

COMMISSION DELEGATED REGULATION (EU) 2019/1820

of 8 August 2019

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include *Saccharomyces cerevisiae* as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 28(1) thereof,

Whereas:

- (1) The active substance *Saccharomyces cerevisiae*, insofar as it constituted food or feed intended for use as a repellent or attractant of product type 19, used to benefit from the food and feed derogation provided for in Article 6 of Commission Regulation (EC) No 1451/2007 ⁽²⁾.
- (2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014 ⁽³⁾ for *Saccharomyces cerevisiae* for product type 19 benefiting from the food and feed derogation. The European Chemicals Agency ('the Agency') declared the notification to be compliant and informed the Commission of the compliance pursuant to Article 17 of that Regulation. *Saccharomyces cerevisiae* was consequently included for product type 19 in the list of substance/product type combinations included in the programme of review of existing active substances contained in biocidal products ⁽⁴⁾.
- (3) On 31 January 2017 the Commission asked the Agency for an opinion on whether *Saccharomyces cerevisiae* gives rise to concern according to Article 28(2) of Regulation (EU) No 528/2012.
- (4) The opinion of the Agency ⁽⁵⁾ concluded that *Saccharomyces cerevisiae* does not give rise to concern and is therefore eligible for inclusion in Annex I to Regulation (EU) No 528/2012.
- (5) Taking into account the opinion of the Agency, it is appropriate to include *Saccharomyces cerevisiae* in Annex I to Regulation (EU) No 528/2012. As *Saccharomyces cerevisiae* is of natural origin, it should be included in category 4 'Traditionally used substances of natural origin'. *Saccharomyces cerevisiae* should be included in that Annex only insofar as it falls within the definition of 'food' or 'feed' referred to in point (u) of Article 3(1) of that Regulation. This is consistent with the fact that *Saccharomyces cerevisiae* only benefited from the food and feed derogation provided for in Article 6 of Regulation (EC) No 1451/2007 if it was food or feed.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

⁽³⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

⁽⁴⁾ Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1).

⁽⁵⁾ Biocidal Products Committee (BPC) Opinion of 14 December 2017 on the eligibility of certain food and feed active substances for inclusion into Annex I to the BPR, ECHA/BPC/186/2017.

- (6) Article 89(3) of Regulation (EU) No 528/2012 contains transitional measures where an existing active substance included in the work programme for the systematic examination of existing active substances is approved in accordance with that Regulation. With respect to *Saccharomyces cerevisiae* for product-type 19, the date of approval for the purposes of Article 89(3) of that Regulation should be set at 1 June 2021, in order to allow sufficient time for applications for authorisation to be submitted in accordance with the second subparagraph of Article 89(3) of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

For the purposes of Article 89(3) of Regulation (EU) No 528/2012, the date of approval of *Saccharomyces cerevisiae* for product-type 19 is 1 June 2021.

Article 3

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, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

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ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 4 of the list of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
Not available	<i>Saccharomyces cerevisiae</i> (yeast) (*)	Excluding <i>Saccharomyces cerevisiae</i> that is not food or feed.	CAS No 68876-77-7

(*) The date of approval of *Saccharomyces cerevisiae* for product-type 19 for the purposes of Article 89(3) is 1 June 2021.: