

COMMISSION IMPLEMENTING REGULATION (EU) 2023/5**of 3 January 2023****authorising the placing on the market of *Acheta domestica* (house cricket) partially defatted powder 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 ⁽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⁾ has established a Union list of authorised novel foods.
- (3) On 24 July 2019, the company Cricket One Co. Ltd ('the applicant') submitted an application to the Commission for an authorisation in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place *Acheta domestica* (house cricket) partially defatted powder on the Union market as a novel food. The application requested for partially defatted powder obtained from whole *Acheta domestica* (house cricket) to be used in multigrain bread and rolls, crackers and breadsticks, cereal bars, dry pre-mixes for baked products, biscuits, dry stuffed and non-stuffed pasta-based products, sauces, processed potato products, legume- and vegetable- based dishes, pizza, pasta-based products, whey powder, meat analogues, soups and soup concentrates or powders, maize flour-based snacks, beer-like beverages, chocolate confectionary, nuts and oilseeds, snacks other than chips, and meat preparations, intended for the general population.
- (4) On 24 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 ⁽³⁾; results of proximate analyses ⁽⁴⁾; analytical data on contaminants ⁽⁵⁾; results of the stability studies ⁽⁶⁾; analytical data on microbiological parameters ⁽⁷⁾; and, results of the protein digestibility studies ⁽⁸⁾.
- (5) On 8 July 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of *Acheta domestica* (house cricket) partially defatted powder 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⁾ Cricket One CO. 2019, 2020 and 2021 (unpublished).

⁽⁴⁾ Cricket One CO. 2019, 2020 and 2021 (unpublished).

⁽⁵⁾ Cricket One CO. 2018, 2019, 2020 and 2021 (unpublished).

⁽⁶⁾ Cricket One CO. 2020 (unpublished).

⁽⁷⁾ Cricket One CO. 2018, 2019, 2020 and 2021 (unpublished).

⁽⁸⁾ Cricket One CO. 2019, 2020 and 2021 (unpublished).

- (6) On 23 March 2022, the Authority adopted its scientific opinion on the ‘Safety of partially defatted whole *Acheta domestica* (house cricket) powder as a novel food pursuant to Regulation (EU) 2015/2283’⁽⁹⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that *Acheta domestica* (house cricket) partially defatted powder is safe under the proposed conditions of use and use levels. Therefore, that scientific opinion gives sufficient grounds to establish that *Acheta domestica* (house cricket) partially defatted powder when used in multigrain bread and rolls, crackers and breadsticks, cereal bars, dry pre-mixes for baked products, biscuits, dry stuffed and non-stuffed pasta-based products, sauces, processed potato products, legume- and vegetable- based dishes, pizza, pasta-based products, whey powder, meat analogues, soups and soup concentrates or powders, maize flour-based snacks, beer-like beverages, chocolate confectionary, nuts and oilseeds, snacks other than chips, and meat preparations, 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) On the basis of limited published evidence on food allergy related to insects in general, which equivocally linked the consumption of *Acheta domestica* to a number of anaphylaxis events and, on the basis of evidence demonstrating that *Acheta domestica* contains a number of potentially allergenic proteins, the Authority concluded in the opinion that consumption of this novel food may trigger sensitisation to *Acheta domestica* proteins. The Authority recommended carrying out further research on the allergenicity of *Acheta domestica*.
- (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 domestica*. Until the data generated by the research is assessed by the Authority, and considering that, to date, evidence directly linking the consumption of *Acheta domestica* to cases of primary sensitisation and allergies is inconclusive, the Commission considers that no specific labelling requirements concerning the potential of *Acheta domestica* to cause primary sensitization should be included in the Union list of authorised novel foods.
- (10) The Authority also considered in its opinion that the consumption of *Acheta domestica* (house cricket) partially defatted powder may cause allergic reactions in persons that are allergic to crustaceans, molluscs and dust mites. Furthermore, the Authority noted that additional allergens may end up in the novel food, if those allergens are present in the substrate fed to insects. Therefore, it is appropriate that foods containing *Acheta domestica* (house cricket) partially defatted powder are appropriately labelled in accordance with Article 9 of Regulation (EU) 2015/2283.
- (11) In its scientific opinion, the Authority also noted that its conclusion on the safety of the *Acheta domestica* (house cricket) partially defatted powder was based on the scientific studies and data on the detailed description of the production process; the results of proximate analyses; the analytical data on contaminants; the results of the stability studies; the analytical data on microbiological parameters; and, the results of the protein digestibility studies, without which it could not have assessed the novel food and reached its conclusion.
- (12) 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)(b) of Regulation (EU) 2015/2283.
- (13) 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; the results of proximate analyses; the analytical data on contaminants; the results of the stability studies; the analytical data on microbiological parameters; and, the results of the protein digestibility studies, 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.

⁽⁹⁾ EFSA Journal 2022;20(5):7258.

