

COMMISSION IMPLEMENTING REGULATION (EU) 2022/169**of 8 February 2022****authorising the placing on the market of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission 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 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list 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⁾ establishing a Union list of authorised novel foods was adopted.
- (3) On 28 December 2018, the company Fair Insects BV ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) on the Union market as a novel food. The applicant requested frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) to be used in a number of foods intended for the general population.
- (4) The applicant also submitted a request to the Commission for the protection of proprietary data for a number of data submitted in support of the application. Namely, detailed description of the production process ⁽³⁾, analytical data on the composition ⁽⁴⁾, stability studies ⁽⁵⁾, protein digestibility study ⁽⁶⁾, cytotoxicity study, including full study reports ⁽⁷⁾, list of analytical data on the composition ⁽⁸⁾, intake assessment and proposed uses and use levels ⁽⁹⁾.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 9 August 2019, asking it to provide a scientific opinion by carrying out an assessment for frozen and dried preparations from yellow mealworm (*Tenebrio molitor* larva) as a novel food.

⁽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⁾ Section 2.3_Production process, including updates; Appendix C11; Appendix C17 – Fair Insects BV, 2020 (unpublished).

⁽⁴⁾ Section 2.4_Compositional data, including updates; Section 2.9_Nutritional information, including updates; Appendix B4, including updates; Appendix B5, including updates; Appendix C20; Appendix D1, including updates; Appendix D2, including updates; Appendix D6, including updates – Fair Insects BV, 2020 (unpublished).

⁽⁵⁾ Section 2.4.4_Stability, including updates; Appendix C21; Appendix C22; Appendix D7, including updates – Fair Insects BV, 2020 (unpublished).

⁽⁶⁾ Appendix D4, including updates, Fair Insects BV, 2020 (unpublished); DIASS study (section 2.8_upd, section 2.9_upd, section 2.11_upd).

⁽⁷⁾ Section 2.10 Toxicological information, including updates; Appendix D5, including updates – Fair Insects BV, 2020 (unpublished).

⁽⁸⁾ Appendix B2, Fair Insects BV, 2020 (unpublished).

⁽⁹⁾ Intake assessment by Schuttelaar & Partners (section 2.7_upd); Proposed use and use levels data estimated by Schuttelaar & Partners (section 2.7_upd) – Fair Insects BV, 2020 (unpublished);

- (6) On 7 July 2021 the Authority, in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283 adopted its scientific opinion on the ‘Safety of frozen and dried formulations from whole yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283’⁽¹⁰⁾.
- (7) In its opinion, the Authority concluded that frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) are safe under the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) under the specific conditions of use fulfils the requirements for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In that opinion and the Authority’s opinion on the ‘Scientific Opinion on the safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283’⁽¹¹⁾, the Authority also concluded on the basis of limited published evidence on food allergy related to insects, that the consumption of the novel food may induce primary sensitisation and allergic reactions to yellow mealworm proteins. In accordance with the Authority’s recommendation to carry out research on the allergenicity to *Tenebrio molitor* larva, the Commission is currently exploring the ways to carry out the necessary research. Until the data is generated by the research and assessed by the Authority, and considering that, to date, only the few allergic cases have been reported according to data available to the insect industry of *Tenebrio molitor* larva⁽¹²⁾, the Commission considers that no specific labelling requirements concerning the potential of *Tenebrio molitor* larva to cause primary sensitisation should be included in the Union list of authorised novel foods.
- (9) In those opinions, the Authority also concluded that the consumption of the novel food may cause allergic reactions in persons that are allergic to crustaceans and dust mites due to cross-reactivity. Furthermore, the Authority noted that additional allergens may end up in the novel food, if these allergens are present in the substrate feed to the insects. This may include allergens, listed in the Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council⁽¹³⁾. Therefore, it is appropriate that frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) made available to the consumer as such and foods containing these preparations are appropriately labelled following the requirements in accordance with Article 9 of Regulation (EU) 2015/2283 and Regulation (EU) No 1169/2011.
- (10) In its opinion, the Authority noted that the detailed description of the production process, analytical data on the composition, stability studies, protein digestibility study, cytotoxicity study, including full study reports, served as a basis to establish the safety of the novel food. The Authority also noted that it could not have reached its conclusion without those data, claimed by the applicant as proprietary.
- (11) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those data and to clarify their claim to an exclusive right of reference to those data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.
- (12) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to those data under national law, and that therefore third parties cannot lawfully access, use or refer to those data.

