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## COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

### **authorising the placing on the market of frozen, dried and powder forms of *Tenebrio molitor* larva (yellow 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<sup>1</sup>, 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<sup>2</sup> has established a Union list of novel foods.
- (3) On 10 May 2018, the Belgian Insect Industry Federation ('the applicant') submitted an application to the Commission for an authorisation in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place frozen, dried and powder forms of *Tenebrio molitor* larva (yellow mealworm) on the Union market as a novel food. The applicant requested for frozen, dried and powder forms of *Tenebrio molitor* larva to be used in the form of snacks, and as a food ingredient in a number of foods for the general population.
- (4) On 2 December 2019, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of frozen, dried and powder forms of *Tenebrio molitor* larva as a novel food.

<sup>1</sup> OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

<sup>2</sup> 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, ELI: [http://data.europa.eu/eli/reg\\_impl/2017/2470/oj](http://data.europa.eu/eli/reg_impl/2017/2470/oj)).

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- (5) On 28 November 2024, the Authority adopted its scientific opinion on the safety of frozen, dried and powder forms of *Tenebrio molitor* larva as a novel food pursuant to Regulation (EU) 2015/2283<sup>3</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.
- (6) In its scientific opinion, the Authority concluded that frozen, dried and powder forms of *Tenebrio molitor* larva is safe for the general population under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that frozen, dried and powder forms of *Tenebrio molitor* larva, when used under the proposed conditions of use, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (7) In that opinion and the Authority's opinions on the 'Safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283'<sup>4</sup>, and the 'Safety of frozen and dried formulations from whole yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283'<sup>5</sup>, 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<sup>6</sup>, 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.
- (8) 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<sup>7</sup>.
- (9) It is therefore appropriate that frozen, dried and powder forms of *Tenebrio molitor* larva made available to the consumers as such and foods containing these preparations

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<sup>3</sup> <https://doi.org/10.2903/j.efsa.2025.9155>

<sup>4</sup> EFSA Journal 2021;19(1):6343

<sup>5</sup> EFSA Journal 2021;19(8):6778

<sup>6</sup> *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.

<sup>7</sup> 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, ELI: <http://data.europa.eu/eli/reg/2011/1169/oj>).

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are appropriately labelled following the requirements in accordance with Article 9 of Regulation (EU) 2015/2283 and Regulation (EU) No 1169/2011.

- (10) Frozen, dried and powder forms of *Tenebrio molitor* larva 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.
- (11) 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 *Tenebrio molitor* (yellow mealworm) larva is authorised to be placed on the market within the Union.

Frozen, dried and powder forms of *Tenebrio molitor* (yellow mealworm) larva 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*

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,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*