COMMISSION IMPLEMENTING REGULATION (EU) 2021/1975

of 12 November 2021

authorising the placing on the market of frozen, dried and powder forms of *Locusta migratoria* 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 ([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]) establishing a Union list of authorised novel foods was adopted.

(3) On 28 December 2018, the company Fair Insects BV ('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 (ground) forms of *Locusta migratoria* (migratory locust) on the Union market as a novel food. The applicant requested for frozen, dried and powder forms of *Locusta migratoria* to be used in the form of snack, and as a 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 ([3]), analytical data on the composition ([4]), analytical data on contaminants ([5]), stability and microbiological status, data on the novel food sales ([6]), an intake assessment ([7]), protein digestibility and the Digestible Indispensable Amino Acid Score ([8]), the solubility and sterility tests on dried *Locusta migratoria* conducted prior to the genotoxicity studies which indicated that no genotoxicity testing was possible ([9]), and a cytotoxicity study ([10]).

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 9 July 2019, asking it to provide a scientific opinion by carrying out an assessment of the safety of frozen, dried and powder forms of *Locusta migratoria* 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]) Fair Insects BV. 2019 (unpublished).
([4]) Fair Insects BV. 2019 (unpublished).
([5]) Fair Insects BV. 2019 (unpublished).
([6]) Fair Insects BV. 2018 (unpublished).
([7]) Fair Insects BV. 2019 (unpublished).
([8]) Fair Insects BV. Digestibility of protein from *Locusta migratoria* during transit through the dynamic *in vitro* gastrointestinal model. Study report V21246/01 (unpublished, 2018).
([9]) Fair Insects BV. Solubility and sterility test on dried *Locusta migratoria* prior to the genotoxicity studies (unpublished, 2018).
([10]) Fair Insects BV. Cellular toxicity of aqueous extracts from *Locusta migratoria* (unpublished, 2018).

(6) On 25 May 2021, the Authority adopted a scientific opinion on the safety of frozen, dried and powder forms of *Locusta migratoria* as a novel food ([11]), in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its opinion, the Authority concluded that frozen, dried and powder forms of *Locusta migratoria* 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 *Locusta migratoria* under the assessed conditions of use comply with Article 12(1) of Regulation (EU) 2015/2283.

(8) In that opinion, the Authority also concluded on the basis of limited published evidence on food allergies related to insects in general, which equivocally linked the consumption of *Locusta migratoria* to a number of anaphylaxis events, and on the basis of evidence demonstrating that *Locusta migratoria* contains a number of potentially allergenic proteins, that the consumption of this novel food may trigger sensitisation to *Locusta migratoria* proteins. The Authority also recommended carrying out further research on the allergenicity of *Locusta migratoria*.

(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 *Locusta migratoria*. Until the data generated by the research is assessed by the Authority, and considering that, to date, only few allergic cases caused by *Locusta migratoria* ([12]) have been reported according to data available to the insect industry, and that the evidence on the allergenicity potential associated with the consumption of *Locusta migratoria* is equivocal, the Commission considers that no specific labelling requirements concerning the potential of *Locusta migratoria* to cause primary sensitization 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 *Locusta migratoria* 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 *Locusta migratoria* 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 opinion, the Authority noted that its conclusion on the safety of the novel food was based on a number of data submitted in support of the application, namely a description of the production process, analytical data on the composition, analytical data on contaminants, stability and microbiological status, data on the novel food sales, an intake assessment, protein digestibility and Digestible Indispensable Amino Acid Score, the solubility and sterility tests on dried *Locusta migratoria* conducted prior to the genotoxicity studies which indicated that no genotoxicity testing was possible, and a cytotoxicity study. It also noted that it could not have reached that conclusion without the data from the unpublished reports of those 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 studies and to clarify their claim to an exclusive right of reference to those data, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.

(13) The applicant declared that they held proprietary and exclusive right of reference to description of the production process, analytical data on the composition, analytical data on contaminants, stability and microbiological status, data on the novel food sales, intake assessment, data on protein digestibility and the Digestible Indispensable Amino Acid Score, the solubility and sterility tests on dried *Locusta migratoria* conducted prior to the genotoxicity studies which indicated that no genotoxicity testing was possible, and cytotoxicity study, at the time they submitted the application and that therefore third parties cannot lawfully access, use or refer to those studies.

([11]) Safety of frozen and dried formulations from migratory locust (*Locusta migratoria*) as a novel food pursuant to Regulation (EU) 2015/2283; EFSA Journal 2021;19(7):6667.

([12]) *Locusta migratoria* is marketed in a number of Member States under the transitional measures laid down in Article 35(2) of Regulation (EU) 2015/2283. According to the applicant, dried and frozen locusts have been sold in the Dutch market since 2016.

(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 specific studies on description of the production process, analytical data on the composition, analytical data on contaminants, stability and microbiological status, data on the novel food sales, intake assessment, protein digestibility and Digestible Indispensable Amino Acid Score, the solubility and sterility tests on dried *Locusta migratoria* conducted prior to the genotoxicity studies which indicated that no genotoxicity testing was possible, and cytotoxicity 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 five 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 *Locusta migratoria* on the market within the Union during that period.

(15) However, restricting the authorisation of frozen, dried and powder forms of *Locusta migratoria* and the reference to the studies 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 an 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 *Locusta migratoria*, 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 five years from 5 December 2021, only the initial applicant,

Company: Fair Insects BV;

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 or with the agreement of Fair Insects BV.

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 data 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 five years from 5 December 2021 without the agreement of Fair Insects BV.

