# Regulation (EU)
## 2015/2283 on novel foods

**Summary Guidelines on the provisions relevant to the commercialization of insect-based products intended for human consumption in the EU**

**Brussels,**
**25 May 2018**

ipiff

International Platform
of Insects for Food and Feed

# Regulation (EU) 2015/2283 on novel foods

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

## Introduction

**Whole insects, their preparations and other derived products** were not consumed as food to a significant degree in Europe before 15 May 1997. As a consequence, these products qualify as 'novel food' under Regulation (EU) 2015/2283 and must be covered by an authorisation granted in accordance with one of the authorisation procedures established by this Regulation (hereafter referred to as the 'EU novel food authorisation procedures') before they can lawfully be placed on the market within the European Union.

These Summary Guidelines are intended to provide an overview of the administrative steps to be followed by insect producers intending to submit an application for authorisation within the European Union, in accordance with this legislation. This document also includes information on the notification procedure applying to traditional foods from third countries, however it does not specifically address all procedural steps associated with this specific regulatory path.

These Summary Guidelines are **accompanied with a comprehensive briefing paper**, which explains the procedural steps in further details. The briefing paper notably contains an in-depth analysis of the provisions of Regulation (EU) 2015/2283 that are relevant for insect producers. Please note that all the topics covered in the briefing paper are not reflected in these Summary Guidelines: every time a topic is covered in the briefing paper that is not and/or is only partially addressed in these Summary Guidelines, a direct reference to the relevant sections or sub-sections of the briefing paper is provided for easy reference.

These Summary Guidelines have been drafted by the **IPIFF Secretariat**, in collaboration with IPCFF novel food task force and the law firm **Bird & Bird LLP**.



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# 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

# 1. EU novel food authorisation procedures apply to insect-based products intended for human consumption

Regulation (EU) 2015/2283 - which has become applicable on 1 January 2018 - **clarifies that whole insects and their preparations must be considered as 'novel food'** unless it can be demonstrated that they have been consumed as food to a significant degree before 15 May 1997, such consumption before that date being commonly considered as not documented within the EU. By contrast, the formerly applying EU legislation on novel food (i.e. Regulation (EC) 258/97 in force until 31 December 2017) left some room for interpretation on the legal status of those products.

The table below provides a summary overview of the legal status of insects and their derived products (or insect-based products) under Regulation (EC) No 258/97 and Regulation (EU) 2015/2283.

| | 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 |

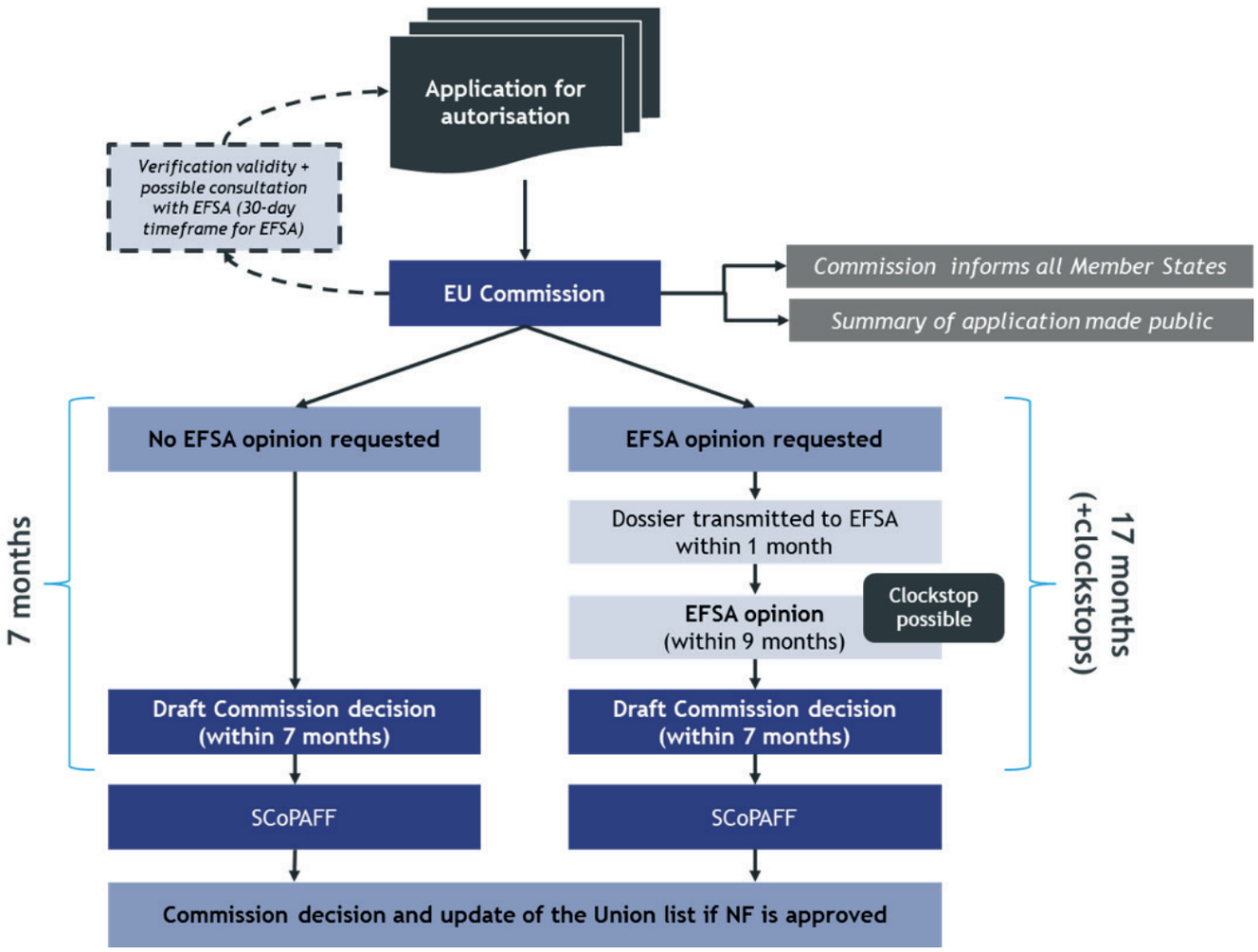
* Diverging national interpretations – Some Member States did consider these categories of products as novel food under Regulation (EC) No 258/97

