

COMMISSION IMPLEMENTING REGULATION (EU) 2023/58

of 5 January 2023

authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ has established a Union list of novel foods.
- (3) On 7 January 2018, the company Ynsect NL B.V. (formerly known as Proti-Farm Holding NV) ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) on the Union market as a novel food. The applicant requested for *Alphitobius diaperinus* larvae in frozen, paste (ground), dried, and powder (ground) forms to be used as a food ingredient in a number of food products for the general population, and in powder form in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ for the adult population.
- (4) The applicant also made a request to the Commission for the protection of proprietary scientific data for a number of studies submitted in support of the application, namely analytical data on the composition of the novel food ⁽⁴⁾, the stability studies on the novel food ⁽⁵⁾, an *in vitro* protein digestibility study ⁽⁶⁾, and a sub-chronic 90-day toxicity study ⁽⁷⁾.
- (5) On 17 July 2018, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of frozen and freeze-dried forms of the *Alphitobius diaperinus* larvae as a novel food.
- (6) On 26 April 2022, the Authority adopted its scientific opinion on the 'Safety of frozen and freeze-dried formulations of the lesser mealworm (*Alphitobius diaperinus* larvae) as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁸⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁴⁾ Ynsect NL B.V. 2018, 2019, 2020 and 2021 (unpublished).

⁽⁵⁾ Ynsect NL B.V. 2019 and 2020 (unpublished).

⁽⁶⁾ Ynsect NL B.V. 2018 and 2019 (unpublished).

⁽⁷⁾ Ynsect NL B.V. 2021 (unpublished).

⁽⁸⁾ EFSA Journal 2022; 20(7):7325.

- (7) In its scientific opinion, the Authority concluded that the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae are safe under the proposed conditions of use at the proposed use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae under the assessed conditions of use fulfil the conditions for their placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In that scientific opinion, the Authority also concluded, based on limited published evidence on food allergy related to insects, that the consumption of the novel food may induce primary sensitisation and allergic reactions to lesser mealworm proteins. The Authority recommended carrying out further research on the allergenicity of *Alphitobius diaperinus* larvae.
- (9) In order to address the Authority's recommendation, the Commission is currently exploring the ways to carry out the necessary research on the allergenicity of *Alphitobius diaperinus* larvae. Until the data generated by the research is assessed by the Authority, and considering that, to date, evidence directly linking the consumption of *Alphitobius diaperinus* larvae to cases of primary sensitisation and allergies is inconclusive, the Commission considers that no specific labelling requirements concerning the potential of *Alphitobius diaperinus* larvae to cause primary sensitization should be included in the Union list of authorised novel foods.
- (10) In its scientific opinion, the Authority also considered that the consumption of *Alphitobius diaperinus* larvae may cause allergic reactions in persons that are allergic to crustaceans and dust mites. Furthermore, the Authority noted that additional allergens may end up in the novel food, if these allergens are present in the substrate fed to insects. Therefore, it is appropriate that frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae as such and foods containing them are appropriately labelled in accordance with Article 9 of Regulation (EU) 2015/2283.
- (11) Food supplements containing the powder form of *Alphitobius diaperinus* larvae should not be consumed by persons under 18 years of age and therefore, a labelling requirement should be provided in order to properly inform the consumers about that.
- (12) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on the analytical data on the composition of the novel food, the stability studies on the novel food, the *in vitro* protein digestibility study, and the sub-chronic 90-day toxicity study submitted by the applicant, without which it could not have assessed the novel food and reached its conclusion.
- (13) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (14) The applicant declared that they held proprietary and exclusive right of reference to the scientific data from those studies at the time they submitted the application.
- (15) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific data on the composition of the novel food, the stability studies on the novel food, the *in vitro* protein digestibility study, and the sub-chronic 90-day toxicity study should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae on the market within the Union during a period of 5 years from the entry into force of this Regulation.
- (16) However, restricting the authorisation of frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae and the reference to the scientific data contained in the applicant's file to the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food, provided that their application is based on legally obtained information supporting such authorisation.

- (17) It is appropriate that the inclusion of frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (18) Frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. The frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) are authorised to be placed on the market within the Union.

The frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Ynsect NL B.V. (*) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from the date of entry into force of this Regulation, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Ynsect NL B.V.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of Ynsect NL B.V.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

(*) Address: Harderwijkerweg 141B, 3852 AB Ermelo, the Netherlands.

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

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

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Frozen, paste, dried and powder forms of <i>Alphitobius diaperinus</i> larvae (lesser mealworm)	Specified food category	Maximum levels (g/100g)	<ol style="list-style-type: none"> The designation of the novel food on the labelling of the foodstuffs containing it shall be “Frozen/paste <i>Alphitobius diaperinus</i> larvae (lesser mealworm)” or “Dried/powder <i>Alphitobius diaperinus</i> larvae (lesser mealworm)” depending on the form used. The labelling of food supplements containing the novel food shall bear a statement that those food supplements should not be consumed by persons under 18 years of age. The labelling of the foodstuffs containing frozen, paste, dried or powder forms of <i>Alphitobius diaperinus</i> larvae (lesser 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. <p>This statement shall appear in close proximity to the list of ingredients.</p>		<p>Authorised on 26.1.2023. This inclusion is based on proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Ynsect NL B.V, Harderwijkerweg 141B, 3852 AB Ermelo, the Netherlands.</p> <p>During the period of data protection, the novel food is authorised for placing on the market within the Union only by Ynsect NL B.V., unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283, or with the agreement of Ynsect NL B.V.</p> <p>End date of the data protection: 26.1.2028.’</p>
	Cereal bars	25 (Dried form) 25 (Powder form)			
	Bread and rolls	20 (Powder form)			
	Processed and breakfast cereals	10 (Dried form) 10 (Powder form)			
	Porridge	15 (Powder form)			
	Pre-mixes (dry) for baked products	10 (Powder form)			
	Dried pasta-based products	10 (Powder form)			
	Stuffed pasta-based products	28 (Frozen or paste form) 10 (Powder form)			
	Whey powder	35 (Powder form)			
	Soups	15 (Powder form)			
	Cereal-, pasta-based dishes	5 (Powder form)			
	Pizza-based dishes	5 (Dried form) 5 (Powder form)			
	Noodles	10 (Powder form)			
Snacks other than chips	10 (Dried form) 10 (Powder form)				

