

Authorizing Edible Insects under **& Bird & Bird** the Novel Food Regulation

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Reading it Right on Novel Food

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SUMMARY

- ❖ Legal Status of Edible Insects under the European Legislation
- ❖ Legal consequences of the novel food qualification
- ❖ Procedures for Authorizing Insects and Insect-based products
- ❖ Information to be included in the dossier
- ❖ Transitional Measures and how they affect the Insect Industry

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LEGAL STATUS OF INSECTS UNDER THE
EUROPEAN LEGISLATION

EDIBLE INSECTS UNDER REG. 258/1997/EC

- Legal uncertainty on the **regulatory classification** of edible insects since in the European legislation no mention is expressly made to insects as food;
- Edible insects fall within the **definition of food** as provided by Article 2(1) of Regulation 178/2002/EC "*food means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*".
- Edible insects are not traditional consumed by the European population.



That's the reason why they are traditionally classified as **NOVEL FOOD**

EDIBLE INSECTS UNDER REG. 258/1997/EC

Under the EU legislation to be considered as novel, a food need to satisfy a twofold condition:

- a. It shall not be used for human consumption to a **significant degree** within the Community before 15 May 1997; and
- b. It shall fall within one of the categories set forth by Article 1(2).

Article 1

1. This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients.

2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

- (e) 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;

DIFFERENT APPROACH OF EU MEMBER STATES

- Some European Member States (i.g. Italy, Spain, Ireland just to mention some of them) considered whole insects and their part as novel food;
- Other Member States (UK, Denmark, The Netherlands, Belgium) consider whole insects and their part out of the scope of the regulation. According to their interpretation, **only substances isolated** from insects (such as proteins, lipids) shall be considered as novel food.



Fragmentation in the insects market

The regulatory classification of insects as novel food implies that they are subject to a pre-market authorizations before being placed on the market.

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EDIBLE INSECTS UNDER THE NEW
NOVEL FOOD REGULATION

NEW NOVEL FOOD REGULATION (REG. 2015/2283/EU)

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** (...)"*



(v) of Article 3 which cover *"food consisting of, isolated from or produced from animals or their parts"*.

LEGAL CONSEQUENCES OF NOVEL FOOD CLASSIFICATION

From 1 January 2018, insects and insect-based products need to be authorized under the new novel food Regulation before being placed on the market **unless it is proved** that they **has been used for human consumption** to a **significant degree** within the Community before 15 May 1997.



Since in the UK, edible insects are **legally** in the market, in 2015 the Food Standard Agency has sent a letter to the interested parties asking for **data to demonstrate the human consumption** to a significant degree.

ASSESSING THE NOVEL FOOD STATUS OF INSECTS

The type of evidence that, according to the Authority, can support a case for significant history of consumption consists of:

- **Comprehensive Sales Information:** invoices, detailing sale of food, including evidence of large quantity of sale in the EU;
- **Sales Information:** invoices
- **Government Import/Export Information:** catalogues, sales brochures;
- **Expert knowledge:** personal testimonies



The amount of information supplied in response to that request does not demonstrate a history of consumption for any type of insect being supplied as parts.

STATUS OF INSECTS UNDER THE NOVEL FOOD REGULATION

From 1 January, Insects food operators that wish to assess the novel food status of their products, need to follow the procedure set forth in the:

DRAFT COMMISSION IMPLEMENTING REGULATION (EU) .../... 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



The insect business operator shall consult the Member State where it intends to place the product for the first time. It shall submit the following information:

- a. a cover letter
- b. a technical dossier**
- c. supporting documentation;
- d. explanatory note clarifying the purpose and relevance of the submitted documentation.



STATUS OF INSECTS UNDER THE NOVEL FOOD REGULATION

DRAFT

Technical Dossier – Food other than extracts and foods resulting from a production process not used for food product within the Union before 15 May 1997:

1. Description of the food;
2. Further characterization of the food and/or source of the food (where relevant);
3. Conditions of use;
4. Production process;
5. History of Human consumption of the food within the Union before 15 May 1997;



The recipient Member State:

- shall verify the **validity of the consultation request**, informing the FBO, the other Member States and the Commission of the decision.
- shall **conclude on the status of the novel food within 4 months** from the date in which it decided on the validity of the consultation request.

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HOW TO AUTHORIZE EDIBLE INSECTS
UNDER THE NEW NOVEL FOOD
REGULATION

AUTHORIZATION PROCEDURES

General Procedure

- It applies to any kind of novel food;
- It takes at least **17 months** (1 + 9 months for EFSA opinion + 7 months to adopt implementing act);
- The applicant shall produce scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
- The applicant can require the protection of data

Notification Procedure

- It applies only to traditional foods from third countries provided that:
 - a. They have been consumed in at least one third country for at least **25 years** as a part of the customary diet of a significant number of people;
 - b. They are derived from primary production as defined in Regulation (EC) No 178/2002, regardless of whether or not they are processed or unprocessed foods.
- It takes only **5 months** when duly reasoned safety objection are not submitted by EFSA and MS
- The applicant shall only demonstrate the history of safe food use in a third country;
- No data protection

EFSA DOCUMENTS



When preparing applications or notifications, reference shall be made to the documents published by EFSA in 2016:

- Guidance on the preparation and presentation of an application for authorization of a novel food in the context of Regulation (EU) 2015/2283;
- Guidance on the preparation and presentation of the notification and application for authorization of traditional food from third countries in the context of Regulation (EU) 2015/2283.

