January 2018**. In practice, such decision lies with each EU Member State. **The final decision of those countries** regarding the lawful placing on the market of such products was essentially based on **their classification or not as 'novel food'** (i.e. their 'novel' status) under Regulation (EC) No 258/97. Member States that regarded the concerned products as 'novel' under Regulation (EC) No 258/97 therefore consider that the product was not (and still not is) 'lawfully placed on the market' if such product has not been authorised in accordance with Regulation (EC) No 258/97. In practice, no novel food authorisation has been granted for any insect product under Regulation (EC) No 258/97.

Considering the restrictive definition of 'novel food' as provided for under Regulation (EC) No 258/97, that did not cover whole animals, the legality of the position of a Member State who deny the benefit of the transitional measures to whole insects and their derived products on the ground that these should already have been considered (in the view of these Member States) as 'novel food' under Regulation (EC) No 258/97 is questionable. It can be observed that no uniform position has been adopted by the EU Member States (see sub section below for more details). **Moreover the French administrative Supreme Court ('Conseil d'Etat') decided on 28 June 2019 to refer to the European Court of Justice - under the preliminary ruling procedure - in order to clarify the scope of the Regulation (EC) No 258/97, in a litigation opposing the French edible insect producing company ENTO-MA to the French administration. The European Court of Justice will clarify with its judgement, whether 'products composed of 'whole insects' fall under the scope of the 'old' novel food regulation'. If the Courts answers negatively, such judgement could create a jurisprudence which could be used by an insect operator - should any MS deny eligibility of the transitional measure in case of production of whole insects or of a product containing whole insects (see last sub section for further details on the specific case of France and the effect on EU MS).**

## EU Member States' approaches on the novel status of 'whole insects and their preparations'

Given the absence of univocal position in relation to the interpretation to be given to the material scope of application of Regulation (EC) No 258/97, diverging approaches have been adopted by the Member States, resulting in a legal patchwork.

This section provides a general overview of the different interpretations and positions adopted by the different EU Member States in relation to whole insects and their preparations under Regulation (EC) No 258/97.

In a nutshell,

- **most competent authorities in the EU Member States refuse to grant the benefit of the transitional measures under Regulation (EU) 2015/2283** to insect operators because they consider that whole insects and/or their preparations/derived products were already falling under the scope of Regulation (EC) No 258/97. Their reasoning entails that the concerned products should have been authorized in accordance with the requirements of Regulation (EC) No 258/97 in order to be considered as 'lawfully placed on the market';
- **a few other countries do however consider that 'whole insects' as well as 'their preparations or their derived products' were clearly out of the scope of Regulation (EC) No 258/97**. On this basis, they apply the transitional measure under Article 35(2) of Regulation (EU) 2015/2283 to whole insects and their preparations;
- **in the rest of the EU Member States**, the situation remains unclear due to the absence of any official position in respect of the issue;
- the **European Commissioner for Health and Food Safety** has acknowledged in an answer to a parliamentary question in 2014<sup>11</sup> that there was a legal uncertainty in Regulation (EC) No 258/97 as to whether whole insects fall under the scope of the regulation, and that therefore, some Member States have tolerated the placing on the market of whole insects –as

<sup>11</sup> Answer to Parliamentary question n° E-008560/2014 given by Mr Andriukaitis on behalf of the Commission, 23 December 2014.

part of the exercise of the Members States' responsibility for the enforcement of the (then unclear) provisions of EU food law, taking into account differences in the perception of consumers. The Commission's view as expressed at that time was that (i) insects are novel foods unless the significant consumption by humans prior to 15 May 1997 is established and (ii) food isolated from insects (e.g. protein) is novel food and requires an authorisation when significant consumption has not been established.