For further information about the legal status of insects and their derived products, you may refer to **section 2 of the briefing paper** (pp. 8 et sqt).

# 2. Edible insect-based products must be authorized following an EU centralised procedure

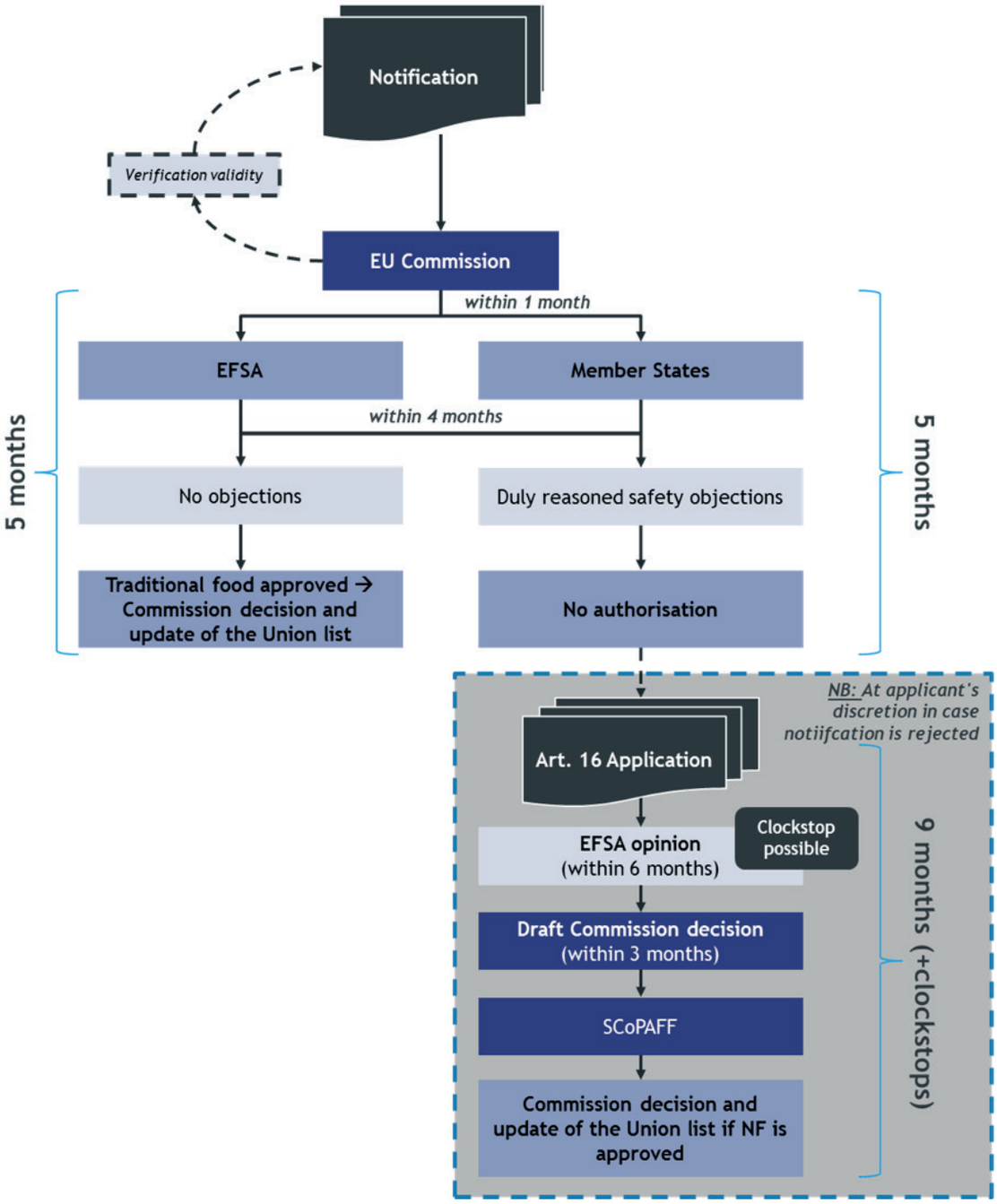
## 2.1. Two distinct procedures are open to insect producers

