



2025/1509

28.7.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1509

of 25 July 2025

**amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food
phytosterols/phytostanols**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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 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) 2017/2470 ⁽²⁾ has established a Union list of novel foods.
- (3) The novel food phytosterols/phytostanols was authorised under certain conditions of use and maximum levels by Commission Decisions 2000/500/EC ⁽³⁾, 2004/333/EC ⁽⁴⁾, 2004/334/EC ⁽⁵⁾, 2004/335/EC ⁽⁶⁾, 2004/336/EC ⁽⁷⁾,

⁽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⁾ Commission Decision 2000/500/EC of 24 July 2000 on authorising the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 200, 8.8.2000, p. 59, ELI: <http://data.europa.eu/eli/dec/2000/500/oj>).

⁽⁴⁾ Commission Decision 2004/333/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 105, 14.4.2004, p. 40, ELI: <http://data.europa.eu/eli/dec/2004/333/oj>).

⁽⁵⁾ Commission Decision 2004/334/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, milk type products, yoghurt type products, and spicy sauces with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 105, 14.4.2004, p. 43, ELI: <http://data.europa.eu/eli/dec/2004/334/oj>).

⁽⁶⁾ Commission Decision 2004/335/EC of 31 March 2004 authorising the placing on the market of milk type products and yoghurt type products with added phytosterol esters as novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 105, 14.4.2004, p. 46, ELI: <http://data.europa.eu/eli/dec/2004/335/oj>).

⁽⁷⁾ Commission Decision 2004/336/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 105, 14.4.2004, p. 49, ELI: <http://data.europa.eu/eli/dec/2004/336/oj>).

2004/845/EC ⁽⁸⁾, 2006/58/EC ⁽⁹⁾, 2006/59/EC ⁽¹⁰⁾, 2007/343/EC ⁽¹¹⁾, 2008/36/EC ⁽¹²⁾, and previously authorised pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽¹³⁾.

- (4) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 therefore includes phytosterols/phytostanols as an authorised novel food.
- (5) On 29 June 2023, the company Advanced Organic Materials SA ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change in the specifications of the novel food phytosterols/phytostanols. The applicant requested to increase the maximum level of 'other sterols/stanols' from 3,0 % to < 7,0 % to better reflect and cover the natural composition and proportions of sunflower-based phytosterols/phytostanols.
- (6) On 29 June 2023, the applicant also made a request to the Commission for the protection of the following proprietary data: compositional data ⁽¹⁴⁾, a microbiological, heavy metals, pesticides, aflatoxins and sulphated ash analytical report ⁽¹⁵⁾, a dioxins and polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAH) and residual solvents analytical report ⁽¹⁶⁾, a particle size distribution report ⁽¹⁷⁾, a stability study report ⁽¹⁸⁾, and a validation report on the in-house method for the determination of phytosterol content using gas chromatography ⁽¹⁹⁾.
- (7) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 4 January 2024, requesting it to provide a scientific opinion on the change of the specifications of the novel food phytosterols/phytostanols.
- (8) On 28 November 2024, the Authority adopted its scientific opinion on the 'change of specifications of phytosterols/phytostanols as a novel food pursuant to Regulation (EU) 2015/2283' ⁽²⁰⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.

⁽⁸⁾ Commission Decision 2004/845/EC of 12 November 2004 on authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 366, 11.12.2004, p. 14, ELI: [http://data.europa.eu/eli/dec/2004/845\(2\)/oj](http://data.europa.eu/eli/dec/2004/845(2)/oj)).

⁽⁹⁾ Commission Decision 2006/58/EC of 24 January 2006 authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 31, 3.2.2006, p. 18, ELI: [http://data.europa.eu/eli/dec/2006/58\(1\)/oj](http://data.europa.eu/eli/dec/2006/58(1)/oj)).

⁽¹⁰⁾ Commission Decision 2006/59/EC of 24 January 2006 authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 31, 3.2.2006, p. 21, ELI: [http://data.europa.eu/eli/dec/2006/59\(1\)/oj](http://data.europa.eu/eli/dec/2006/59(1)/oj)).

⁽¹¹⁾ Commission Decision 2007/343/EC of 15 May 2007 authorising the placing on the market of oil enriched with phytosterols/phytostanols as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 129, 17.5.2007, p. 63, ELI: <http://data.europa.eu/eli/dec/2007/343/oj>).

⁽¹²⁾ Commission Decision 2008/36/EC of 10 January 2008 authorising the placing on the market of rice drinks with added phytosterols/phytostanols as novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 8, 11.1.2008, p. 15, ELI: [http://data.europa.eu/eli/dec/2008/36\(1\)/oj](http://data.europa.eu/eli/dec/2008/36(1)/oj)).