- One should note that the EU and national institutions/authorities, which have opposed to the placing on the market of whole insects, do not pretend that they are clearly included in the 'old definition'. It seems that most of them have based their positions on the uncertainty/lack of clarity of the 'old definition' even though, as explained above, it appears that the old definition is clear from its very wording ('food ingredients isolated from animals') and most authorities which have shown unfavourable opinions, could have done so by precaution. These authorities tend to interpret the old definition in the light of the new one (provided under the new novel food regulation), also implying that whole insects are not safe because they have not been evaluated under the previously stated context thus applying the 'principle of precaution' and not authorising the product on the market along with the application of the transitional period being invalid. This can be legally challenged (see following section).

## The fallout from ENTOMA legal case and possible impact

According to the French administrative Supreme Court ('Conseil d'Etat') there is a serious doubt that whole insects are included in the 'old' definition of 'novel food' as provided by Article 1 of Regulation 258/97. The Judges have further referred to the European Union Court of Justice (CJEU) under the 'Preliminary ruling procedure' to decide on the following question: Does Article 1, paragraph 2, point 'e' of Reg. 258/97 – which cov-

ers, "foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use" ('old definition'), **include insects consumed as 'whole' or products composed of whole insects in its scope, or does it solely applies to food ingredients isolated from insects?**

The CJEU is expected to respond to the question advanced by the 'Conseil d'Etat' within one year and half (there is no legal deadline for the Court to give a ruling, but in fact, the average length of time for which pre-trial applications are dealt with under the ordinary procedure is currently 16 month). This judgment is of central importance for edible insect producers, as it will be binding for all national courts which would be seized of a question of identical scope (EU jurisprudence). In case the answer to the above question is negative (i.e. whole insects do not fall under the scope of the 'old definition') it means **that insect producers who did not benefit from the transitional measure could claim its application towards their national competent authorities in the case of whole insects or products composed of whole insects** (provided that the product was lawfully placed on the market by 1 January 2018 and an application submitted by 1 January 2019). A Member State authority opposing it on the sole ground that the respective whole insects-product(s) were falling within the scope of Reg. 258/97 would be challenged by National Courts.

## Possibilities for producers or their suppliers of insect-based food products'

In addition to the ruling from the CJEU, the opinions from EFSA and other national food safety agencies - that safety can be ensured by appropriate risk management measures during farming and production ( Please refer to IPIFF Guide on Good Hygiene Practices for EU producers of insects as food and feed) - can be used as a catalyst by producers or their suppliers of insect-based food products to the respective competent authorities to claim benefit from the transitional measure if not currently.

As indicated above, it is not because whole insects are not subject to specific regulations, that they are not regulated at all. The new novel food regulation sets a specific framework for the evaluation of these products, however, the general food legislation provides for a comprehensive framework that is likely to ensure the compliance and the safety of these products during the transition period.

National authorities have identified several pieces of legislation and provisions that are applicable to the placing on the market of whole insects :

- General Food Legislation Regulation No 178/2002,
- Food Hygiene Package Regulations No 852/2004 and 853/2004,
- Food Information to Consumers Regulation No 1169/2001,
- Regulations relating to contaminants and undesirable substances, even if whole insects are not expressly covered by these regulations, the thresholds can be used as references for whole insects,

Etc.

Operators could have the possibility to establish to the national authorities, that they do comply with these provisions. However, national authorities could furthermore oppose to the placing on the market of whole insects, if they prove that the above-mentioned legal provisions are not met. The benefit of the transitional measure could very well be used by operators if the CJEU decision comes before an authorisation covering the application submitted by the operator or its supplier.<sup>12</sup>

<sup>12</sup> IPIFF - 'Product law firm' Legal Analysis: 'Legal Advice on the EU regulatory status of insects – proposed roadmap & description of received offers'. STATUS OF INSECTS FOR HUMAN CONSUMPTION & USE OF TRANSITIONAL PERIOD UNDER REGULATION 2015/2283

The map below outlines the novel food status of whole insects and their preparations in most EU countries.

