



2025/89

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**COMMISSION IMPLEMENTING REGULATION (EU) 2025/89**

**of 20 January 2025**

**authorising the placing on the market of UV-treated powder of whole *Tenebrio molitor* larvae (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 30 July 2019, the company Nutri'Earth ('the applicant') submitted an application to the Commission for an authorisation in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place UV-treated powder of whole *Tenebrio molitor* larvae (yellow mealworm) on the Union market as a novel food. The applicant requested for UV-treated powder obtained from whole *Tenebrio molitor* larvae to be used in bread and rolls, cakes, pasta-based products, processed potato products, cheese and cheese products and fruit and vegetable compotes, intended for the general population.
- (4) On 30 July 2019, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data submitted in support of the application, namely, a detailed description of the production process <sup>(3)</sup> and the detailed results of the composition analyses <sup>(4)</sup>.
- (5) On 17 May 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of UV-treated powder of whole *Tenebrio molitor* larvae as a novel food.
- (6) On 28 March 2023, the Authority adopted its scientific opinion on the 'Safety of UV-treated powder of whole yellow mealworm (*Tenebrio molitor* larvae) as a novel food pursuant to Regulation (EU) 2015/2283' <sup>(5)</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.

<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)).

<sup>(3)</sup> Nutri'Earth 2019, 2020, 2021 and 2022 (unpublished).

<sup>(4)</sup> Nutri'Earth 2019, 2020, 2021, 2022 and 2023 (unpublished).

<sup>(5)</sup> EFSA Journal 2023;21(5):8009.

- (7) In its scientific opinion, the Authority concluded that UV-treated powder of whole *Tenebrio molitor* larvae is safe under the proposed conditions of use and at the proposed use levels. Therefore, that scientific opinion gives sufficient grounds to establish that UV-treated powder of whole *Tenebrio molitor* larvae, when used in bread and rolls, cakes, pasta-based products, processed potato products, cheese and cheese products and fruit and vegetable compotes, intended for the general population, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In that opinion, the Authority also noted that although the UV treatment of the powder obtained from whole *Tenebrio molitor* larvae enhances its vitamin D<sub>3</sub> content, the novel food is not a significant dietary contributor of vitamin D<sub>3</sub>. Nevertheless, taking into consideration that foods containing the novel food may end up containing an amount of vitamin D that is considered significant under Point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>(6)</sup>, the Commission considers that it is appropriate to inform consumers about that fact. In such cases the designation of the novel food shall be accompanied by the statement 'contains vitamin D produced by UV-treatment' and the nutrition declaration shall contain the amount of vitamin D.
- (9) On the basis of limited published evidence of food allergies linked to the consumption of *Tenebrio molitor* larvae and evidence demonstrating that members of the phylum Arthropoda to which *Tenebrio molitor* belongs, contain a number of potentially allergenic proteins, the Authority concluded in its opinion that consumption of the novel food may also trigger sensitisation to *Tenebrio molitor* larvae proteins. The Authority therefore recommended to carry out further research on the allergenicity of *Tenebrio molitor* larvae.
- (10) 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 *Tenebrio molitor* larvae. Until the data of that research is assessed by the Authority, and considering that, to date, evidence directly linking the consumption of *Tenebrio molitor* larvae to cases of primary sensitisation and allergies is limited, the Commission considers that no specific labelling requirements concerning the potential of UV-treated powder obtained from whole *Tenebrio molitor* larvae to cause primary sensitisation should be included in the conditions of use of the novel food.
- (11) The Authority also considered in its opinion that the consumption of UV-treated powder obtained from whole *Tenebrio molitor* larvae may cause allergic reactions in persons that are allergic to crustaceans and dust mites. Furthermore, the Authority noted that additional allergens might end up in the novel food, if those allergens are present in the substrate fed to insects. Therefore, it is appropriate that foods containing UV-treated powder obtained from whole *Tenebrio molitor* larvae are appropriately labelled in accordance with Article 9 of Regulation (EU) 2015/2283.
- (12) In its scientific opinion, the Authority also noted that its conclusion on the safety of the UV-treated powder obtained from whole *Tenebrio molitor* larvae was based on the scientific studies and data on the detailed description of the production process and the detailed results of the composition analyses, 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 scientific studies and data, and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2), point (b), of Regulation (EU) 2015/2283.

<sup>(6)</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>).

- (14) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data on the detailed description of the production process and the detailed results of the composition analyses, under national law at the time they submitted the application and that third parties cannot lawfully access, use or refer to those data and studies.
- (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 studies and data on the detailed description of the production process and the detailed results of the composition analyses should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place UV-treated powder obtained from whole *Tenebrio molitor* larvae on the market within the Union during a period of five years from the entry into force of this Regulation.
- (16) However, restricting the authorisation of UV-treated powder obtained from whole *Tenebrio molitor* larvae and the reference to the scientific studies and data contained in the applicant's file for 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 an authorisation.
- (17) UV-treated powder obtained from whole *Tenebrio molitor* 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.
- (18) 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. UV-treated powder obtained from whole *Tenebrio molitor* larvae is authorised to be placed on the market within the Union.

UV-treated powder obtained from whole *Tenebrio molitor* 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 Nutri'Earth<sup>(7)</sup> 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 10 February 2025, 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 Nutri'Earth.

