Authorizing Edible Insects under the Novel Food Regulation

Dr. Francesca Lotta

Reading it Right on Novel Food

London, 27 September 2017
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
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.e., Italy, Spain, Ireland just to mention some of them) considered whole insects and their parts as novel food;

• Other Member States (UK, Denmark, The Netherlands, Belgium) consider whole insects and their parts 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.
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".

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.
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.
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:


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

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.
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
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, intend role in the diet, precautions and restriction of use;

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

& Bird & Bird

francesca.lotta@twobirds.com