⁽¹⁰⁾ EFSA Journal 2021;19(8):6778.

⁽¹¹⁾ EFSA Journal 2021;19(1):6343.

⁽¹²⁾ *Tenebrio molitor* larva is marketed in a number of Member States under the transitional measures laid down in Article 35(2) of Regulation (EU) 2015/2283.

⁽¹³⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (13) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, detailed description of the production process ⁽¹⁴⁾, analytical data on the composition ⁽¹⁵⁾, stability studies ⁽¹⁶⁾, protein digestibility study ⁽¹⁷⁾, cytotoxicity study, including full study reports ⁽¹⁸⁾, contained in the applicant's file, on which the Authority based its conclusion on the safety of the novel food and without which it could not have assessed the novel food, should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, only the applicant should be authorised to place frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) on the market within the Union during that period.
- (14) However, restricting the authorisation of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) and of the reference to the data contained in the applicant's file for the sole use of the applicant, does not prevent other 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 under Regulation (EU) 2015/2283.
- (15) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (16) 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. Frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva), as specified in the Annex to this Regulation, shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation, only the initial applicant:

company: Fair Insects BV;

address: Industriestraat 3, 5107 NC Dongen, the Netherlands,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Fair Insects BV.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

⁽¹⁴⁾ Section 2.3_Production process, including updates; Appendix C11; Appendix C17 – Fair Insects BV, 2020 (unpublished).

⁽¹⁵⁾ Section 2.4_Compositional data, including updates; Section 2.9_Nutritional information, including updates; Appendix B4, including updates; Appendix B5, including updates; Appendix C20; Appendix D1, including updates; Appendix D2, including updates; Appendix D6, including updates – Fair Insects BV, 2020 (unpublished).

⁽¹⁶⁾ Section 2.4.4_Stability, including updates; Appendix C21; Appendix C22; Appendix D7, including updates – Fair Insects BV, 2020 (unpublished).

⁽¹⁷⁾ Appendix D4, including updates, Fair Insects BV, 2020 (unpublished); DIASS study (section 2.8_upd, section 2.9_upd, section 2.11_upd).

⁽¹⁸⁾ Section 2.10 Toxicological information, including updates; Appendix D5, including updates – Fair Insects BV, 2020 (unpublished).

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Fair Insects BV.

Article 3

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

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, 8 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

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, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva)	Specified food category	Maximum levels (g/100g) (marketed as such or reconstituted according to the instructions)	<p>1. Depending on the form used, the designation of the novel food on the labelling of the foodstuffs containing it shall be 'frozen yellow mealworm (<i>Tenebrio molitor</i> larva)', 'dried yellow mealworm (<i>Tenebrio molitor</i> larva)', or 'yellow mealworm (<i>Tenebrio molitor</i> larva) powder'.</p> <p>2. The labelling of the foodstuffs containing frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva) 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.</p>		<p>Authorised on 1 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Fair Insects BV, Industriestraat 3, 5107 NC Dongen, 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 Fair Insects BV, 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 Fair Insects BV.</p> <p>End date of the date protection: 1 March 2027.'</p>	
		Frozen				Dried or powder
	Frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva)					
	Multigrain bread and rolls; crackers and breadsticks	30				10
	Cereal bars	30				15
	Dried pasta based products; pasta based dishes (excluding dried puffed pasta); pizza and pizza-like dishes	15				10
	Dried stuffed pasta based products	30				15
	Pre-mixes (dry) for baked products	30				15
	Sauces	30				10
	Potato, legumes based dishes	15				10
	Whey powder	40				20
	Meat analogues	80				50
	Soups and salads	20				5
	Chips/crisps	40				20
	Beer-like beverages; mixed alcoholic drinks; alcoholic drink mixes	1				1
Chocolate confectionary	30	10				
Nuts, oilseeds and chickpeas	40	30				

