

The EU novel food legislation and insect food

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The Concept of 'Novel Food'

Current novel food Regulation (EC) 258/07
applicable until 31.12.2017

'**Novel food**' means any food that was not used for
human consumption to a significant degree within
EU before 15 May 1997

Falls at least in one of **listed categories** one being

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Insects Novel Foods?

Current NF Regulation (EC) 258/97
unclear as regards whole animals e.g.
 insects

Some EU States **tolerate** whole insects as food

New NF Regulation (EU) 2015/2283 **clarifies**

- insects are novel foods unless proven history of food use before 1997



Regulation (EU) 2015/2283

Will be **fully implemented from January 2018**

- **Food** as defined in Reg. (EC) 178/2002
- **Respects** the current time limit for novelty *i.e.* not used for human consumption before 15.5.1997
- **Categories** reconsidered and updated
- Transitional measures
 - open files
 - 'clarification' in coverage



Comparison with the old system

A new fully centralized system:

- requests to **EU Commission**
- **EFSA** for risk assessment
- generic authorization, the **'Union list'**

'Traditional food' from third countries

Member States (*still*) responsible for determination of novel food status and Commission may decide if food a novel food



Updated categories cover insects

Article 3 point (a) sub-point (v) category:

Food **consisting of**, isolated from or produced from animals or their parts without history of safe food use

Results in that:

- **All insect products** clearly covered and authorisation is needed
- **Full application** for EU produce
- **Notification** for third country traditional products having history of safe use as food



Full Authorisation Procedure

A request is sent to EU Commission with information on:

- *the applicant* (name, address)
- *the food* (name, description of the food and the production process)
- detailed composition of the food
- scientific evidence demonstrating safety
- proposal for conditions of use, labelling
- analysis method (*when appropriate*)



Full Authorisation Procedure (*cont.*)

Safety assessed by EFSA (9 months)

EFSA guidance (*EFSA Journal 2016;14(11):4594*)

Key principles:

- 'As safe as a comparable food on the market'
- Composition and conditions of use does not pose a risk to human health
- Not nutritionally disadvantageous

Commission to present a draft implementing act for authorization in *7 months (comitology procedure)*



Traditional food from 3rd countries

A simplified notification procedure possible if food:

- originates from **primary production**
- has history of safe food use
- has continuously been used as food for **25 years** as part of **customary diet** by a **significant number** of people
- EFSA guidance (*EFSA Journal 2016;14(11):4509*)



The Notification Process

The notification is sent to EU Commission with information on:

- *the applicant* (name, address)
- *the food* (name, description and detailed composition of the food)
- country/countries of origin of the food
- documented data on history of safe food use
- proposal for intended use incl. conditions of use, labelling proposal



The Notification Process *(cont.)*

EU Member States and EFSA may present **objections** within *4 months*

- duly reasoned concerns on safety
- EFSA guidance

No objections → inclusion in the Union List

Objections → application needs to be submitted with data to answer concerns



Additional noteworthy rules

By 1st January 2018 implementing acts on

- requirements for presentation of notifications and applications, procedures for their validation, information exchange with Member States etc.

Transitional measures

Open files transferred to new system January 2018

Possibility to extend set time limits

- EFSA opinion, Commission draft proposals

Possibility for data protection (for 5 years)



Insects from January 2018 onwards

Insects **from 3rd countries** through the notification procedure possible

In all EU Member States insects as food whether whole, parts or processed need authorization

Transitional measure for tolerance of whole insects if application submitted by 1.1.2020

EFSA guidance on preparation of dossiers published

EFSA opinion on risk profile related to insects published



Insects under consideration

A limited number of insects discussed

for instance by EFSA <https://www.efsa.europa.eu/en/efsajournal/pub/4257>

<i>Musca domestica</i>	Common housefly
<i>Hermetia illucens</i>	Black soldier fly
<i>Tenebrio molitor</i>	Mealworm
<i>Zophobas atratus morio</i>	Superworm
<i>Alphitobius diaperinus</i>	Lesser mealworm
<i>Galleria mellonella</i>	Waxworm
<i>Achroia grisella</i>	Lesser waxworm
<i>Bombyx mori</i>	Silkworm
<i>Acheta domesticus</i>	House cricket
<i>Gryllobasys signatus</i>	Banded cricket
<i>Locusta migratoria migratorioides</i>	African migratory locust
<i>Schistocerca americana gregaria</i>	American desert locust





Thank you! Questions?

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