

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/188****of 10 February 2022****authorising the placing on the market of frozen, dried and powder forms of *Acheta domesticus* 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 <sup>(1)</sup>, 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 <sup>(2)</sup> establishing a Union list of authorised novel foods was adopted.
- (3) On 28 December 2018, the company Fair Insects B.V. ('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 *Acheta domesticus* (house cricket) on the Union market as a novel food. The application requested for whole *Acheta domesticus* in frozen, dried, and powder (ground) forms to be used as snacks and as food ingredient in a number of food products for the general population.
- (4) The applicant also made a request to the Commission for the protection of proprietary scientific data for a number of data submitted in support of the application, namely a description of the production process <sup>(3)</sup>; results of proximate analyses <sup>(4)</sup>; analytical data on contaminants <sup>(5)</sup>; the results of the stability studies <sup>(6)</sup>; the analytical data on microbiological parameters <sup>(7)</sup>; information on the company sales of the novel food <sup>(8)</sup>; the solubility test results of the novel food for the genotoxicity study <sup>(9)</sup>; the results of the protein digestibility studies <sup>(10)</sup>; and the cytotoxicity/cellular toxicity study <sup>(11)</sup>.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 4 September 2019, asking it to provide a scientific opinion by carrying out an assessment for frozen and dried *Acheta domesticus* as a novel food.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

<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).

<sup>(3)</sup> Fair Insects B.V. 2017 and 2019 (unpublished).

<sup>(4)</sup> Fair Insects B.V. 2018 and 2019 (unpublished).

<sup>(5)</sup> Fair Insects B.V. 2018 and 2019 (unpublished).

<sup>(6)</sup> Fair Insects B.V. 2018 and 2019 (unpublished).

<sup>(7)</sup> Fair Insects B.V. 2018 and 2019 (unpublished).

<sup>(8)</sup> Fair Insects B.V. 2018 (unpublished).

<sup>(9)</sup> Fair Insects B.V. 2018 (unpublished).

<sup>(10)</sup> Fair Insects B.V. 2018 (unpublished).

<sup>(11)</sup> Fair Insects B.V. 2018 and 2019 (unpublished).

- (6) On 7 July 2021, the Authority in accordance with Article 11 of Regulation (EU) 2015/2283 adopted a scientific opinion on the 'Safety of frozen and dried formulations from whole crickets (*Acheta domesticus*) as a novel food pursuant to Regulation (EU) 2015/2283 <sup>(12)</sup>'.
- (7) In its opinion, the Authority concluded that frozen, dried and powder forms of *Acheta domesticus* 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 *Acheta domesticus* 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) On the basis of limited published evidence on food allergy related to insects in general, which equivocally linked the consumption of *Acheta domesticus* to a number of anaphylaxis events and, on the basis of evidence demonstrating that *Acheta domesticus* contains a number of potentially allergenic proteins, the Authority in the opinion concluded that consumption of this novel food may trigger sensitisation to *Acheta domesticus* proteins. The Authority recommended carrying out further research on the allergenicity of *Acheta domesticus*.
- (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 *Acheta domesticus*. Until the data generated by the research is assessed by the Authority, and considering that, to date, evidence directly linking the consumption of *Acheta domesticus* to cases of primary sensitisation and allergies is inconclusive, the Commission considers that no specific labelling requirements concerning the potential of *Acheta domesticus* to cause primary sensitisation should be included in the Union list of authorised novel foods.
- (10) The Authority in its opinion also considered that the consumption of frozen, dried and powder forms of *Acheta domesticus* may cause allergic reactions in persons that are allergic to crustaceans, molluscs and 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, dried and powder forms of *Acheta domesticus* made available to the consumer as such and foods containing them are appropriately labelled following the requirements in accordance with Article 9 of Regulation (EU) 2015/2283.
- (11) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on detailed description of the production process; results of proximate analyses; analytical data on contaminants; the results of the stability studies; the analytical data on microbiological parameters; information on the company sales of the novel food; the solubility test results of the novel food for the genotoxicity study; the results of the protein digestibility studies; and the cytotoxicity/cellular toxicity study, and 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.
- (12) 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 them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (13) The applicant declared that they held proprietary and exclusive right of reference to data from the detailed description of the production process, results of proximate analyses, analytical data on contaminants, the results of the stability studies, the analytical data on microbiological parameters, information on the company sales of the novel food, the solubility test results of the novel food for the genotoxicity study, the results of the protein digestibility studies, and the cytotoxicity/cellular toxicity study, at the time they submitted the application and therefore third parties cannot lawfully access, use or refer to those studies.

