# COMMISSION IMPLEMENTING REGULATION (EU) 2021/670

## of 23 April 2021

## authorising the placing on the market of *Schizochytrium* sp. (WZU477) oil 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 14 March 2019, the company Progress Biotech bv ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 for an extension of use of the novel food *Schizochytrium* sp. oil. The application requested to extend the use of *Schizochytrium* sp. oil to infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]) intended for infants and young children. The strain of *Schizochytrium* sp. used by the applicant and concerned by this application is specified as strain WZU477.

(4) The applicant also submitted a request to the Commission for the protection of proprietary data for a number of original data submitted in support of its application, being data submitted in support of the initial application of 14 March 2019 namely, application 2012 ([4]); detailed description of the production process ([5]); chemical characteristics ([6]); fatty acid analysis ([7]); sterol analysis ([8]); heavy metals analysis ([9]); PAH analysis ([10]); mycotoxin analysis ([11]); dioxin, dioxin like, PCB, pesticides analysis ([12]); microbiological analysis ([13]); retrospective stability

([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]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).
([4]) Annex I (NF application 2012), Progress Biotech bv, 2012 (unpublished).
([5]) Detailed description of the production process, Progress Biotech bv, 2019 (unpublished).
([6]) Annex II (chemical characteristics), Progress Biotech bv, 2019 (unpublished).
([7]) Annex III (fatty acid analysis), Progress Biotech bv, 2019 (unpublished).
([8]) Annex IV (sterol analysis), Progress Biotech bv, 2019 (unpublished).
([9]) Annex V (heavy metals analysis), Progress Biotech bv, 2019 (unpublished).
([10]) Annex VI (PAH analysis), Progress Biotech bv, 2019 (unpublished).
([11]) Annex VII (mycotoxin analysis), Progress Biotech bv, 2019 (unpublished).
([12]) Annex VIII (dioxin, dioxin like, PCB, pesticides analysis), Progress Biotech bv, 2019 (unpublished).
([13]) Annex IX (microbiological analysis), Progress Biotech bv, 2019 (unpublished).

study ([14]); analytical lab certificates ([15]); compositional data ([16]). The applicant also requested data protection for the additional data submitted in the course of the safety assessment carried out by the Authority: protein analysis ([17]); 3 MCPD & glycidyl ester analyses ([18]); physicochemical analysis ([19]); microbiological analysis ([20]); heavy metals analysis ([21]); mycotoxin analysis ([22]); PAH, dioxin and dioxin-like contaminants analysis ([23]); fatty acid profile analysis ([24]); sterol composition analysis ([25]); hydrolytic rancidity analysis over time ([26]); marine biotoxin analysis ([27]); stability study ([28]); certificate of analysis ([29]).

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 24 June 2019, requesting it to provide a scientific opinion by carrying out an assessment for an extension of use of *Schizochytrium* sp. oil as a novel food in infant formula and follow-on formula.

(6) On 31 August 2020, the Authority adopted its scientific opinion on the "Safety of *Schizochytrium* sp. oil as a novel food pursuant to Regulation (EU) 2015/2283" ([30]). That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In that opinion, the Authority confirmed that the identity of the strain WZU477 belongs to the species *Schizochytrium limacinum*, which was attributed the qualified presumption of safety ('QPS') status and included in 2020 in the list of QPS-recommended biological agents intentionally added to food or feed ([31]). In its opinion, the Authority concluded that *Schizochytrium* sp. oil produced from the strain WZU477 belonging to species *Schizochytrium limacinum* is safe under the proposed conditions of use. Data submitted by the applicant did not allow for a conclusion on the safety of oil produced from other strains of the *Schizochytrium* microalgae genus. The opinion of the Authority gives sufficient grounds to establish that *Schizochytrium* sp. (WZU477) oil under the proposed uses and use levels complies with the requirements of Article 12(1) of Regulation (EU) 2015/2283.

(8) Therefore, the opinion of the Authority does not give sufficient grounds to establish that oil produced from other strains of the *Schizochytrium* microalgae genus when used in infant formula and follow on formula, complies with Article 12(1) of Regulation (EU) 2015/2283. Following the Authority's opinion and taking into account that the authorised *Schizochytrium* sp. oil for which an extension of use was requested is neither species-specific nor strain-specific, it is therefore necessary to authorise the placing on the market of oil from strain WZU477 of *Schizochytrium* sp., and not an extension of use of oil from all strains of the *Schizochytrium* genus as requested by the applicant.