## NB:

1. this map does not refer to the position of Member States regarding the novel status of ingredients derived from insects (i.e. ingredients other than (made from) whole insects), as these products undoubtedly fall within the scope of Regulation (EC) No 258/97 and are thus not eligible for the transitional measures foreseen under article 35(2) of Regulation (EU) 2015/2283;
2. Given the absence of univocal position in relation to the interpretation to be given to the material scope of application of Regulation (EC) No 258/97, diverging approaches have been adopted by the Member States, resulting in a legal patchwork.

## Legend

- Countries indicated in **green** are those in which the **national authorities agreed to grant the transitional measure** to whole insects and/or their derived products;
- Countries indicated in **orange** are those in which the **'novel status' of those products is uncertain** (e.g. due to the absence of official position taken by competent authorities, due to differentiated regimes in one region to another, or in case the uncertainty results from a pending legal case on the subject);
- Countries indicated in **yellow** refer to countries in which the production and commercialisation of whole insects and their products is permitted, but however **restricted in its scope** (i.e. limited to certain insect species) or in which the transitional measure is **not applied in full compliance with EU legislation**;
- Countries indicated in **red** correspond to EU Member States which considered whole insects and their derived products as novel food under Regulation (EC) No 258/97, and therefore **refuse to apply the transitional measure to these products**. The production and commercialisation of insects is therefore also prohibited in these countries until an authorisation or notification is approved under Regulation (EU) 2015/2283;
- Countries indicated in **grey** are Member States whose **position is unknown** to the authors at the time of drafting these Guidelines

## EU Member States' approaches on the novel status of 'whole insects and their preparations'



	Novel status of 'whole Insects' and 'products thereof'	Authorisation for production and marketing within the country?	Authorisation subject to certain restrictions)?	Application of the transitional measure	Import conditions	Reference document
<b>Denmark</b>	The Danish Veterinary & Food Administration (DVFA) considered that 'whole insects' and their parts <b>were not covered under Regulation (EC) No 258/97</b> , provided that it can be documented that whole insects are used and that no parts thereof have been removed.	Yes, if the products conform with other applicable legislations (e.g. General EU food law and EU 'Hygiene Package' requirements).	No	Yes	Imports from EU and non-EU exporting countries are allowed but subject to an import authorisation from the Danish Food Authority (DVFA). The insect product must originate from a production site that is approved or registered by the local authorities in the country of origin, as attested by official certificate) and veterinary control at border point apply.	Insects -rearing as feed and food in Denmark and in the EU – what is allowed and what is not' (20 March 2017)
<b>The Netherlands</b>	The Dutch Office for risk Assessment and Research (Bureau Risicobeoordeling en Onderzoeksprogrammering – BuRo) considered that 'whole insects' and their parts <b>were not covered under the former EU 'novel food' Regulation</b> .	Yes. Or factual tolerance policy ?? the products must conform with other applicable legislations (e.g. <b>General EU Food Law, traceability and reporting obligations, labelling</b> and EU 'Hygiene Package' requirements).	No	Yes	N/A	<b>Nederlandse Voedselen Warenautoriteit. Nieuwe voedingsmiddelen op de markt brengen</b>
<b>The United Kingdom</b>	The UK Food Standard Agency (FSA) considered that 'whole insects' and their parts <b>were not covered under Regulation (EC) No 258/97</b> .	Yes, provided that the products conform with other EU (e.g. General EU food law and EU 'Hygiene Package' requirements) and national (e.g. Food Safety Act 1999) applicable legislations.	No	Yes	N/A	Food Standards Agency (FSA) letter to interested parties on 'the status of insects under the novel food legislation' (29 June 2015)
<b>Finland</b>	In September 2017, on request of the Government, the Finnish Food Safety Authority (EVIRA) changed its interpretation of the scope of the novel food legislation and considered that 'whole insects' <b>were not covered under Regulation (EC) No 258/97</b> , to the effect of considering insect production as lawful, subject to the requirements and controls under the food legislation.	Yes, provided that the products conform with other EU (e.g. General EU food law and EU 'Hygiene Package' requirements) and national (e.g. National Animal Welfare Decree 396/1996 or the Animal Diseases Act 441/2013).	No	Yes		Evira Guide 'Insects as food' (19 December 2017)