Chips/crisps	10 (Powder form)			
Crackers and bread sticks	10 (Powder form)			
Peanut butter	15 (Powder form)			
Ready-to-eat savoury based sandwich	20 (Powder form)			
Meat preparations	14 (Frozen or paste form) 5 (Powder form)			
Meat analogues	40 (Frozen or paste form) 15 (Powder form)			
Milk and dairy analogues	10 (Powder form)			
Chocolate confectionary	5 (Powder form)			
Food supplements as defined in Directive 2002/46/EC for the adult population	4 g/day (Powder form)			

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

Authorised novel food	Specification
Frozen, paste, dried and powder forms of <i>Alphitobius diaperinus</i> larvae (lesser mealworm)	<p>Description/Definition: The novel food consists of the frozen, paste, dried, and powder forms of the whole lesser mealworm. The term “lesser mealworm” refers to the larval form of <i>Alphitobius diaperinus</i>, an insect species that belongs to the family of <i>Tenebrionidae</i> (darkling beetles). The entire lesser mealworms are meant for human consumption, no parts are removed. The novel food is intended to be marketed in 4 different forms, namely: (i) whole blanched and frozen <i>A. diaperinus</i> larvae (ADL frozen), (ii) paste from whole blanched, ground, and frozen <i>A. diaperinus</i> larvae (ADL paste), (iii) whole blanched, and freeze-dried <i>A. diaperinus</i> larvae (ADL dried), and (iv) powder from whole blanched, freeze-dried and ground <i>A. diaperinus</i> larvae (ADL powder). A minimum 24 hours fasting period is required to allow the larvae to discard their bowel content before killing the insects by a thermal treatment.</p>

Characteristics/Composition (ADL frozen or paste):	Characteristics/Composition (ADL dried or powder):
Ash (% w/w): ≤ 1,5	Ash (% w/w): ≤ 5
Moisture (% w/w): 65-80	Moisture (% w/w): 1-5
Crude protein (N × 6,25) (% w/w): 12-25	Crude protein (N × 6,25) (% w/w): 50-70
Digestible Carbohydrates (% w/w): 0,4-2	Digestible Carbohydrates (% w/w): 1,5-3,5
Fat (% w/w): 5-12	Fat (% w/w): 20-35
Peroxide value (Meq O ₂ /kg fat): ≤ 0,2	Peroxide value (Meq O ₂ /kg fat): ≤ 5
Dietary fibre (% w/w): 1-4	Dietary fibre (% w/w): 3-6
(*)Chitin (% w/w): 1,0-2,6	(*)Chitin (% w/w): 3,0-9,1
Heavy metals:	Heavy metals:
Lead: ≤ 0,1 mg/kg	Lead: ≤ 0,1 mg/kg
Cadmium: ≤ 0,05 mg/kg	Cadmium: ≤ 0,05 mg/kg
Mycotoxins:	Mycotoxins:
Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg	Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg
Aflatoxin B1 (µg/kg): ≤ 2	Aflatoxin B1 (µg/kg): ≤ 2
Deoxynivalenol: ≤ 200 µg/kg	Deoxynivalenol: ≤ 200 µg/kg
Ochratoxin A: ≤ 1 µg/kg	Ochratoxin A: ≤ 1 µg/kg
Microbiological criteria:	Microbiological criteria:
Total aerobic colony count: ≤ 10 ⁵ (**)CFU/g	Total aerobic colony count: ≤ 10 ⁵ CFU/g
Yeasts and moulds: ≤ 100 CFU/g	Yeasts and moulds: ≤ 100 CFU/g
<i>Escherichia coli</i> : ≤ 50 CFU/g	<i>Escherichia coli</i> : ≤ 50 CFU/g
<i>Salmonella</i> spp.: Absence in 25 g	<i>Salmonella</i> spp.: Absence in 25 g
<i>Listeria monocytogenes</i> : Absence in 25 g	<i>Listeria monocytogenes</i> : Absence in 25 g
Sulphite-reducing Anaerobes: ≤ 30 CFU/g	Sulfite-reducing Anaerobes: ≤ 30 CFU/g
<i>Bacillus cereus</i> : ≤ 100 CFU/g	<i>Bacillus cereus</i> : ≤ 100 CFU/g
Enterobacteriaceae: ≤ 100 CFU/g	Enterobacteriaceae: ≤ 100 CFU/g
Coagulase-positive <i>staphylococci</i> : ≤ 100 CFU/g	Coagulase-positive <i>staphylococci</i> : ≤ 100 CFU/g

(*) Chitin calculated as Acid Detergent Fibre.

(**) CFU: Colony Forming Units.