([14]) Annex XI (retrospective stability study), Progress Biotech bv, 2019 (unpublished).
([15]) Annex XII (analytical lab certificates), (unpublished).
([16]) Appendix B.2 (compositional data), Progress Biotech bv, 2019 (unpublished).
([17]) Annex IV (protein analysis), Progress Biotech bv, 2020 (unpublished).
([18]) Annex VI (3 MCPD & glycidyl ester analyses), Progress Biotech bv, 2020 (unpublished).
([19]) Annex VII (physicochemical analysis), Progress Biotech bv, 2020 (unpublished).
([20]) Annex VIII (microbiological analysis), Progress Biotech bv, 2020 (unpublished).
([21]) Annex IX (heavy metals analysis), Progress Biotech bv, 2020 (unpublished).
([22]) Annex X (mycotoxin analysis), Progress Biotech bv, 2019 (unpublished).
([23]) Annex XI (PAH, dioxin and dioxin-like contaminants analysis), Progress Biotech bv, 2020 (unpublished).
([24]) Annex XII (fatty acid profile analysis), Progress Biotech bv, 2020 (unpublished)
([25]) Annex XIV (sterol composition analysis), Progress Biotech bv, 2020 (unpublished).
([26]) Annex XVII (hydrolytic rancidity analysis over time), Progress Biotech bv, 2020 (unpublished).
([27]) Annex 1 (marine biotoxin analysis), Wageningen Food Safety Research Lab, 2020 (unpublished).
([28]) Annex 3 (stability study), Progress Biotech bv, 2018 (unpublished).
([29]) Annex I (certificate of analysis), Progress Biotech bv, 2016 (unpublished).
([30]) *EFSA Journal* 2020;18(10):6242.
([31]) EFSA BIOHAZ Panel, 2020. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 11: suitability of taxonomic units notified to EFSA until September 2019. *EFSA Journal* 2020;18(2):5965, 57 pp.

(9) In its opinion, the Authority considered that the data from the application 2012, detailed description of the production process, chemical characteristics, fatty acid analysis, sterol analysis, heavy metals analysis, PAH analysis, mycotoxin analysis, dioxin, dioxin like, PCB, pesticides analysis, microbiological analysis, retrospective stability study, analytical lab certificates, compositional data, 3 MCPD & glycidyl ester analyses, physicochemical analysis, microbiological analysis, heavy metals analysis, mycotoxin analysis, PAH, dioxin and dioxin-like contaminants analysis, fatty acid profile analysis, sterol composition analysis, hydrolytic rancidity analysis over time, marine biotoxin analysis, stability study and certificate of analysis served as a basis to establish the safety of the novel food. On this basis, the Commission considers that the conclusions on the safety of *Schizochytrium* sp. (WZU477) oil could not have been reached without the data from the reports of those studies.

(10) Following the authority's opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the application 2012, detailed description of the production process, chemical characteristics, fatty acid analysis, sterol analysis, heavy metals analysis, PAH analysis, mycotoxin analysis, dioxin, dioxin like, PCB, pesticides analysis, microbiological analysis, retrospective stability study, analytical lab certificates, compositional data, 3 MCPD & glycidyl ester analyses, physicochemical analysis, microbiological analysis, heavy metals analysis, mycotoxin analysis, PAH, dioxin and dioxin-like contaminants analysis, fatty acid profile analysis, sterol composition analysis, hydrolytic rancidity analysis over time, marine biotoxin analysis, stability study and certificate of analysis, and to clarify their claim to an exclusive right of reference to that data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to that data under national law, and that therefore third parties cannot lawfully access or use those studies or refer to that data.

(12) 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 application 2012, detailed description of the production process, chemical characteristics, fatty acid analysis, sterol analysis, heavy metals analysis, PAH analysis, mycotoxin analysis, dioxin, dioxin like, PCB, pesticides analysis, microbiological analysis, retrospective stability study, analytical lab certificates, compositional data, 3 MCPD & glycidyl ester analyses, physicochemical analysis, microbiological analysis, heavy metals analysis, mycotoxin analysis, PAH, dioxin and dioxin-like contaminants analysis, fatty acid profile analysis, sterol composition analysis, hydrolytic rancidity analysis over time, marine biotoxin analysis, stability study and certificate of analysis contained in the applicant's file should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of *Schizochytrium* sp. (WZU477) oil should be restricted to the applicant for that period.

(13) However, restricting the authorisation of *Schizochytrium* sp. (WZU477) oil and of 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 under Regulation (EU) 2015/2283.

(14) Implementing Regulation (EU) 2017/2470 should be therefore amended accordingly.

(15) 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. *Schizochytrium* sp. (WZU477) oil 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 the date of entry into force of this Regulation only the initial applicant:

— Company: Progress Biotech bv,

— Address: Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, 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 that novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Progress Biotech 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 has 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 any subsequent applicant for a period of five years from the date of entry into force of this Regulation, without the agreement of Progress Biotech 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, 23 April 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 |
|---|---|---|---|---|---|
| '*Schizochytrium* sp. (WZU477) oil | *Specified food category* | *Maximum levels of DHA* | The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the microalgae *Schizochytrium* sp." | | Authorised on 16 May 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.<br>Applicant: Progress Biotech bv, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands.<br>During the period of data protection, the novel food is authorised for placing on the market within the Union only by Progress Biotech 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 Progress Biotech bv.<br>End date of the data protection: 16 May 2026 (5 years).' |
| | Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 | In accordance with Regulation (EU) No 609/2013 | | | |

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

| Authorised Novel Food | Specification |
|---|---|
| '*Schizochytrium* sp. (WZU477) oil | **Description/Definition:**<br>The novel food is an oil produced from the strain WZU477 of the microalgae *Schizochytrium* sp.<br>**Composition:**<br>Acid value: ≤ 0,5 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq/kg oil<br>Moisture and volatiles: ≤ 0,05 %<br>Unsaponifiables: ≤ 4,5 %<br>Trans-fatty acids: ≤ 1,0 %<br>Docosahexaenoic acid (DHA): ≥ 32,0 %<br>p-anisidine value: ≤ 10' |