COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

concerning the renewal of the authorisation of organic form of selenium produced by
Saccharomyces cerevisiae CNCM I-3060 and of selenomethionine produced by
Saccharomyces cerevisiae NCYC R397 as feed additives for all animal species and

(Text with EEA relevance)
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concerning the renewal of the authorisation of organic form of selenium produced by Saccharomyces cerevisiae CNCM I-3060 and of selenomethionine produced by Saccharomyces cerevisiaeNCYC R397 as feed additives for all animal species and repealing Regulations (EC) No 1750/2006 and No 634/2007

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) The organic form of selenium produced by Saccharomyces cerevisiae CNCM I-3060 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EC) No 1750/2006². Selenomethionine produced by Saccharomyces cerevisiae NCYC R397 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EC) No 634/2007³.

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, applications were submitted for the renewal of the authorisation of the organic form of selenium produced by Saccharomyces cerevisiae CNCM I-3060 and of selenomethionine produced by Saccharomyces cerevisiae NCYC R397 as feed additives for all animal species, requesting those additives to be classified in the additive category ‘nutritional additives’. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 5 July 2018⁴ and 28 November 2018⁵ that the applicants have provided data demonstrating that the additives comply with the conditions of authorisation under the proposed conditions of use. The Authority confirmed its previous conclusions that the organic form of selenium produced by Saccharomyces cerevisiae CNCM I-3060 and

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¹ OJ L 268, 18.10.2003, p. 29.
⁴ EFSA Journal 2018;16(7):5386.
⁵ EFSA Journal 2019;17(1):5539.
the selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 are safe for the animals, consumers and the environment. Considering the capacities of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 to be a respiratory sensitizer and hazardous upon inhalation, and the capacities of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 to be an eye and mucosae irritant, a skin and respiratory sensitizer and hazardous upon inhalation, appropriate protective measures with respect to the handling of the additive should be taken in order to avoid that safety concerns for the users would arise. Finally, the Authority recommends changing the denomination of the additives.

(5) It is appropriate to update the methods of analysis for selenium and selenomethionine based on the respective recent reports of the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of those additives should be renewed as specified in the Annex to this Regulation.

(7) As a consequence of the renewal of the authorisations of the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1750/2006 and No 634/2007 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and for selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(9) 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 authorisation of the additives specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’, is renewed subject to the conditions laid down in that Annex.

*Article 2*

1. The organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060, selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 and premixtures containing these substances, which are produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the
Service responsible for the publication] may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substances referred to in point 1, which are produced and labelled before [12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Feed materials and compound feed containing the substances referred to in point 1, which are produced and labelled before [24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Regulations (EC) No 1750/2006 and No 634/2007 are repealed.

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,

For the Commission
The President
Jean-Claude JUNCKER