



2025/2242

10.11.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2242

of 7 November 2025

**authorising the placing on the market of yellow tomato extract 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 1852/2001 ⁽¹⁾, 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 ⁽²⁾ has established a Union list of novel foods.
- (3) On 30 April 2024, the company Lycored Ltd ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place yellow tomato extract on the Union market as a novel food. The applicant requested for the novel food to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ for adult population.
- (4) On 30 April 2024, the applicant also made a request to the Commission for the protection of the following proprietary data: Reverse Mutation Assay Ames Test ⁽⁴⁾ and Micronucleus Test in Human Lymphocytes *in vitro* ⁽⁵⁾.
- (5) On 13 August 2024, the Commission requested the European Food Safety Authority ('the Authority') to provide a scientific opinion on yellow tomato extract as a novel food.
- (6) On 24 March 2025, the Authority adopted its scientific opinion on the 'Safety of yellow tomato extract as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁶⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that yellow tomato extract is safe under the proposed conditions of use.
- (8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the proprietary data: Reverse Mutation Assay Ames Test and Micronucleus Test in Human Lymphocytes *in vitro*, without which it could not have assessed the novel food and reached its conclusion.

⁽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⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

⁽⁴⁾ Annex 4.5 to the application.

⁽⁵⁾ Annex 4.6 to the application.

⁽⁶⁾ EFSA Journal. 2025;23:e9373.

- (9) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies 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.
- (10) The applicant declared that they held proprietary and exclusive rights of reference to Reverse Mutation Assay Ames Test and Micronucleus Test in Human Lymphocytes *in vitro*, at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.
- (11) The Commission assessed all the information provided by the applicant and considers that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data on Reverse Mutation Assay Ames Test and Micronucleus Test in Human Lymphocytes *in vitro*, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place yellow tomato extract on the market within the Union during a period of five years from the entry into force of this Regulation.
- (12) However, such restriction of the authorisation and the reference to the data contained in the applicant's file for their sole use 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.
- (13) It is appropriate that the inclusion of yellow tomato extract a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In line with the conditions of use of food supplements containing yellow tomato extract as proposed by the applicant, it is necessary to inform the consumers in that regard by appropriate labelling about the uses of food supplements containing yellow tomato extract.
- (14) Yellow tomato extract 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.
- (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. Yellow tomato extract is authorised to be placed on the market within the Union. Yellow tomato extract 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 Lycored Ltd ⁽⁷⁾ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 30 November 2025, unless a subsequent applicant obtains an authorisation for the novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of the company Lycored Ltd.

⁽⁷⁾ Address: P.O Box 320, Beer Sheva 8410202, Israel.

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 5 years from the date of entry into force of this Regulation without the agreement of the company Lycored Ltd.

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, 7 November 2025.

For the Commission
The President
Ursula VON DER LEYEN

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
Yellow tomato extract	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “yellow tomato extract”. 2. The labelling of food supplements containing yellow tomato extract shall bear a statement that the food supplements should be consumed by adults only.		Authorised on 30 November 2025. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Lycored Ltd, P.O Box 320, Beer Sheva 8410202, Israel. During the period of data protection, the novel food yellow tomato extract is authorised for placing on the market within the Union only by Lycored Ltd, 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 Lycored Ltd. End date of the date protection: 30 November 2030’.
	Food supplements as defined in Directive 2002/46/EC for the adult population	100 mg/day			

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

Authorised Novel Food	Specifications
Yellow tomato extract	Description/Definition: The novel food is a carotenoid-rich extract derived from the pulp of ripe yellow tomatoes (<i>Lycopersicon esculentum</i> Mill.) using supercritical CO₂ extraction Characteristics/composition: Appearance: Viscous, dark brown liquid Moisture: < 0,5 % Proteins: 0,2 %– 0,6 % Total lipids: > 95 % Saturated fat: 12 %–25 % Monounsaturated fat: 17 %–30 % Polyunsaturated fat: 50 %–65 % Trans fatty acids: ≤ 2 % Unsaponifiable matter: < 20 % Acid value: < 5 mg KOH/g(*) Peroxide value: ≤ 15 meqO₂/kg(**) Carotenoids: Total carotenoids: 10-13 g/100 g Phytoene + phytofluene (including cis- and all-trans isomers): 7-10 g/100 g beta-Carotene: 0,1-0,5 g/100 g zeta-Carotene: 2-4 g/100 g Lycopene: 0,1-0,4 g/100 g Heavy metals Lead: ≤ 1 mg/kg Cadmium: ≤ 1 mg/kg Mercury: ≤ 0,1 mg/kg Arsenic: ≤ 1 mg/kg Microbiological criteria: Total aerobic microbial count: ≤ 1 000 CFU/g <i>E. coli</i>: Not detected in 10 g <i>Salmonella</i>: Not detected in 25 g <i>Staphylococcus aureus</i>: Not detected in 10 g Yeasts/moulds: ≤ 100 CFU/g (*) Acid value based all fatty acids. (**) Based on Codex Alimentarius guidelines for peroxid value in concentrated oil https://www.fao.org/3/y2774e/y2774e04.htm Abbreviation: CFU, colony forming units'