

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

of **XXX**

**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 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<sup>1</sup>, 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) 2017/2470<sup>2</sup> 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<sup>3</sup>, 2004/333/EC<sup>4</sup>, 2004/334/EC<sup>5</sup>, 2004/335/EC<sup>6</sup>, 2004/336/EC<sup>7</sup>, 2004/845/EC<sup>8</sup>, 2006/58/EC<sup>9</sup>,

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

<sup>2</sup> 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](http://data.europa.eu/eli/reg_impl/2017/2470/oj)).

<sup>3</sup> 2000/500/EC: Commission Decision 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 (notified under document number C(2000) 2121)( OJ L 200, 8.8.2000, p. 59, ELI: <http://data.europa.eu/eli/dec/2000/500/oj>).

<sup>4</sup> 2004/333/EC: Commission Decision 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 (notified under document number C(2004) 1243)( OJ L 105, 14.4.2004, p. 40, ELI: <http://data.europa.eu/eli/dec/2004/333/oj>).

<sup>5</sup> 2004/334/EC: Commission Decision 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 (notified under document number C(2004) 1244) (OJ L 105, 14.4.2004, p. 43, ELI: <http://data.europa.eu/eli/dec/2004/334/oj>).

<sup>6</sup> 2004/335/EC: Commission Decision 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 (notified under document number C(2004) 1245)( OJ L 105, 14.4.2004, p. 46, ELI: <http://data.europa.eu/eli/dec/2004/335/oj>).

2006/59/EC<sup>10</sup>, 2007/343/EC<sup>11</sup>, 2008/36/EC<sup>12</sup>, and also authorised pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council<sup>13</sup>.

- (4) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 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 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<sup>14</sup>, microbiological, heavy metals, pesticides, aflatoxins and sulphated ash analytical report<sup>15</sup>, dioxins and polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAH) and residual solvents analytical report<sup>16</sup>, particle size distribution report<sup>17</sup>, stability study

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<sup>7</sup> 2004/336/EC: Commission Decision 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 (notified under document number C(2004) 1246)( OJ L 105, 14.4.2004, p. 49, ELI: <http://data.europa.eu/eli/dec/2004/336/oj>).

<sup>8</sup> 2004/845/EC: Commission Decision 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 (notified under document number C(2004) 4289)( 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)).

<sup>9</sup> 2006/58/EC: Commission Decision 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 (notified under document number C(2006) 42) (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)).

<sup>10</sup> 2006/59/EC: Commission Decision 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 (notified under document number C(2006) 115)( 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)).

<sup>11</sup> 2007/343/EC: Commission Decision 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 (notified under document number C(2007) 2073)( OJ L 129, 17.5.2007, p. 63, ELI: <http://data.europa.eu/eli/dec/2007/343/oj>).

<sup>12</sup> 2008/36/EC: Commission Decision 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 (notified under document number C(2008) 6)( 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)).

<sup>13</sup> 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>).

<sup>14</sup> Annexes 11a and 12a – 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.

<sup>15</sup> Annexes 11b and 12b – microbes, heavy metals, pesticides, aflatoxins and sulphated ash of five batches each of Advasterol 90 S F and of Advasterol Ester S.

<sup>16</sup> Annex 11c and 12c – dioxins and polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAH) and residual solvents of five batches each of Advasterol 90 S F

<sup>17</sup> Annexes 13a and 13b – particle size distribution of Advasterol 90 S F and Advasterol Ester S

report<sup>18</sup>, and validation report on the in-house method for the determination of phytosterol content using gas chromatography<sup>19</sup>.

- (7) On 4 January 2024, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of a change of the specifications for phytosterols/phytostanols as a novel food.
- (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'<sup>20</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.
- (9) In its scientific opinion, four phytosterols from the 'other sterols/stanols' fraction were identified, representing at least two-thirds of this fraction. As one of these phytosterols, 'delta-7-stigmastenol', accounts for half of the 'other sterols/stanols' fraction, it is appropriate to include this phytosterol separately in the specifications with a level of  $\leq 4,0$  %, while maintaining the current authorised level of  $< 3,0$  % for 'other sterols/stanols'. Additionally, considering the slight variation in the 'other phytosterols' fraction between phytosterols sourced from sunflower and those from other plant sources, and the fact that phytosterols/phytostanols from different plant origins have already been extensively assessed by the Authority and Member States, it is deemed appropriate not to restrict the proposed change in specifications to sunflower oil only.
- (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 on the additional specification was based on scientific studies and data, namely, from the compositional data, and validation report on the in-house method for the determination of phytosterol content using gas chromatography 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, namely from compositional data, and 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 validation report on the in-house method for the determination of phytosterol content using gas chromatography should be protected in accordance

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<sup>18</sup> Annex 17a – stability study of Advasterol 90 S F and Advasterol Ester S

<sup>19</sup> Annex 17e – validation data of the in-house method for the determination of phytosterol content using gas chromatography.

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

with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place phytosterols/phytostanols 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 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) It is appropriate that the inclusion of phytosterols/phytostanols 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.
- (17) Phytosterols/phytostanols 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*

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<sup>21</sup> 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 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.

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<sup>21</sup> Address: Street 14, No 507, Parque Industrial Pilar, B1629, Provincia de Buenos Aires, Argentina

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*