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, 12 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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
	Specified food category	**Maximum levels (g/100 g) (marketed as such or reconstituted according to the instructions)**				
		Frozen	**Dried or Powder**			
'Frozen, dried and powder forms of *Locusta migratoria* (migratory locust)	Frozen, dried and powder forms of *Locusta migratoria*			1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'frozen *Locusta migratoria* (migratory locust)', 'dried/powder *Locusta migratoria* (migratory locust)', 'Whole *Locusta migratoria* (migratory locust) powder' depending on the form used. 2. The labelling of the foodstuffs containing frozen dried or powder forms of *Locusta migratoria* (migratory locust) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, molluscs and products thereof, and to mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 5.12.2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Fair Insects BV, Industriestraat 3, 5107 NC Dongen, the Netherlands. 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. End date of the data protection: 5.12.2026.'
	Processed potato products; legumes-based dishes and pasta-based products	15	5			
	Meat analogues	80	50			
	Soups and concentrated soups	15	5			
	Canned/jarred legumes and vegetables	20	15			
	Salads	15	5			
	Beer-like beverages, Alcoholic drink mixes	2	2			
	Chocolate confectionery	30	10			
	Nuts, oilseeds and chickpeas		20			
	Frozen fermented milk-based products	15	5			
	Sausages	30	10			

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

<table>
<tr><th>Authorised Novel Food</th><th>Specifications</th></tr>
<tr><td>‘Frozen, dried and powder forms of Locusta migratoria (migratory locust)</td><td>
Description/Definition:
The novel food consists of the frozen, dried and powder forms of migratory locust. The term ‘migratory locust’ refers to the adult of Locusta migratoria, an insect species that belongs to the Acrididae family (subfamily Locustinae).
The novel food is intended to be marketed in three different forms, namely: (i) thermally processed and frozen L. migratoria (LM frozen); (ii) thermally processed and freeze-dried L. migratoria (LM dried), and (iii) thermally processed freeze-dried and ground whole L. migratoria (whole LM powder). The LM dried may be marketed as such or in powder.
For LM frozen and LM dried, legs and wings must be removed to reduce the risk of intestinal constipation that could be possibly caused by ingestion of the large spines on the insect tibia. The whole LM powder is obtained via mechanical grinding of the insect with legs and wings, and sieving to reduce particle size below 1 mm.
A minimum 24 hours fasting period is required before killing the insects by freezing, to allow the adults to discard their bowel content.
<table>
<tr><th>Parameters</th><th>LM frozen</th><th>LM dried</th><th>Whole LM powder</th></tr>
<tr><td colspan="4">Characteristics/Composition</td></tr>
<tr><td>Ash (% w/w)</td><td>0,6-1,0</td><td>2,0-3,1</td><td>1,8-1,9</td></tr>
<tr><td>Moisture (% w/w)</td><td>67-73</td><td>≤ 5</td><td>≤ 5</td></tr>
<tr><td>Crude protein (N × 6,25) (% w/w)</td><td>11-21</td><td>43-53</td><td>50 – 60</td></tr>
<tr><td>Fat (% w/w)</td><td>7-13</td><td>31-41</td><td>31-41</td></tr>
<tr><td>Saturated fatty acids (% fat)</td><td>35-43</td><td>35-43</td><td>35-43</td></tr>
<tr><td>Digestible carbohydrates (% w/w)</td><td>0,1-2,0</td><td>0,1-2,0</td><td>1,0-3,5</td></tr>
<tr><td>(*)Dietary fibre (% w/w)</td><td>1,5-3,5</td><td>5,5-9,0</td><td>5,5-9,0</td></tr>
<tr><td>Chitin (% w/w)</td><td>1,7-2,4</td><td>6,4-10,4</td><td>10,5-13,9</td></tr>
<tr><td>Peroxide value (Meq O_2/kg fat)</td><td>≤ 5</td><td>≤ 5</td><td>≤ 5</td></tr>
<tr><td colspan="4">Contaminants</td></tr>
<tr><td>Lead (mg/kg)</td><td>≤ 0,07</td><td>≤ 0,07</td><td>≤ 0,07</td></tr>
<tr><td>Cadmium (mg/kg)</td><td>≤ 0,05</td><td>≤ 0,05</td><td>≤ 0,05</td></tr>
</table>
</td></tr>
</table>

	Aflatoxins (Sum of B1, B2, G1, G2) (µg/kg)	≤ 4	≤ 4	≤ 4	
	Aflatoxin B1 (µg/kg)	≤ 2	≤ 2	≤ 2	
	Deoxynivalenol (µg/kg)	≤ 200	≤ 200	≤ 200	
	Ochratoxin A (µg/kg)	≤ 1	≤ 1	≤ 1	
	Sum of dioxins and dioxins-like PCBs UB ((**)WHO_{2005} PCDD/F-PCB-TEQ) (pg/g fat)	≤ 1,2	≤ 1,2	≤ 1,2	
	Microbiological criteria				
	Total aerobic colony count ((***)CFU/g)	≤ 10^5	≤ 10^5	≤ 10^5	
	Enterobacteriaceae (presumptive) (CFU/g)	≤ 100	≤ 100	≤ 100	
	Escherichia coli (CFU/g)	≤ 50	≤ 50	≤ 50	
	Listeria monocytogenes	Not detected in 25g	Not detected in 25g	Not detected in 25g	
	Salmonella spp.	Not detected in 25g	Not detected in 25g	Not detected in 25g	
	Bacillus cereus (presumptive) (CFU/g)	≤ 100	≤ 100	≤ 100	
	Coagulase positive *Staphylococci* (CFU/g	≤ 100	≤ 100	≤ 100	
	Sulfite-reducing Anaerobes (CFU/g)	≤ 30	≤ 30	≤ 30	
	Yeasts and moulds (CFU/g)	≤ 100	≤ 100	≤ 100	

(*) 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'.