	Frozen fermented milk-based products	15	5			
	Meat preparations	40	16			

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

Authorised Novel Food	Specification		
'Frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva)	Description/Definition:		
	The novel food are frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva). The term 'mealworm' refers to the larval form of <i>Tenebrio molitor</i> , an insect species that belongs to the family of Tenebrionidae (darkling beetles). Another identified scientific synonym is <i>Tenebrio molitor</i> Linnaeus.		
	The entire mealworms are meant for human consumption, no parts are removed. A minimum 24 hours fasting period is required before killing the insects by freezing, to allow the larvae to discard their bowel content.		
	The novel food is intended to be placed on the market in three different forms, namely: whole, blanched and frozen <i>T. molitor</i> larva (frozen); whole, blanched and freeze-dried <i>T. molitor</i> larva (dried) which may be in powder form (powder).		
	Parameters	Frozen	Dried or powder
	Characteristics/Composition		
	Ash	0,9-1,10	3,6-4,1
	Moisture (% w/w)	69-75	≤ 5
	Crude protein (N x 6,25) (% w/w)	14-19	54-60
	Fat (% w/w)	7-12,5	27-30
— of which saturated fatty acids (% fat)	20-29	20-29	
Digestible carbohydrates (% w/w)	1-2	4-8	
Dietary fibre (% w/w)	1,2-3,5	4-6	
Chitin(*) (% w/w)	≤ 3	4-9	

Peroxide value (Meq O ₂ /kg fat)	≤ 5	≤ 5
Contaminants		
<i>Heavy metals</i>		
Lead (mg/kg)	≤ 0,01	≤ 0,075
Cadmium (mg/kg)	≤ 0,05	≤ 0,1
<i>Mycotoxins</i>		
Aflatoxins (Sum of B1, B2, G1, G2) (µg/kg)	≤ 4	≤ 4
Aflatoxin B1 (µg/kg)	≤ 2	≤ 2
Deoxynivalenol (µg/kg)	≤ 200	≤ 200
Ochratoxin A (µg/kg)	≤ 1	≤ 1
<i>Dioxins and PCBs</i>		
Sum of dioxins and dl-PCBs (UB, WHO-TEQ2005)(**) (pg/g fat)	≤ 0,75	≤ 0,75
Microbiological criteria		
Total aerobic colony count (CFU/g)	≤ 10 ⁵	≤ 10 ⁵
Enterobacteriaceae (presumptive) (CFU/g)	≤ 100	≤ 100
<i>Escherichia coli</i> (CFU/g)	≤ 50	≤ 50
<i>Listeria monocytogenes</i>	Absence in 25g	Absence in 25g
<i>Salmonella</i> spp.	Absence in 25g	Absence in 25g
<i>Bacillus cereus</i> (presumptive) (CFU/g)	≤ 100	≤ 100
Coagulase positive Staphylococci (CFU/g)	≤ 100	≤ 100
Sulfite-reducing Anaerobes (CFU/g)	≤ 30	≤ 30
Yeasts and moulds (CFU/g)	≤ 100	≤ 100
(*) Chitin calculated as the difference between the Acid Detergent Fibre fraction and the Acid Detergent Lignin fraction (ADF-ADL), as described by Hahn et al. (2018).		
(**) Upper bound sum of polychlorinated dibenzo-para-dioxins (PCDDs)-polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCBs) expressed as World Health Organization toxic equivalent (using WHO-TEFs of 2005).		
CFU: colony forming units.		