### The 'Standard' authorisation procedure




Procedure length: From approximately 8 months in case no opinion is requested from EFSA to 18 months where such opinion is requested from EFSA, with a possibility of clock stops.

## The Notification (and, where applicable, authorisation) procedure for traditional foods from third countries




Procedure length: 4 months may suffice from the date of submission of a valid and complete notification, provided that no safety concerns ('duly reasoned safety objections') are raised by any Member State or EFSA during that period.

For further information about the authorisation procedure, you may refer to **section 1 of the briefing paper** (pp. 6 et sqt).

The notification procedure can notably be a relevant regulatory path for the authorisation of insect-based products produced outside the EU, **in third countries or regions** in which **insects form part of the traditional diets of local populations**. Insect producers who seek to use this regulatory path must demonstrate that the following cumulative conditions are met:

1. Their products are derived from **primary production**;
2. Their products have a **history of safe use in a third country**, substantiated **by 25 years of uninterrupted consumption,** based on both anecdotal and documented evidence.

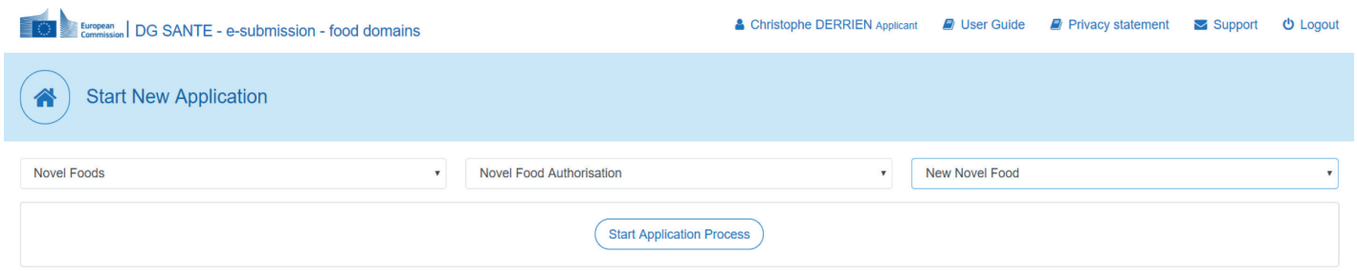
By way of principle, the notification procedure may also be applied by insect producers established on the territory of the European Union, although in practice it may be difficult for them to substantiate that their products are similar - e.g. in terms of preparation mode or processing methods used- to insect products that are traditionally consumed in EU third countries.

For further information about the criteria for eligibility to the notification procedure, you may refer to **section 3 of the briefing paper** (pp. 10 et sqt).

# 2.2. Applications must be submitted through the e submission system

Novel Food applications for authorisation 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.

**Illustration: starting page of the e-submission system**




For practical guidance on how to submit an application, you may refer to 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 .