DOSSIER REQUIREMENTS

GENERAL PROCEDURE

- 1. Administrative data**
- 2. Characterization of the novel food, technical and scientific data:**
 - i. Identity
 - ii. Production process
 - iii. Compositional data
 - iv. Specifications
 - v. Proposed uses and use levels and anticipated intake
 - vi. Absorption, distribution, metabolism and excretion
 - vii. Nutritional information
 - viii. Toxicological information
 - ix. Allergenicity

3. Annexes

NOTIFICATION PROCEDURE

- 1. Administrative data**
- 2. Characterisation of the traditional food, technical and scientific data**
 - i. Identity of the traditional food
 - ii. Production process
 - iii. Compositional data
 - iv. Data from experience of continued use
 - v. Proposed conditions of use for the EU market (target population, use levels, intended role in the diet, precautions and restriction of use;
- 3. Annexes**

RISK PROFILE OF INSECT AS FOOD AND FEED

When authorising edible insects, the applicant shall take into account also the EFSA Scientific Opinion **Risk profile of insects as food and feed** (2015).

EFSA Scientific Committee

SCIENTIFIC OPINION



ADOPTED: 5 October 2015
doi:10.2833/ej.2015.4257

PUBLISHED: 8 October 2015

Risk profile related to production and consumption of insects as food and feed

EFSA Scientific Committee

Abstract

The present opinion has the format of a risk profile and presents potential biological and chemical hazards as well as allergenicity and environmental hazards associated with farmed insects used as food and feed taking into account of the entire chain, from farming to the final product. The opinion also addresses the occurrence of these hazards in non-processed insects, grown on different substrate categories, in comparison to the occurrence of these hazards in other non-processed sources of protein of animal origin. When currently allowed feed materials are used as substrate to feed insects, the possible occurrence of microbiological hazards is expected to be comparable to their occurrence in other non-processed sources of protein of animal origin. The possible occurrence of prions in non-processed insects will depend on whether the substrate includes protein of human or ruminant origin. Data on transfer of chemical contaminants from different substrates to the insects are very limited. Substrates like kitchen waste, human and animal manure are also considered and hazards from insects fed on these substrates need to be specifically assessed. It is concluded that for both biological and chemical hazards, the specific production methods, the substrate used, the stage of harvest, the insect species and developmental stage, as well as the methods for further processing will all have an impact on the occurrence and levels of biological and chemical contaminants in food and feed products derived from insects. Hazards related to the environment are expected to be comparable to other animal production systems. The opinion also identifies the uncertainties (lack of knowledge) related to possible hazards when insects are used as food and feed and notes that there are no systematically collected data on animal and human consumption of insects. Studies on the occurrence of microbial pathogens of vertebrates as well as published data on hazardous chemicals in reared insects are scarce. Further data generation on these issues are highly recommended.

Keywords: insects, food, feed, microbes, allergenicity, chemicals, safety, production, consumption

Requestor: European Commission

Question number: EFSA-Q-2014-00578

Correspondence: scor@efsa.europa.eu

www.efsa.europa.eu/efsajournal

[EFSA Journal 2015;13\(10\):4257](https://doi.org/10.2833/ej.2015.4257)

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GENERAL REMARKS

- ✓ Both procedures are **costly and time consuming** even though the notification procedure can be cheaper and faster in the light of the type of information required;
- ✓ Authorizations are general but **really specific** since the applicant is required in both cases to specify the conditions of use and anticipate intakes



i.g. 10% of cricket flour in bakery products

- ✓ **New uses would require a new application** for a modification of the conditions of use of an already authorized novel food;
- ✓ When authorizing insects, the **type of species**, the **time of harvesting**, the **substrate used**, the **methods for farming and processing** are aspects that need to be addressed since they can affect safety;
- ✓ The Insect Business Operator that wishes to place on the market an authorized insect-based product shall pay attention to make **exactly the same product**.

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TRANSITIONAL MEASURES AND HOW THEY
AFFECT THE FOOD INDUSTRY

TRANSITIONAL MEASURES

Article 35

Transitional measures

1. Any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application under this Regulation.

The Commission shall not apply Article 11 of this Regulation, where a risk assessment has already been provided by a Member State on the basis of Regulation (EC) No 258/97 and no other Member State has raised any reasoned objection to that assessment.

2. 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.

COMMISSION IMPLEMENTING REGULATION (EU) .../... 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



EFFECTS ON FOOD INDUSTRY

Article 35(2) implies that:

- ✓ Insects and insects based products cannot be legally placed on the market **unless they are proved to be outside the scope** of the NFR or **they are authorized** under the NFR;
- ✓ Insects and insects based products which on 1 January 2018 are **legally** on the market may continue to be placed on the market **until 2 January 2020**, provided that the food business operator submit an application by **1 January 2019**;
- ✓ **Lacking an application** submitted by 1 January 2019, insects and insect-based product which are **legally** on the market may continue to be placed on the market only until 1 January 2019.

Thank you
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