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

of **XXX**

authorising the placing on the market of *Acheta domesticus* (house cricket) 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 1852/2001¹, 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) 2017/2470² has established a Union list of novel foods.
- (3) On 11 June 2020, the company Società Agricola Italian Cricket Farm S.r.l. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place *Acheta domesticus* (house cricket) powder on the Union market as a novel food. The applicant requested for the *Acheta domesticus* (house cricket) powder to be used as an ingredient in cakes, biscuits, pasta-based products, whey powder, meat analogues, sandwiches, pizza and other stuffed bread-like cereal products, and chocolate confectionery, intended for the general population.
- (4) On 11 June 2020, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, the study to identify the identity of the novel food³, production process and feed

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

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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

3 Systematic review on the history of use of *Acheta domesticus* (unpublished)

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composition⁴, batch-to-batch analyses of compositional data⁵, nutritional information and digestibility study⁶.

- (5) On 26 January 2022, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of *Acheta domesticus* (house cricket) powder as a novel food.
- (6) On 26 June 2024, the Authority adopted its scientific opinion on "Safety of *Acheta domesticus* (house cricket) powder as a Novel food pursuant to Regulation (EU) 2015/2283"⁷ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that *Acheta domesticus* (house cricket) powder is safe when use as an ingredient in cakes, biscuits, pasta-based products, whey powder, meat analogues, sandwiches, pizza and other stuffed bread-like cereal products, and chocolate confectionery, intended for the general population. Therefore, that scientific opinion gives sufficient grounds to establish that *Acheta domesticus* (house cricket) powder 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 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

4 Breeding method for the house cricket (*Acheta domesticus*) (unpublished)

Analytical data on Cricket Feed (unpublished)

5 Analysis on macronutrients (unpublished)

Analysis on heavy metals (unpublished)

Microbiological analyses (unpublished)

Analysis on micronutrients (unpublished)

Analysis on mycotoxins (unpublished)

Determination of Chitin (unpublished)

Analysis on Dioxin and Dioxin like PCBs (unpublished)

Analysis on fatty acid and aminoacidic profile (unpublished)

Analytical data on Cricket Pasta (unpublished)

Analytical data on Cricket Biscuit (unpublished)

Analytical data on Cricket Cake (unpublished)

Shelf-life study on Biogenic amines (unpublished)

Shelf-life study on oxidative parameters (unpublished)

Shelf-life study on *Pseudomonas* sp. (unpublished)

6 Analysis on Antinutritional factors (unpublished)

Antinutritional factors systematic review (unpublished)

[Protein digestibility \(unpublished\)](#)

7 DOI: 10.2903/j.efsa.2024.8919

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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 powder form of *Acheta domesticus* 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 these allergens are present in the substrate fed to insects. Therefore, it is appropriate that powder forms of *Acheta domesticus* made available to the consumer in 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 also noted that its conclusion on the safety of the novel food was based on scientific evidence from the study to identify the identity of the novel food, production process and feed composition, batch-to-batch analyses of compositional data, nutritional information and digestibility study 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 evidence studies and data, namely, the study to identify the identity of the novel food, production process and feed composition, batch-to-batch analyses of compositional data, nutritional information and digestibility study.
- (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 submitted in support of the application, namely, the study to identify the identity of the novel food, production process and feed composition, batch-to-batch analyses of compositional data, nutritional information and digestibility study 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) powder on the market within the Union during a period of five years from the entry into force of this Regulation.
- (15) However, restricting the authorisation of *Acheta domesticus* (house cricket) 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) It is appropriate that the inclusion of *Acheta domesticus* (house cricket) powder as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

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- (17) *Acheta domesticus* (house cricket) 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.
- (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. *Acheta domesticus* (house cricket) powder is authorised to be placed on the market within the Union.

Acheta domesticus (house cricket) 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 Società Agricola Italian Cricket Farm S.r.l.⁸ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from [the date of entry into force of this Regulation] [OP please insert the date], 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 Società Agricola Italian Cricket Farm S.r.l..

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 five years from the date of entry into force of this Regulation without the agreement of Società Agricola Italian Cricket Farm S.r.l..

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.

⁸ Address: Via Vigone, N° 20, Scalenghe, 10060 Torino, Italy

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Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

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