



Council of the  
European Union

073214/EU XXVI. GP  
Eingelangt am 12/08/19

Brussels, 12 August 2019  
(OR. en)

11645/19

ENV 730  
MI 618  
AGRI 408  
CHIMIE 112  
DELECT 157

#### COVER NOTE

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 8 August 2019

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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No. Cion doc.: C(2019) 5890 final

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Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 8.8.2019  
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

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Delegations will find attached document C(2019) 5890 final.

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Encl.: C(2019) 5890 final



Brussels, 8.8.2019  
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**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 8.8.2019**

**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)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

Article 28(1) of Regulation (EU) No 528/2012 (the BPR) empowers the Commission to adopt delegated acts in order to include an active substance into Annex I to the BPR after receiving the opinion of the European Chemicals Agency (ECHA), provided that there is evidence that the active substance does not give rise to concern according to the conditions set out in Article 28(2) of that Regulation. A simplified authorisation procedure is provided in Chapter V of the BPR for biocidal products containing active substances listed in Annex I to the BPR and fulfilling other conditions set out in Article 25 of that Regulation.

Article 15(b) of Regulation (EU) No 1062/2014 (the Review Regulation) provided economic operators with an opportunity to support those active substances that benefitted from the food and feed derogation provided for by Article 6 of Regulation (EC) No 1451/2007. The concerned active substances are food and feed used in biocidal products of product-type 19 "Repellents and Attractants". The products supplied on the market as biocidal products containing these substances do not benefit from the exemption of the scope of the BPR set out in Article 2(5)(a) of the BPR, as this exemption covers only food or feed being placed on the market as food or feed in compliance with EU food or feed legislation (e.g. manufacturing, marketing and labelling requirements) but used by the user for biocidal purposes. As these active substances do not benefit from derogation under the BPR anymore, and following the submission of successful notifications by economic operators pursuant to Articles 15 to 17 of the Review Regulation, ECHA was able to identify potential candidates for inclusion into Annex I to the BPR among these substances.

After discussion with Member States Competent Authorities for Biocidal Products, the Commission requested on 31 January 2017 an opinion to the European Chemicals Agency in accordance with Article 75(1)(g) of Regulation (EU) No 528/2012 as to whether any of the food or feed active substances for which ECHA accepted a declaration of interest to notify gives rise to concern in accordance with Article 28(2) of the BPR.

The opinion of the European Chemicals Agency was formulated on 14 December 2017 by the Biocidal Products Committee and confirmed that *Saccharomyces cerevisiae* does not give rise to concern and is eligible for inclusion in Annex I to Regulation (EU) No 528/2012. This opinion is considered as an opinion of the Agency pursuant to Article 28(1) of Regulation (EU) No 528/2012.

This draft Delegated Regulation therefore proposes to include *Saccharomyces cerevisiae* in Annex I to Regulation (EU) No 528/2012.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

The Commission has consulted an expert group (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products, of the European Chemicals Agency, of the biocides industry and of the civil society in the meetings of 27-28 September 2018, 13-15 March 2019 and 16-17 May 2019.

**3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The delegated act amends Annex I to Regulation (EU) No 528/2012.

COMMISSION DELEGATED REGULATION (EU) .../...

of 8.8.2019

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<sup>1</sup>, 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<sup>2</sup>.
- (2) A notification was submitted pursuant to Article 16(5) of Commission Delegated Regulation (EU) No 1062/2014<sup>3</sup> 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<sup>4</sup>.
- (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.

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<sup>1</sup> OJ L 167, 27.6.2012, p. 1.

<sup>2</sup> 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).

<sup>3</sup> 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).

<sup>4</sup> 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).

- (4) The opinion of the Agency<sup>5</sup> 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.
- (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, 8.8.2019

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*

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<sup>5</sup> 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.