- (14) 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; the results of proximate analyses; the analytical data on contaminants; the results of the stability studies; the analytical data on microbiological parameters; and, the results of the protein digestibility studies, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place *Acheta domesticus* (house cricket) partially defatted powder on the market within the Union during a period of 5 years from the entry into force of this Regulation.
- (15) However, restricting the authorisation of *Acheta domesticus* (house cricket) partially defatted powder 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.
- (16) *Acheta domesticus* (house cricket) partially defatted powder 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.
- (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) *Acheta domesticus* (house cricket) partially defatted powder is authorised to be placed on the market within the Union.

Acheta domesticus (house cricket) partially defatted powder 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 Cricket One Co. Ltd ⁽¹⁰⁾ 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 24 January 2023, 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 Cricket One Co. Ltd.

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 Cricket One Co. Ltd.

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*.

⁽¹⁰⁾ Cricket One Co. Ltd 383/3/51 Quang Trung Street, Ward 10, Go Vap district, Ho Chi Minh City, Vietnam.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 January 2023.

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
'Acheta domesticus (house cricket) partially defatted powder	Specified food category	Maximum levels (g/100 g) (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 '<i>Acheta domesticus</i> (house cricket) partially defatted powder'.</p> <p>2. The labelling of the foodstuffs containing <i>Acheta domesticus</i> (house cricket) partially defatted powder 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 24.1.2023. 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: "Cricket One Co. Ltd", 383/3/51 Quang Trung street, Ward 10, Go Vap district, Ho Chi Minh City, Vietnam.</p> <p>During the period of data protection, the novel food <i>Acheta domesticus</i> (house cricket) partially defatted powder is authorised for placing on the market within the Union only by "Cricket One Co. Ltd", 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 "Cricket One Co. Ltd".</p> <p>End date of the data protection: 24.1.2028.'</p>
	Multigrain bread and rolls; crackers and breadsticks	2			
	Cereal bars	3			
	Pre-mixes for baked products (dry)	3			
	Biscuits	1,5			
	Pasta-based products (dry)	0,25			
	Stuffed pasta-based products (dry)	3			
	Sauces	1			
	Processed potato products, legume- and vegetable-based dishes, pizza, pasta-based dishes	1			
Whey powder	3				

Meat analogues	5			
Soups and soup concentrates or powders	1			
Maize flour based snacks	4			
Beer-like beverages	0,1			
Chocolate confectionary	2			
Nuts and oilseeds	2			
Snacks other than chips	5			
Meat preparations	2			

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

Authorised novel food	Specification
' <i>Acheta domesticus</i> (house cricket) partially defatted powder	<p>Description/Definition:</p> <p>The novel food is partially defatted powder obtained from whole <i>Acheta domesticus</i> (house cricket) following a series of steps involving a 24 hours fasting period of the insects to allow them to discard their bowel content, the sacrifice of the insects by freezing, washing, thermal processing, drying, oil extraction (mechanical extrusion), and grinding.</p>
	<p>Characteristics/Composition:</p> <p>Crude protein (N x 6,25) (% w/w): 74,0 - 78,0</p> <p>Fat (% w/w): 9,0 – 12,0</p> <p>Moisture (% w/w): 3,0 – 6,0</p> <p>Crude fibre (% w/w): 8,0 – 10,0</p> <p>Chitin (*) (% w/w): 4,0-8,5</p> <p>Ash (% w/w): ≤ 5,6</p> <p>Peroxide value (Meq O₂/kg fat): ≤ 5,0</p> <p>Manganese: ≤ 100,0 mg/kg</p> <p>Cyanide: ≤ 5,0 mg/kg</p>

Heavy metals:Lead: $\leq 0,1$ mg/kgCadmium: $\leq 0,025$ mg/kg**Mycotoxins:**Aflatoxins (Sum of B1, B2, G1, G2): $\leq 0,4$ $\mu\text{g}/\text{kg}$ Deoxynivalenol: $\leq 200,0$ $\mu\text{g}/\text{kg}$ Ochratoxin A: $\leq 1,0$ $\mu\text{g}/\text{kg}$ **Dioxins and dioxin like PCBs:**Sum of dioxins and dioxin-like PCBs UB, ((**)WHO₂₀₀₅ PCDD/F-PCB-TEF): $\leq 1,25$ pg/g fat**Microbiological criteria:**Total aerobic microbial count: $\leq 10^5$ CFU/gYeasts and moulds: ≤ 100 CFU/g*Escherichia coli*: ≤ 50 CFU/g*Salmonella* spp.: Not detected in 25 g*Listeria monocytogenes*: Not detected in 25 g*Bacillus cereus* (presumptive): ≤ 100 CFU/gEnterobacteriaceae (presumptive): < 100 CFU/gCoagulase-positive *staphylococci*: ≤ 100 CFU/g

(*) 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 Factors (using WHO-TEFs of 2005).

CFU: Colony Forming Units.'