# 3. The responsibility for submitting a novel food application or notification mainly lies with insect primary producers

According to Regulation (EU) 2015/2283, the responsibility for submitting a novel food application or initiating a notification procedure lies on actors 'placing the novel food on the EU market'.

In practice the main responsibility for submitting an application will generally lie on **insect primary producers** (or insect breeders). Two main situations can be envisaged:

- Scenario 1: the insect primary producer sells insect-based products (e.g. insect meal) to a subsequent operator, who further processes and/or incorporates them into a final product (most common situation);
- Scenario 2: the primary producer commercializes the final product directly to consumers or through an intermediary or a distributor (in that case the operator controls the entire production chain).

In both abovementioned cases, the **insect primary producer controls the 'critical' production operations**, which determine the composition/ intrinsic characteristics of the final insect product or of the insect ingredient(s) that is(are) incorporated into a final product. This explains why the responsibility for submitting an application or initiating a notification procedure lies with the primary producer. In the first abovementioned scenario, the application or notification will have to be accompanied with additional information transmitted by the 'subsequent operator' (e.g. on the intended use of the final product) whereas in the second scenario, the insect primary producer already possesses all relevant information that shall form the subject-matter of the application or notification.

Furthermore, the application or notification may be submitted:

- by a **single applican**t or;
- **jointly by several applicants** (e.g. application or notification submitted on behalf of several producers that are active in the production of the same insect species).

The latter option is relevant for operators who intend to share the costs associated with the preparation and submission of the application or notification dossiers. In practice, such option seems feasible for products originating from the same insect species and/or produced under 'similar conditions' only.

> For further information on the responsibility of primary producers and/or on options for submitting a joint application or notification, you may refer to **section 4 of the briefing paper** (see 'remarks regarding non-institutional applicants' p. 11 et sqt).

Besides food business operators, 'institutional' actors are also empowered to initiate an application or a notification.

- Initiative from EU and non-EU countries is possible but seems in practice mostly relevant in the case of a joint application or notification submitted by a third country: in a number of EU third countries, authorities may indeed be 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 dossier.
- Furthermore, the European Commission has a right of initiative for the authorisation and update of authorisation of novel foods, notably when public safety concerns are at stake.

> For further information on criteria and modalities for 'institutional' actors to submit an application or a notification, you may refer to **section 4 of the briefing paper** (see 'remarks regarding 'institutional applicants' pp. 12).

# 4. The application dossier must conform to a specific format and contain exhaustive information to enable appropriate risk assessment of the product

**Note:** the present Summary Guidelines only refer to the requirements associated with the preparation and submission of a 'standard' application for authorisation. For further information about the specific requirements related to the notification procedure, you should refer to article 14 et seq. of Regulation (EU) 2015/2283.

## 4.1. Main information to be included in the application

Insect producers who wish to apply the 'standard' application procedure (see section II.1 above for more details) to authorize their products under the novel food legislation must ensure that their dossier contains the following information:

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

The abovementioned technical dossier should be composed of the following information:

- **Administrative data**, including references to personal details of the applicant, the overall structure/organisation of the dossier (e.g. through a table of contents, list of annexes) and indications as to whether the dossier (or certain parts of it) is (are) subject to a request for data protection and/or confidentially treatment by the applicant. In the latter case, the applicant must specify which parts of the dossier are to be treated as confidential and provide information and explanations substantiating the existence of the applicant's right of reference to the proprietary scientific evidence.
- **Scientific data**, including references to the documentation substantiating the absence of safety risks of the product (i.e. raw data of the individual studies referred in the application) and more generally information on the overall safety evaluation strategy followed (e.g. justifications for excluding certain studies) and overall conclusion on the safety of the proposed uses of the novel food.

As part of the scientific data requirements, a description of the production process(es) is notably required. For the particular case of insect products, the production conditions, including inputs used for the consumption of insects (as main determinant of potential hazards) as well as all measures implemented for the production, control and quality and safety assurance (e.g. HACCP, GMP, ISO) should be described. Notably, adherence to recognized professional guides of good hygiene practices is a critical element to substantiate the safety of the product.

