




Insect culture in Circular Agriculture - Agroinsecta
23 November 2023

The Novel Foods Regulation and insects in human nutrition

A photograph of the European Union flag, which is blue with twelve yellow stars in a circle, waving in the wind. Two hands are visible at the bottom, holding the corners of the flag.

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Innovation*



Insects and the Novel Foods Regulation

Regulation (EU) 2015/2283 on novel foods.

- ✓ Food not used for human consumption to a significant degree before 15 May 1997. Insects as food fall under
 - ❖ Art 3(v) "food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union"

Definition of insects

Commission Delegated Regulation (EU) 2022/2292

➤ 'Insects' means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and included in the Union list of novel foods (Implementing Regulation (EU) 2017/2470).

2. NF authorisation process



European
Commission

Application¹
or COM initiative

COM²

Application made
available to Member
States

Summary made
publicly available

EFSA not consulted⁴

COM (7 months from the
date of the valid
application, impl. act)

Standing Committee

Update of Union list

EFSA consulted
(9 months)

Applicant &
MS

COM (7 months from
EFSA opinion, impl.
act)

Standing Committee

Update of Union list³

Authorisation process Novel food - Article 10

¹Applicant may withdraw its application at any time

²COM may terminate the update at any stage

³Generic authorisation, except if authorisation based on protected data

⁴When an update related to an authorised NF is not liable to have an effect on human health

2-EFSA Novel Food Guidance



- Identity of the novel food
- Production process
- Compositional data
- Specifications
- History of use of the novel food and of its source
- Proposed uses and use levels and anticipated intake
- Absorption, distribution, metabolism, and excretion (ADME)
- Nutritional information
- Toxicological information

- Allergenicity
- Concluding remarks
- References

EFSA must consider the following:

- ✓ whether the Novel Food in question is **safe**
- ✓ whether the composition of the food and the conditions of its use **do not pose a safety risk** to human health in the Union
- ✓ whether the normal consumption of the NF/TF would be **nutritionally disadvantageous** for the consumer

Data protection

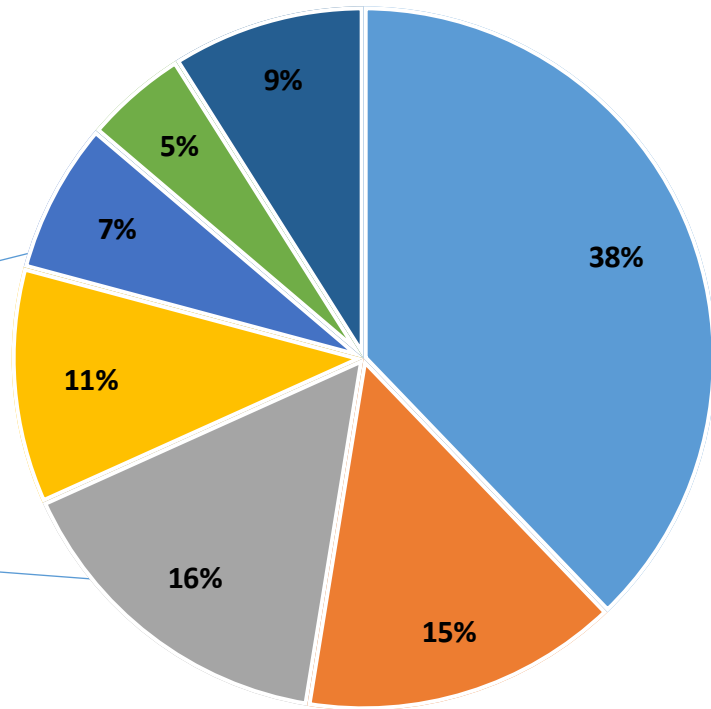
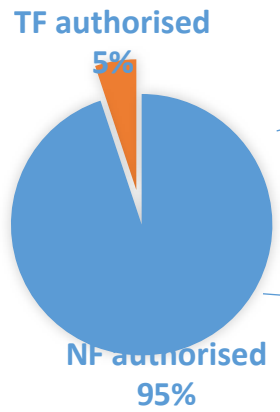
To support innovation within the agri-food industry, a market exclusivity of 5 years may be granted upon request, that protects the proprietary data used for the authorisation. It does not prevent any other applicant to apply for the authorisation of the same product, using its own data.

Currently, the data in the application dossiers for all insect species authorised under the NF Regulation are protected.

The Union list of novel foods



Total of authorised novel foods



- Food Supplement
- Bread category
- Milk based prod
- Breakfast cereals
- Infant formula
- Fruit juices
- Beverages

Insects as Novel food

4 Insect species authorised (data protected)



Acheta domesticus



Locusta migratoria



Tenebrio molitor



Alphitobius diaperinus

Under EFSA risk assessment



Acheta domesticus



Tenebrio molitor



Hermetia illucens



*Apis mellifera male
pupae*

Protein powders from Acheta domesticus, Alphitobius diaperinus and T. molitor larvae

The Union list of novel foods (*an example*)