#### 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 Nutri'Earth.

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(7) Nutri'Earth, 68, rue Louis Joseph Gay Lussac, 62220 Carvin, France.

*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, 20 January 2025.

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

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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
<b>'UV-treated powder of whole <i>Tenebrio molitor</i> larvae (yellow mealworm)</b>	<i>Specified food category</i>	<i>Maximum levels (g/100 g) (Maximum levels of vitamin D<sub>3</sub> (µg/100 g food))</i>	<ol style="list-style-type: none"> <li>The designation of the novel food on the labelling of the foodstuffs containing it shall be “UV-treated <i>Tenebrio molitor</i> larvae (yellow mealworm) powder”.</li> <li>The labelling of the foodstuffs containing UV-treated powder of whole <i>Tenebrio molitor</i> larvae (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 or, in the absence of a list of ingredients, in close proximity to the name of the food.</li> <li>Where the novel food is added to final product that contain an amount of vitamin D that is considered significant in accordance with Point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011, the designation of the novel food shall be accompanied by “containing vitamin D produced by UV treatment”, and the nutrition declaration shall contain the amount of vitamin D.</li> </ol>		<p>Authorised on 10 February 2025. 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: “Nutri’Earth”, 68 rue Louis Joseph Gay Lussac, 62220 Carvin, France.</p> <p>During the period of data protection, the novel food UV-treated powder of whole <i>Tenebrio molitor</i> larvae (yellow mealworm) is authorised for placing on the market within the Union only by “Nutri’Earth”, 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 “Nutri’Earth”.</p> <p>End date of the data protection: 10 February 2030.’</p>
	Bread and rolls	4,0 (≤ 3,2 µg vitamin D <sub>3</sub> /100 g food)			
	Cakes	4,0 (≤ 3,2 µg vitamin D <sub>3</sub> /100 g food)			
	Pasta-based products	3,5 (≤ 2,8 µg vitamin D <sub>3</sub> /100 g food)			
	Processed potato products	3,0 (≤ 2,4 µg vitamin D <sub>3</sub> /100 g food)			
	Cheese and cheese products	1,0 (≤ 0,8 µg vitamin D <sub>3</sub> /100 g food)			
	Fruit and vegetable compotes	3,5 (≤ 2,8 µg vitamin D <sub>3</sub> /100 g food)			

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

Authorised novel food	Specification
<p><b>'UV-treated powder of whole <i>Tenebrio molitor</i> larvae (yellow mealworm)</b></p>	<p><b>Description/Definition:</b>            The novel food is the ultra-violet (UVB) light treated powder obtained from whole, thermally treated and ground <i>Tenebrio molitor</i> larvae (yellow mealworm).            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.            A minimum 24 hours fasting period is required before the thermal drying step, to allow the larvae to discard their bowel content.</p> <p><b>Characteristics/Composition:</b>            Crude protein (N x 6,25) (% w/w): 50,0 – 55,0            Fat (% w/w): 30,0 – 37,0            Total carbohydrates (% w/w): 6,0 – 7,5            Crude fibre (% w/w): 3,0 – 4,5            Chitin* (% w/w): 5,5-8,5            Ash (% w/w): 3,0 – 4,0            Moisture (% w/w): 1,4 – 3,5            Peroxide value (meq O<sub>2</sub>/kg fat): ≤ 5,0            Water activity (a<sub>w</sub>): &lt; 0,6            Vitamin D<sub>3</sub> (µg/100 g): 35,0 – 79,0            Manganese (mg/kg): ≤ 11,5            Copper (mg/kg): ≤ 16,0</p> <p><b>Heavy metals:</b>            Lead (mg/kg): ≤ 0,02            Cadmium (mg/kg): ≤ 0,1            Mercury (mg/kg): ≤ 0,005            Arsenic (mg/kg): ≤ 0,05</p> <p><b>Mycotoxins:</b>            Aflatoxin B1 (µg/kg): ≤ 2            Aflatoxins (Sum of B1 + B2 + G1 + G2, µg/kg): ≤ 4            Deoxynivalenol (µg/kg): ≤ 200            Ochratoxin A (µg/kg): ≤ 1</p> <p><b>Dioxins and PCBs:</b>            PCDDs/F + PCB TEQ (pg/g fat): ≤ 0,75</p>

Authorised novel food	Specification
	<p><b>Microbiological criteria:</b>  <i>Bacillus cereus</i>: ≤ 100 CFU**/g  <i>Clostridium perfringens</i>: ≤ 10 CFU/g  β-Glucuronidase-positive <i>Escherichia coli</i>: ≤ 10 CFU/g  Aerobic mesophilic bacteria: ≤ 10<sup>5</sup> CFU/g  <i>Listeria monocytogenes</i>: Not detected in 25 g  Yeasts and moulds: ≤ 100 CFU/g  Enterobacteriaceae: &lt; 10 CFU/g  Coagulase-positive staphylococci: ≤ 100 CFU/g  Sulfite-reducing anaerobes: &lt; 10 CFU/g  <i>Salmonella</i> spp.: Not detected in 25 g</p> <p>* 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); PCDDs/F + PCB TEQ: 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 Factors (TEQ) (using WHO-TEFs of 2005).</p> <p>** CFU: Colony Forming Units.'</p>