**The following illustration indicates how the sub section on 'administrative data' is structured in the online application (i.e. extract e submission web page)**

**1. Identity of the novel food to be authorised** *

Novel Food category *

-- Please select Food Category type --

**2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283**

Applicant Name *

Email *

This field is required

Address *

Phone *

Post code *

Website

Country *

-- Please Select --

**5. Confidentiality**

Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

○ Yes ◉ No

**6. Data Protection**

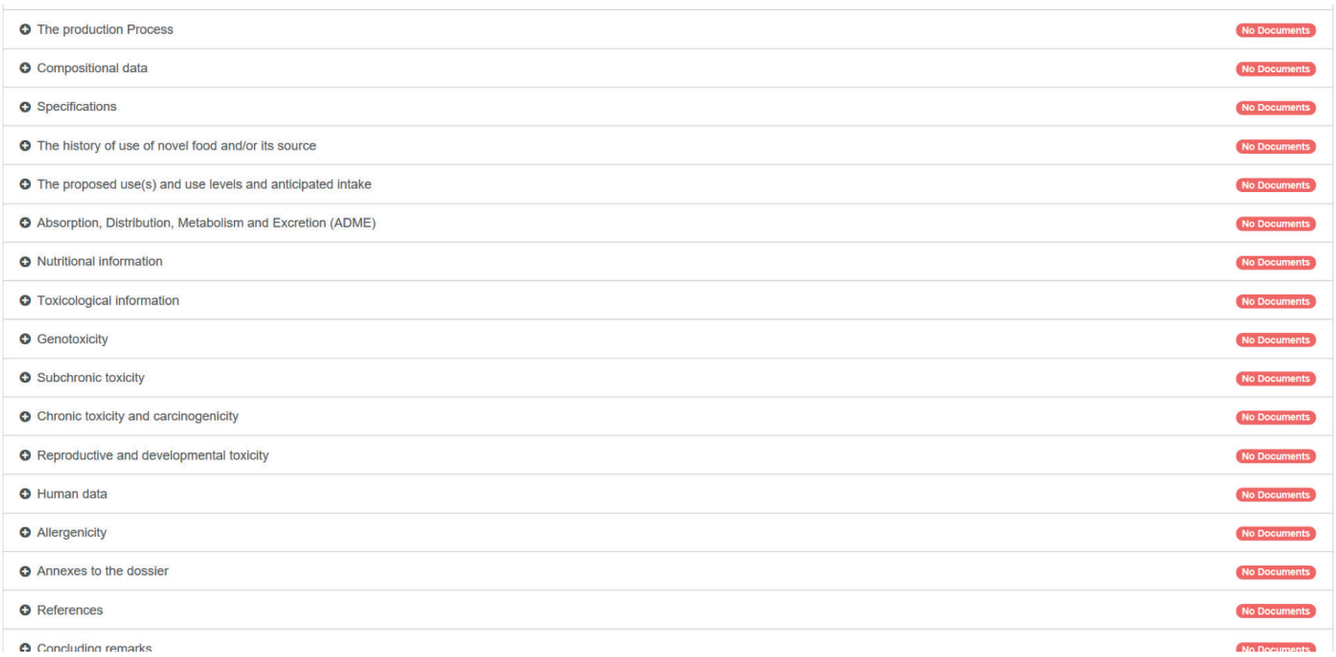
Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283

○ Yes ◉ No

**7. Proposed entry in the union list**

Add new Novel food category +

**The following illustration indicates the different sections to be documented as part of the scientific data requirements (i.e. extract e-submission web page)**



## 4.2. Conditions of intended use

The application dossier shall specify the **conditions of intended use of the product** (later referred as the 'food uses'), i.e.:

- The 'food category' of the final product in which the insect novel food product/ingredient is intended to be incorporated;
- The maximum inclusion level of the insect novel food product/ingredient in the final product.

**Careful consideration** should be given by the applicant to **the framing of the above conditions**, in order to ensure that these **adequately cover all intended uses** of the insect novel food product/ingredient for which an authorisation is sought: indeed, the food uses that are not listed in the approved application or notification will not be covered by the authorisation granted to the applicant. Consequently, an operator seeking to commercialise a product for such new food use will need to submit a request for **extending the previous authorisation** (see chapter VI below).

> See Scientific Opinion that EFSA published on 8 October 2015 on the risk profile related to production and consumption of insects as food and feed. Available at http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4257/epdf

## 4.3. Specifications of the product

Besides the conditions of intended uses, the applicant shall provide detailed information as regards **the product specifications**: i.e. information enabling to characterise and/or identify the product in its main constituents, including limits on the presence of certain contaminants (e.g. biological and chemical contaminants) in the final product.

In the particular case of insect products, such specifications may notably include:

- the **concentrations of the main constituents** in products (compositional requirements)
- **microbiological criteria**
- **acceptable 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'[1].