Table 1

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Dried <i>Tenebrio molitor</i> larva (yellow mealworm)	<i>Specified food category</i>	<i>Maximum levels</i>	<ol style="list-style-type: none"> The designation of the novel food on the labelling of the foodstuffs containing it shall be “Dried <i>Tenebrio molitor</i> larva (yellow mealworm)”. The labelling of the foodstuffs containing dried <i>Tenebrio molitor</i> larva (yellow mealworm) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans and products thereof, and to dust mites. This statement shall appear in close proximity to the list of ingredients. 		Authorised on 22 June 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: SAS EAP Group, 35 Boulevard du Libre Échange, 31650 Saint-Orens-de-Gameville, France. During the period of data protection, the novel food is authorised for placing on the market within the Union only by SAS EAP Group, unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283, or with the agreement of SAS EAP Group. End date of the data protection: 22 June 2026.
	Dried <i>Tenebrio molitor</i> larva, whole or in powder				
	Protein products	10 g/100 g			
	Biscuits	10 g/100 g			
	Legumes-based dishes	10 g/100 g			
Pasta-based products	10 g/100 g				



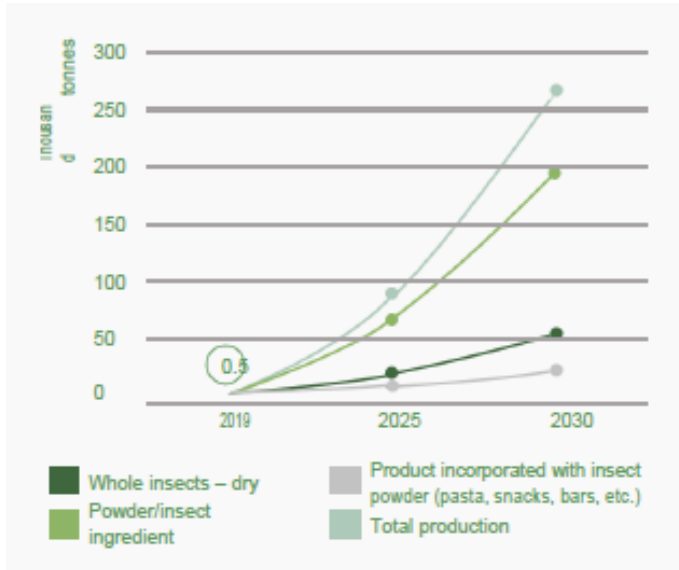
(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised Novel Food	Specification
Dried <i>Tenebrio molitor</i> larva (yellow mealworm)	<p>Description/Definition: The novel food is the whole, thermally dried yellow mealworm, either whole (blanched, oven-dried larva) or in the form of a powder (blanched, oven-dried, ground larva). The term "mealworm" refers to the larval form of <i>Tenebrio molitor</i>, an insect species that belongs to the family of <i>Tenebrionidae</i> (darkling beetles). The entire mealworms are meant for human consumption and no parts are removed. A minimum 24 hours fasting period is required before the thermal drying step, to allow the larvae to discard their bowel content.</p> <p>Characteristics/Composition:</p> <p>Ash (% w/w): 3,5 – 4,5 Moisture (% w/w): 1-8 Crude protein (N x 6,25) (% w/w): 56–61 Digestible Carbohydrates (*) (% w/w): 1–6 Fat (% w/w): 25–30 of which saturated (% w/w): 4–9 Peroxide value (Meq O₂/kg fat): ≤ 5 Dietary fibre (% w/w): 4–7 Chitin (% w/w): 4–7</p> <p>Heavy metals:</p> <p>Lead: ≤ 0,075 mg/kg Cadmium: ≤ 0,1 mg/kg</p> <p>Mycotoxins:</p> <p>Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg Aflatoxin B1: ≤ 2 µg/kg Deoxynivalenol: ≤ 200 µg/kg Ochratoxin A: ≤ 1 µg/kg</p> <p>Microbiological criteria:</p> <p>Total aerobic colony count: ≤ 10⁵ CFU (**)/g Yeasts and moulds: ≤ 100 CFU/g <i>Escherichia coli</i>: ≤ 50 CFU/g</p>

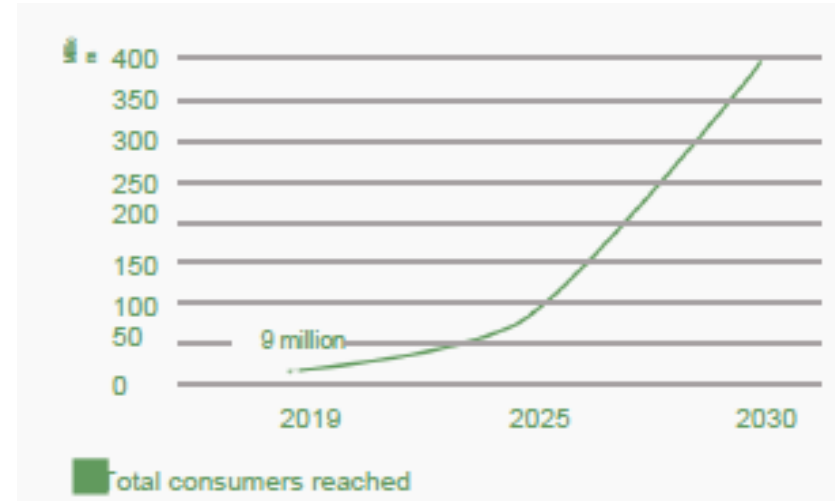


European
Commission

Production and forecast in EU (Insects as food – niche market only 5% as compared to feed)



EU consumers reached and forecast



Thank you for your attention !

Useful links:

https://food.ec.europa.eu/safety/novel-food_en

<https://www.efsa.europa.eu/en/topics/topic/novel-food>



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