⁽¹³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1, ELI: <http://data.europa.eu/eli/reg/1997/258/oj>).

⁽¹⁴⁾ Annexes 11a and 12a to the application – phytosterol/phytostanol composition of five batches each of Advasterol 90 S F and of Advasterol Ester S; Annexes 17b and 17c – certificates of analysis of Advasterol 90 S F and of Advasterol Ester S.

⁽¹⁵⁾ Annexes 11b and 12b to the application – microbes, heavy metals, pesticides, aflatoxins and sulphated ash of five batches each of Advasterol 90 S F and of Advasterol Ester S.

⁽¹⁶⁾ Annex 11c and 12c to the application – dioxins and polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAH) and residual solvents of five batches each of Advasterol 90 S F.

⁽¹⁷⁾ Annexes 13a and 13b to the application – particle size distribution of Advasterol 90 S F and Advasterol Ester S.

⁽¹⁸⁾ Annex 17a to the application – stability study of Advasterol 90 S F and Advasterol Ester S.

⁽¹⁹⁾ Annex 17e to the application – validation data of the in-house method for the determination of phytosterol content using gas chromatography.

⁽²⁰⁾ <https://doi.org/10.2903/j.efsa.2025.9162>.

- (9) In its scientific opinion, the Authority identified four phytosterols from the 'other sterols/stanols' fraction, representing at least two-thirds of this fraction when phytosterols/phytostanols are produced from sunflower oil. Given the higher proportion of the 'other phytosterols' fraction in phytosterols/phytostanols sourced from sunflower, it is deemed appropriate to increase the authorised level of 'other sterols/stanols' from < 3,0 % to < 7,0 %.
- (10) The opinion of the Authority concluded that phytosterols/phytostanols is safe under the proposed change of the specifications. Therefore, that scientific opinion gives sufficient grounds to establish that the change to the specifications of the novel food phytosterols/phytostanols fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (11) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food based on the additional specification relied on scientific studies and data, specifically the compositional data and the validation report on the in-house method for the determination of phytosterol content using gas chromatography. Without that information, it would not have been possible to assess the novel food and reached a 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), point (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, specifically compositional data and the validation report on the in-house method for the determination of phytosterol content using gas chromatography at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.
- (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 compositional data and the validation report on the in-house method for the determination of phytosterol content using gas chromatography should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised during a period of five years from the entry into force of this Regulation to place on the market within the Union phytosterols/phytostanols that are extracted from the sunflower plant and that have equal or more than 3 % and less than 7 % of 'other sterols/stanols' fraction.
- (15) However, the restriction to this authorisation of phytosterols/phytostanols 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) Under the Union list set out in the Annex to Implementing Regulation (EU) 2017/2470, the novel food 'phytosterols/phytostanols' that are extracted from plants, including sunflower, having 'other sterols/stanols' fraction less than 3,0 %, are authorised as generic, without any data protection. This existing authorisation is not affected by the present amendment.
- (17) 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

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Advanced Organic Materials SA ⁽²¹⁾ is authorised to place on the market within the Union the novel food 'phytosterols/phytostanols' composed of 3,0 % to < 7,0 % of other sterols/stanols and as specified in the Annex to this Regulation for a period of five years from 17 August 2025, 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 Advanced Organic Materials SA.

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 Advanced Organic Materials SA.

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, 25 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

⁽²¹⁾ Address: Street 14, No 507, Parque Industrial Pilar, B1629, Provincia de Buenos Aires, Argentina.

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 2 (Specifications), the following entry for Phytosterols/phytostanols is inserted in alphabetical order:

Authorised Novel Food	Specifications
Phytosterols/phytostanols	Description/Definition: Phytosterols and phytostanols are sterols and stanols that are extracted from the sunflower plant and may be presented as free sterols and stanols or esterified with food grade fatty acids. Composition (with GC-FID or equivalent method): β-sitosterol: < 81 % β-sitostanol: < 35 % campesterol: < 40 % campestanol: < 15 % stigmasterol: < 30 % brassicasterol: < 3,0 % other sterols/stanols: 3,0 % to < 7,0 % ⁽¹⁾

⁽¹⁾ Authorised on 17 August 2025.
This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
Applicant: Advanced Organic Materials SA, Street 14, No 507, Parque Industrial Pilar, B1629, Provincia de Buenos Aires, Argentina.
During the period of data protection, the novel food phytosterols/phytostanols composed of 3,0 % to < 7,0 % of other sterols/stanols is authorised for placing on the market within the Union only by Advanced Organic Materials SA, unless a subsequent applicant obtains authorisation for the 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 Advanced Organic Materials SA.
End date of the data protection: 17 August 2030.