

# The Novel Food Regulation (EU) 2015/2283

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27.10.2016



# Regulation (EU) 2015/2283

- **New** novel food regulation is in force but will be **fully implemented January 2018**
- **Food** as defined in Reg. (EC) 178/2002
- Food additives, flavourings, enzymes, extraction solvents or gmo's not in scope
- *Medicinal herbs (i.e. drugs) are not food*

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# The Concept of '*Novel Food*'

**'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**

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# Novel Food Categories

- New or modified molecular structure
- Food **consisting of**, isolated from or produced from:
  - microorganisms, fungi, algae
  - material from **mineral origin**
  - **plants\*** or their parts without history of use
  - **animals** or their parts without history of use
  - **cell or tissue cultures**

*\* special case 'non-traditional propagating practices'*

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# Novel Food Categories *(cont.)*

- Food produced with a novel method which significantly changes the food's composition or structure
- **Nanomaterials**
- Prior use **only** in/as food supplements
- Vitamins and minerals (*in food supplements, special foods or for enrichment*) produced with a **new method** or which are in **nanofom**

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# Comparison with the old system

## A new centralized system:

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

'**Traditional food**' from third countries (*new*)

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



# The Union List of Novel Foods

## Initial list 1st January 2018

- current authorizations and substantially equivalent foods notified to the EU Commission *with specifications*

## Updating the list with new foods if:

- food does not pose a safety risk to health
- food does not mislead the consumer
- food not nutritionally disadvantageous compared to existing food

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# 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

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# The concept of '*Primary Production*'

Regulation (EC) 178/2002, Article 3 defines:  
*(i.e. general principles of EU food law)*

**'*Primary Production*'** means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

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# 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

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# The Notification Process *(cont.)*

Commission forwards the **notification** to the Member States (MS) and to EFSA

**Objections** may be presented within **4 months**

- duly reasoned concerns on safety
- EFSA guidance under preparation

**No objections** → inclusion in the Union List

**Objections** → application to be submitted  
→ data to answer MS's concerns



# The Notification Process *(cont.)*

Commission forwards the **application** to **EFSA** and makes it available to the MS

**EFSA** opinion in **6 months**

- history of safe food use
- composition and conditions of use
- nutritionally not disadvantageous

**Commission** to submit draft implementing act for authorization in **3 months** (*comitology procedure*)



# Full Authorisation Procedure

**A request** is sent to the 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*)

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# Full Authorisation Procedure *(cont.)*

## **EFSA** to carry out safety assessment

- 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

## **EFSA Opinion** in *9 months*

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

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# Additional noteworthy rules

## **By 1<sup>st</sup> January 2018 implementing acts on**

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

## **Possibility to extend set time limits for**

- EFSA opinion, Commission draft proposals

## **Possibility for data protection** (for 5 years)

## **Open files** transferred to new system January 2018

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# Case - Insects

**Current NF Regulation** (EC) 258/97

*not clear* 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 in EU
- may qualify as traditional food in 3rd countries
- applicable from **1st January 2018**

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# Case - Insects

**A limited number of insects** under discussion

for instance the Belgian list (<http://www.favv-afsca.fgov.be/foodstuffs/insects/>)

*Acheta domesticus*

*Locusta migratoria migratorioides*

*Zophobas atratus morio*

*Tenebrio molitor*

*Alphitobius diaperinus*

*Galleria mellonella*

*Schistocerca americana gregaria*

*Gryllodes sigillatus*

*Achroia grisella*

*Bombyx mori*

House cricket

African migratory locust

Superworm

Mealworm

Lesser mealworm

Waxworm

American dessert locust

Banded cricket

Lesser waxworm

Silkworm

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# Insects from January 2018 onwards

Introduction of insects (whole, parts or processed)  
**from 3rd countries** to European food market  
through the notification procedure possible

**In all EU MS** insects to be used as food (whole, parts or processed) need authorization

**EFSA** guidance on dossiers for safety assessment

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***Thank you! Questions?***

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