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<sup>(12)</sup> Safety of frozen and dried formulations from whole crickets (*Acheta domesticus*) as a novel food pursuant to Regulation (EU) 2015/2283; EFSA Journal 2021:19(8):6779.

- (14) 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 data from production process, results of proximate analyses, analytical data on contaminants, the results of the stability studies, the analytical data on microbiological parameters, information on the company sales of the novel food, the solubility test results of the novel food for the genotoxicity study, the results of the protein digestibility studies, and the cytotoxicity/cellular toxicity study, 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 5 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 *Acheta domesticus* on the market within the Union during that period.
- (15) However, restricting the authorisation of frozen, dried and powder forms of *Acheta domesticus* and 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.
- (16) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (17) 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 *Acheta domesticus*, 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 5 years from the date of entry into force of this Regulation, only the initial applicant:  
  
company: Fair Insects B.V.;  
  
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 B.V.
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 5 years from the date of entry into force of this Regulation without the agreement of Fair Insects B.V.

#### 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, 10 February 2022.

*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>'Frozen, dried and powder forms of <i>Acheta domesticus</i> (house cricket)</b>	<i>Specified food category</i>	<i>Maximum levels (g/100g)</i> (marketed as such or reconstituted according to the instructions)	<p>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Frozen <i>Acheta domesticus</i> (house cricket)', 'Dried/powdered <i>Acheta domesticus</i> (house cricket)' depending on the form used.</p> <p>2. The labelling of the foodstuffs containing frozen, dried or powder forms of <i>Acheta domesticus</i> (house cricket) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, molluscs and products thereof, and to dust mites.</p> <p>This statement shall appear in close proximity to the list of ingredients.</p>		<p>Authorised on 3 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 data protection: 3 March 2027.'</p>	
		Frozen				Dried or powder
	Frozen, dried, and powder forms of <i>Acheta domesticus</i>					
	Protein products other than meat analogues	40				20
	Bread and rolls	30				10
	Bakery wares, cereal bars, and stuffed pasta products	30				15
	Biscuits	30				8
	Pasta-based products (dry)	3				1
	Soups and soup concentrates or powders	20				5
	Processed potato products, legumes- and vegetable- based dishes, and pasta- or pizza-based products	15				5
	Corn flour based snacks	40				20
	Beer-like beverages, alcoholic drink mixes	1				1
Nuts, oilseeds and chickpeas	40	25				

Sauces	30	10			
Meat preparations	40	16			
Meat analogues	80	50			
Chocolate confectionary	30	10			
Frozen fermented milk based products	15	5			