	Novel status of 'whole Insects' and 'products thereof'	Authorisation for production and marketing within the country?	Authorisation subject to certain restrictions)?	Application of the transitional measure	Import conditions	Reference document
Belgium	The Belgian federal public service refers to <b>'legal uncertainty'</b> regarding the applicability of Regulation (EC) No 258/97 to whole insects and their preparations and had provided for a tolerance policy in relation to 10 insect species.	Tolerance policy applying	Yes, initially the limitation extended to 10 insect species (until 31 December 2017), but it has then been restricted to 3 species and their preparations (Tenebrio Molitor, Acheta Domestica and Locusta migratoria) as of 1st January 2018 (i.e. date of application of Regulation (EU) 2015/2283).	Yes, but only for the 3-insect species listed above, based on the consideration that an application for authorisation of these species has been filed before 1 January 2018 and is thus pending.	Imports originating from EU Member States in which the insect products are lawfully placed on the market under national law (e.g. Finland, Denmark) are allowed. Imports from non-EU countries or from EU Member States where such products were not lawfully on the market before 1 January 2018 are not permitted.	Technical note – 'state of play on the commercialization of insect products after January 2018 on the Belgian market'.
Austria	The Austrian authorities considered that whole insects <b>were not covered under the Regulation (EC) No 258/97</b> .	Yes, if the products conform with other applicable legislations (e.g. General EU food law and EU 'Hygiene Package' requirements).	Yes, authorisation limited to 10 species (i.e. Acheta domestica, Locusta migratoria migratorioides, Zophobas atratus morio, Tenebrio Molitor, Alphitobius diaperinus, Galleria mellonella, Schistocerca Americana gregaria, Gryllodes sigillatus, Gryllus assimilis and Gryllus bimaculatus).	Yes, but only to insect species included in the list of 10 species.	N/A	'Leitlinie für gezüchtete Insekten als Lebensmittel' (15 February 2017)
Czech Republic	The Czech authorities considered that 'whole insects and their derived products' shall be classified as 'novel food' under Regulation (EC) No 258/97. However, stores can sell insect food when it comes to an insect species that has been consumed by people in an EU country before.	Yes, provided that, the food must be made of an insect species that is already being consumed in an EU Member State and sold there before 1 January 2018. Furthermore, producers are required to apply for an authorisation to the European Commission by the beginning of 2019. The current possibility of placing insects on the market is time-limited and conditional. Only those authorised, and registered on the Union list, may be sold after 2 January 2020.	The rules apply only to whole insects, possibly to insect flour, not to substances extracted from insect bodies (e.g. proteins). Species that can be legally consumed include: domestic cricket, buffalo mealworm, short-winged cricket, migratory locust, mealworm. Insect foods are subject to the same legislation as any other food	No	N/A	Centrální informace bezpečnosti potravin. nové potravinyhmyz

	Novel status of 'whole Insects' and 'products thereof'	Authorisation for production and marketing within the country?	Authorisation subject to certain restrictions?	Application of the transitional measure	Import conditions	Reference document
France	The French authorities considered that 'whole insects and their derived products' <b>shall be classified as 'novel food' under Regulation (EC) No 258/97</b> . The French agency for food safety (ANSES) indicated in a 2015 Opinion that the risk analysis regarding insects needed to be performed in accordance with Regulation (EC) No 258/97.	No, according to the French authorities but pending lawsuit case before the French tribunal which has currently referred the case to the EU Court of Justice which will clarify under the 'Preliminary ruling procedure' the inclusion of whole insects falling in or out of the scope of the 'old definition'	No authorisation	Currently not but conditioned by the final decision of the EU Court of Justice	No imports allow	DGCCRF 'information note n° 2014-157 sur la commercialisation d'insectes destinés à la consommation humaine'
Germany	No official position at German federal level. Differentiated approaches among the different German Landers (e.g. authorities from the Schleswig Holstein consider that 'whole insects' including if chopped and pulverised are outside the scope of Regulation (EC) No 258/97 vs. authorities from the North Rhine-Westphalia consider that 'whole insects' should be classified as NF).	No official position at federal level. <b>Yes</b> , in certain landers. <b>No</b> in a few others. Unclear situation in many landers.	No	<b>Yes</b> within a few lander / <b>No</b> in several others	Imports from EU Member States are allowed. Specific import procedures (incl. veterinary border inspection via a border inspection post) apply when importing insects and their products) from non-EU countries.	

