

COMMISSION IMPLEMENTING REGULATION (EU) 2021/882**of 1 June 2021****authorising the placing on the market of dried *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 13 February 2018, the company SAS EAP Group ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place dried *Tenebrio molitor* larva (yellow mealworm) on the Union market as a novel food. The application requested for dried *Tenebrio molitor* larva to be used as whole, dried insect in the form of snacks, and as a food ingredient in a number of food products, the target population being the general population. The applicant also made a request to the Commission for the protection of proprietary data submitted in the application.
- (4) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 3 July 2018, asking it to provide a scientific opinion by carrying out an assessment for dried *Tenebrio molitor* larva as a novel food.
- (5) On 24 November 2020, the Authority adopted a scientific opinion on the safety of *Tenebrio molitor* larva as a novel food ⁽³⁾, in accordance with Article 11 of Regulation (EU) 2015/2283.
- (6) In its opinion, the Authority concluded that dried *Tenebrio molitor* larva is safe under the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that dried *Tenebrio molitor* larva under the assessed conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.
- (7) In that opinion, the Authority also concluded on the basis of limited published evidence on food allergy related to insects and in particular from two studies in humans where a total of four suspect allergic reactions were attributed to dried *Tenebrio molitor* larva and one study in animals, that consumption of this novel food may trigger sensitisation to yellow mealworm proteins as well as to tropomyosin from other sources such as crustaceans and mites. The Authority recommended carrying out further research on the allergenicity of dried *Tenebrio molitor* larva. To address the Authority's recommendation the Commission is currently exploring the ways to carry out the necessary research on the allergenicity of *Tenebrio molitor* larvae.

⁽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⁾ Safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283; *EFSA Journal* 2021:19(1):6343.

- (8) Until the data generated by the research is assessed by the Authority, and considering that, to date, only the abovementioned few allergic cases have been reported according to data available to the insect industry of dried *Tenebrio molitor* larva ⁽⁴⁾, the Commission considers that no specific labelling requirements concerning the potential of dried *Tenebrio molitor* larva to cause primary sensitization should be included in the Union list of authorised novel foods.
- (9) The Authority in its opinion also considered that the consumption of dried *Tenebrio molitor* larva may cause allergic reactions to 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 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 ⁽⁵⁾. Therefore, it is appropriate that dried *Tenebrio molitor* larva made available to the consumer as such and foods containing dried *Tenebrio molitor* larva 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 its conclusion on the safety of the novel food was based on analyses of contaminants in the novel food ⁽⁶⁾, a detailed description of the drying process ⁽⁷⁾, analytical data on chitin levels ⁽⁸⁾, and data on the oxidative and microbiological status of the novel food during storage ⁽⁹⁾. It also noted that it could not have reached that conclusion without the data from the unpublished reports of the studies contained in the applicant's file.
- (11) 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 those studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.
- (12) The applicant declared that they held proprietary and exclusive right of reference to analyses of contaminants in the novel food, the detailed description of the drying process, the analytical data on chitin levels, and the data on the oxidative and microbiological status of the novel food during storage, at the time they submitted the application and that therefore third parties cannot lawfully access, use or refer to those studies.
- (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, the specific studies on analyses of contaminants in the novel food, the detailed description of the drying process, the analytical data on chitin levels, and the data on the oxidative and microbiological status of the novel food during storage, 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 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 dried *Tenebrio molitor* larva on the market within the Union during that period.
- (14) However, restricting the authorisation of dried *Tenebrio molitor* larva and the reference to the studies 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.
- (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,

⁽⁴⁾ *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.

⁽⁵⁾ 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).

⁽⁶⁾ SAS EAP Group 2016 (unpublished).

⁽⁷⁾ SAS EAP Group 2013 (unpublished).

⁽⁸⁾ SAS EAP Group 2018 (unpublished).

⁽⁹⁾ SAS EAP Group 2020 (unpublished).

HAS ADOPTED THIS REGULATION:

Article 1

1. Dried *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: SAS EAP Group;
Address: 35 Boulevard du Libre Échange, 31650 Saint-Orens-de-Gameville, France,
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 SAS EAP Group.
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.

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 SAS EAP Group.

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, 1 June 2021.

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 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. 		<p>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.</p> <p>Applicant: SAS EAP Group, 35 Boulevard du Libre Échange, 31650 Saint-Orens-de-Gameville, France.</p> <p>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.</p> <p>End date of the data protection: 22 June 2026.’</p>			
	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: 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: Lead: ≤ 0,075 mg/kg Cadmium: ≤ 0,1 mg/kg</p> <p>Mycotoxins: 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: Total aerobic colony count: ≤ 10⁵ CFU (**)/g Yeasts and moulds: ≤ 100 CFU/g <i>Escherichia coli</i>: ≤ 50 CFU/g</p>

Salmonella spp.: Not detected in 25 g

Listeria monocytogenes: Not detected in 25 g

Sulfite-reducing Anaerobes: ≤ 30 CFU/g

Bacillus cereus (presumptive): ≤ 100 CFU/g

Enterobacteriaceae (presumptive): < 10 CFU/g

Coagulase-positive *staphylococci*: ≤ 100 CFU/g

(*) Digestible carbohydrates = 100 – (crude protein + fat + dietary fibre + ash + moisture).

(**) CFU: colony forming units.