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

Authorised Novel Food	Specification	
<b>'Frozen, dried and powder forms of <i>Acheta domesticus</i> (house cricket)</b>	<p><b>Description/Definition:</b></p> <p>The novel food consists of the whole, frozen, dried and powder forms of the house cricket. The term 'house cricket' refers to the adult <i>Acheta domesticus</i>, an insect species that belongs to the Gryllidae family.</p> <p>The novel food is intended to be marketed in three different forms, namely: (i) thermally processed and frozen whole <i>A. domesticus</i> (AD frozen); (ii) thermally processed and freeze-dried whole <i>A. domesticus</i> (AD dried), and (iii) thermally processed freeze-dried and ground whole <i>A. domesticus</i> (whole AD powder).</p> <p>A minimum 24 hours fasting period is required before killing the insects by freezing, to allow the adults to discard their bowel content.</p>	
	<table border="0"> <tr> <td style="vertical-align: top;"> <p><b>Characteristics/Composition (AD frozen):</b></p> <p>Ash (% w/w): 0,6–1,2</p> <p>Moisture (% w/w): 76–82</p> <p>Crude protein (N x 6,25) (% w/w): 12–21</p> <p>Digestible Carbohydrates (% w/w): 0,1–2</p> <p>Fat (% w/w): 3–12</p> <p style="padding-left: 20px;">of which saturated (% w/w): 36–45</p> <p>Peroxide value (Meq O<sub>2</sub>/kg fat): ≤ 5</p> <p>Dietary fibre (% w/w): 0,8–3</p> <p>*Chitin (% w/w): 0,7–3,0</p> <p><b>Heavy metals:</b></p> <p>Lead: ≤ 0,05 mg/kg</p> <p>Cadmium: ≤ 0,06 mg/kg</p> <p><b>Mycotoxins:</b></p> <p>Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg</p> </td> <td style="vertical-align: top;"> <p><b>Characteristics/Composition (AD dried or powder):</b></p> <p>Ash (% w/w): 2,9–5,1</p> <p>Moisture (% w/w): ≤ 5</p> <p>Crude protein (N x 6,25) (% w/w): 55–65</p> <p>Digestible Carbohydrates (% w/w): 1–4</p> <p>Fat (% w/w): 29–35</p> <p style="padding-left: 20px;">of which saturated (% w/w): 36–45</p> <p>Peroxide value (Meq O<sub>2</sub>/kg fat): ≤ 5</p> <p>Dietary fibre (% w/w): 3–6</p> <p>*Chitin (% w/w): 5,3-10,0</p> <p><b>Heavy metals:</b></p> <p>Lead: ≤ 0,05 mg/kg</p> <p>Cadmium: ≤ 0,06 mg/kg</p> <p><b>Mycotoxins:</b></p> <p>Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg</p> </td> </tr> </table>	<p><b>Characteristics/Composition (AD frozen):</b></p> <p>Ash (% w/w): 0,6–1,2</p> <p>Moisture (% w/w): 76–82</p> <p>Crude protein (N x 6,25) (% w/w): 12–21</p> <p>Digestible Carbohydrates (% w/w): 0,1–2</p> <p>Fat (% w/w): 3–12</p> <p style="padding-left: 20px;">of which saturated (% w/w): 36–45</p> <p>Peroxide value (Meq O<sub>2</sub>/kg fat): ≤ 5</p> <p>Dietary fibre (% w/w): 0,8–3</p> <p>*Chitin (% w/w): 0,7–3,0</p> <p><b>Heavy metals:</b></p> <p>Lead: ≤ 0,05 mg/kg</p> <p>Cadmium: ≤ 0,06 mg/kg</p> <p><b>Mycotoxins:</b></p> <p>Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg</p>
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	<p>Aflatoxin B1 (µg/kg): ≤ 2</p> <p>Deoxynivalenol: ≤ 200 µg/kg</p> <p>Ochratoxin A: ≤ 1 µg/kg</p> <p><b>Dioxins and dioxin like PCBs</b></p> <p>Sum of dioxins and dioxin-like PCBs UB, ( **WHO<sub>2005</sub> PCDD/F-PCB-TEQ): ≤ 1,25 pg/g fat</p> <p><b>Microbiological criteria:</b></p> <p>Total aerobic colony count: ≤ 10<sup>5</sup> ***CFU/g</p> <p>Yeasts and moulds: ≤ 100 CFU/g</p> <p><i>Escherichia coli</i>: ≤ 50 CFU/g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p><i>Listeria monocytogenes</i>: Absence in 25 g</p> <p>Sulfite-reducing Anaerobes: ≤ 30 CFU/g</p> <p><i>Bacillus cereus</i> (presumptive): ≤ 100 CFU/g</p> <p>Enterobacteriaceae (presumptive): &lt; 100 CFU/g</p> <p>Coagulase-positive <i>staphylococci</i>: ≤ 100 CFU/g</p>	<p>Aflatoxin B1 (µg/kg): ≤ 2</p> <p>Deoxynivalenol: ≤ 200 µg/kg</p> <p>Ochratoxin A: ≤ 1 µg/kg</p> <p><b>Dioxins and dioxin like PCBs</b></p> <p>Sum of dioxins and dioxin-like PCBs UB, ( **WHO<sub>2005</sub> PCDD/F-PCB-TEQ): ≤ 1,25 pg/g fat</p> <p><b>Microbiological criteria:</b></p> <p>Total aerobic colony count: ≤ 10<sup>5</sup> CFU/g</p> <p>Yeasts and moulds: ≤ 100 CFU/g</p> <p><i>Escherichia coli</i>: ≤ 50 CFU/g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p><i>Listeria monocytogenes</i>: Absence in 25 g</p> <p>Sulfite-reducing Anaerobes: ≤ 30 CFU/g</p> <p><i>Bacillus cereus</i> (presumptive): ≤ 100 CFU/g</p> <p>Enterobacteriaceae (presumptive): &lt; 100 CFU/g</p> <p>Coagulase-positive <i>staphylococci</i>: ≤ 100 CFU/g</p>
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\* Dietary fibre may not include chitin due to different analytical methods.

\*\* 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.