	Novel status of 'whole Insects' and 'products thereof'	Authorisation for production and marketing within the country?	Authorisation subject to certain restrictions)?	Application of the transitional measure	Import conditions	Reference document
Spain	The Spanish authorities considered that 'whole insects and their derived products' were already subject to the requirements of Regulation (EC) No 258/97.	No. However, by virtue of the Principle of Mutual Recognition provided in the treaty of the European Union, it could be possible to commercialise said specific insects. The principle of mutual recognition stems from Regulation (EC) No 764/2008. It defines the rights and obligations for public authorities and enterprises that wish to market their products in another EU country. The Regulation also defines how a country can deny mutual recognition of a product.	No authorisation	No	No imports allowed	AECOSAN information note 'SITUACION DE LOS EN ALIMENTACION HUMANA' (30 March 2016, updated on 21 March 2018)

	Novel status of 'whole Insects' and 'products thereof'	Authorisation for production and marketing within the country?	Authorisation subject to certain restrictions?	Application of the transitional measure	Import conditions	Reference document
Italy	The Italian authorities considered that 'whole insects and their derived products' <b>shall be classified as 'novel food' under Regulation (EC) No 258/97.</b>	No	No authorisation	No	No imports allowed	'Controlli Ufficiali in merito all'uso di insetti in campo alimentare con specifico riferimento all'applicabilità del reg. (CE) 258/97 sui 'novel foods' (Ministero della Salute, 29 October 2013)
Sweden	The Swedish authorities considered that 'whole insects and their derived products' <b>shall be classified as 'novel food' under Regulation (EC) No 258/97.</b>	No	No authorisation	No	No imports allowed	Public declaration from the Livsmedelsverket (6 December 2017)
Poland	N/A	N/A	N/A	N/A	N/A	N/A
Hungary	N/A	N/A	N/A	N/A	N/A	N/A
Portugal	The Portuguese authorities considered that 'whole insects and their derived products' shall be classified as 'novel food' under Regulation (EC) No 258/97.	It may be possible to produce food products in Portugal using raw materials imported from EU countries where they are legally marketed and export them to where their consumption is legal, wprovided the requirements of the countries concerned are met.	N/A	No	N/A	Direcção-Geral de Alimentação e Veterinária (DGAV)

## 4.9. May insect-based products be lawfully exported outside the European Union?

The Novel Food Regulation does not lay down specific export requirements. The rules on export as laid down under Article 12 of the General Food Law apply:

### General Food Law – Article 12

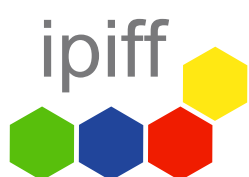
“1. Food [...] exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health [...], food [...] can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food [...] concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.”

Exports outside the EU can only be envisaged taking into account the **country of destination, in order to ascertain whether or not the requirements under the Novel Food Regulation** (e.g. authorisation granted in accordance with the procedure laid down in Regulation 2015/2283) **must be met** for the export activity to be performed.

For products that benefit from the transitional provisions (i.e. lawfully marketed in a country of the EU, pending an EU authorisation under Regulation 2015/2283), a **country-by-country assessment** is required, given that the scope and extent of the transitional arrangements varies between Member States (See above, Section 8, for more details).



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