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.

> For further information on the requirements associated with the conditions of intended uses and specifications of the product, you may refer to **section 5 of the briefing paper** (sub-section 'conditions of intended uses, product specifications and labelling requirements', p. 16 and following sub sections).

[2] See 'IPIFF report on approaches to addressing data requirements for insects as novel food" (published on 24 May 2018), p 7.

# 5. Applicants may request to keep certain information confidential and/or to protect scientific evidence

**Note:** the following rules are solely applicable to applications filed in accordance with the 'standard' procedure.

## 5.1. Confidentiality

Any request for keeping certain information confidential must **be duly justified** and recorded in a specific annex accompanying the application dossier.

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

The above request for confidential treatment is subject to **approval by the European Commission.**

## 5.2. Data protection

Aside from requests for confidentiality treatment of (some parts) of the application dossier, applicants may apply for a **five-year period** of regulatory data protection.

In order for such operators to be eligible to data protection, the data submitted shall meet the **three cumulative conditions**, i.e.:

- Condition 1: the data must consist of newly developed scientific evidence or scientific data that the applicant has designated as proprietary upon the first application;
- Condition 2: at the time the first application was made, the initial applicant had an exclusive right of reference to data;
- Condition 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.

It is the competence and responsibility of the **European Commission** to decide on the grant of data protection against the set of the above criteria, at the end of the authorisation process.

**The applicant who has obtained such data protection benefits from a market exclusivity** in respect of those data for a period of 5 years following the authorisation of the product. The grant of data protection does however 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. Furthermore, the initial applicant may agree with subsequent applicants on the use of the data that benefits data protection, e.g. by means of a letter of access. Alternatively, the subsequent applicants may submit their 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.

For further information about the eligibility criteria and legal consequence associated with confidential treatment and data protection, you may refer to **section 7 of the briefing paper** (pp. 22 et seqt).

# 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 |
|---|---|---|---|---|---|---|
| **Denmark** | The Danish Veterinary & Food Administration (DVFA) considered that 'whole insects' and their parts were not covered under Regulation (EC) No 258/97, 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 form 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) |
| **The Netherlands** | The Dutch Office for risk Assessment and Research (Bureau Risicoboordeling en Onderzoeksprogrammering' – BuRo') considered that 'whole insects' and their parts were not covered under the former EU 'novel food' Regulation. | Yes. Or factual tolerance policy ?? the products must conform with other applicable legislations (e.g. General EU food law and EU 'Hygiene Package' requirements). | No | Yes | N/A | N/A |
| **The United Kingdom** | The UK Food Standard Agency (FSA) considered that 'whole insects' and their parts were not covered under Regulation (EC) No 258/97. | 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) |
| **Finland** | In September 2017, on request of the Government, the Finish Food Safety Authority (EVIRA) changed its interpretation of the scope of the novel food legislation and considered that 'whole insects' were not covered under Regulation (EC) No 258/97, 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 'legal uncertainty' 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 Domesticus 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 where 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 were not covered under the Regulation (EC) No 258/97. | 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 domesticus, Locusta migratoria migratorioides, Zophobas atratus morio, Tenebio 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) |

| | 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' shall be classified as 'novel food' under Regulation (EC) No 258//97. 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 tribunals (the final judgment of the French Tribunals may contradict the position of the French authorities on the novel status of 'whole insects and products thereof'). | No authorisation | Currently not but conditioned by the final decision of the French tribunals. | 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. Yes, in certain landers. No in a few others. Unclear situation in many landers. | No | Yes within a few lander / No 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 | No authorisation | No | No imports allowed | AECOSAN information note 'SITUACION DE LOS EN ALIMENTACION HUMANA' (30 March 2016, updated on 21 March 2018) |
| Italy | The Italian authorities considered that 'whole insects and their derived products' shall be classified as 'novel food' under Regulation (EC) No 258/97. | No | No authorisation | No | No imports allowed | 'Controli Uffciali in merito all'uso di insetti in campo alimentare con specifico riferimento all'applicabilita 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' shall be classified as 'novel food' under Regulation (EC) No 258/97. | 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 |

For further information about article 35.2 transitional measure and associated subjects that are not covered through these Summary Guidelines (e.g. legal background on position of EU Member States and/or on possibilities for producers to exports their products outside the European Union) you may refer to **section 8 of the briefing paper** (pp. 25 et seqt)

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