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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/52

of 4 January 2023

authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21(DE3) 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 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) Commission Implementing Regulation (EU) 2021/2029 ⁽³⁾ authorised the placing on the Union market of 3-Fucosyllactose obtained by microbial fermentation using the genetically modified strain K12 MG1655 of *Escherichia coli* ('*E. coli*') as a novel food under Regulation (EU) 2015/2283.
- (4) On 17 March 2020, the company Chr. Hansen A/S ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 3-fucosyllactose ('3-FL') obtained by microbial fermentation using one genetically modified strain of *E. coli* BL21(DE3), on the Union market as a novel food. The applicant requested for 3-fucosyllactose to be used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁴⁾, processed cereal-based

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽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).

⁽³⁾ Commission Implementing Regulation (EU) 2021/2029 of 19 November 2021 authorising the placing on the market of 3-Fucosyllactose (3-FL) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 415, 22.11.2021, p. 9).

⁽⁴⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

food for infants and young children and baby food for infants and young children as defined in Regulation (EU) No 609/2013, foods for infants and young children for special medical purposes as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children, in milk-based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁵⁾ intended for the general population. Subsequently, on 17 June 2022, the applicant modified the initial request in the application on the use of 3-FL in food supplements to exclude infants and young children. The applicant also proposed that food supplements containing 3-FL should not be used if other foods with added 3-fucosyllactose are consumed the same day.

- (5) On 17 March 2020, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data submitted in support of the application, namely, the mass spectrometry ('MS'), nuclear magnetic resonance ('NMR') spectroscopy and high-performance anion-exchange chromatography with pulsed amperometric detection ('HPAEC-PAD') method validation and the results for the determination of the identity of 3-FL and carbohydrate by-products ⁽⁶⁾; a description of the genetically modified 3-FL production strain ⁽⁷⁾; a certificate of deposition of the genetically modified 3-FL production strain ⁽⁸⁾; real time quantitative polymerase chain reaction ('qPCR') system and method validation reports for the genetically modified 3-FL production strain ⁽⁹⁾; a bacterial reverse mutation test with 3-FL ⁽¹⁰⁾; an *in vitro* mammalian cell micronucleus test with 3-FL ⁽¹¹⁾; a 7-day dose range finding oral toxicity study in rats with 3-FL ⁽¹²⁾; and, a 90-day oral toxicity study in rats with 3-FL ⁽¹³⁾.
- (6) On 23 September 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3-Fucosyllactose obtained by microbial fermentation using a genetically modified production strain derived from the host strain *E. coli* BL21(DE3), as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.
- (7) On 29 April 2022, the Authority adopted its scientific opinion on the 'Safety of 3-fucosyllactose produced by a derivative strain of *Escherichia coli* BL21(DE3) as a novel food pursuant to Regulation (EU) 2015/2283' ⁽¹⁴⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority concluded that 3-FL is safe under the proposed conditions of use for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 3-FL, when used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013, processed cereal-based food for infants and young children and baby food for infants and young children as defined in Regulation (EU) No 609/2013, foods for infants and young children for special medical purposes as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children, in milk-based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC, complies with the authorisation requirements of Article 12(1) of Regulation (EU) 2015/2283.

⁽⁵⁾ 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).

⁽⁶⁾ Chr. Hansen 2019 and 2021 (unpublished).

⁽⁷⁾ Chr. Hansen 2019 and 2021 (unpublished).

⁽⁸⁾ Chr. Hansen 2020 (unpublished).

⁽⁹⁾ Chr. Hansen 2021 (unpublished).

⁽¹⁰⁾ Chr. Hansen 2018 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹¹⁾ Chr. Hansen 2018 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹²⁾ Chr. Hansen 2018 and 2021 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹³⁾ Chr. Hansen 2019 and 2021 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹⁴⁾ EFSA Journal 2022;20(5):7329.

- (9) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the 3-FL without the scientific studies and data on the MS, NMR and HPAEC-PAD method validation and the results for the determination of the identity of 3-FL and of the carbohydrate by-products present in the novel food; the description of the genetically modified 3-FL production strain; the certificate of deposition of the genetically modified 3-fucosyllactose production strain; the qPCR system and method validation report for the genetically modified 3-FL production strain; the bacterial reverse mutation test with 3-FL; the *in vitro* mammalian cell micronucleus test with 3-FL; the 7-day dose range finding oral toxicity study in rats with 3-FL; and, the 90-day oral toxicity study in rats with 3-FL.
- (10) 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.
- (11) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data on MS, NMR and HPAEC-PAD method validation and the results for the determination of the identity of 3-FL and of the carbohydrate by-products present in the novel food; the description of the genetically modified 3-FL production strain; the certificate of deposition of the genetically modified 3-FL production strain; the qPCR system and method validation report for the genetically modified 3-FL production strain; the bacterial reverse mutation test with 3-FL; the *in vitro* mammalian cell micronucleus test with 3-FL; the 7-day dose range finding oral toxicity study in rats with 3-FL; and, the 90-day oral toxicity study in rats with 3-FL, under national law at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data and studies.
- (12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific studies and data on MS, NMR and HPAEC-PAD method validation and the results for the determination of the identity of 3-FL and of the carbohydrate by-products present in the novel food; the description of the genetically modified 3-FL production strain; the certificate of deposition of the genetically modified 3-FL production strain; the qPCR system and method validation report for the genetically modified 3-FL production strain; the bacterial reverse mutation test with 3-FL; the *in vitro* mammalian cell micronucleus test with 3-FL; the 7-day dose range finding oral toxicity study in the rat with 3-FL; and, the 90-day oral toxicity study in the rat with 3-FL, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place 3-fucosyllactose produced with a derivative strain of *E. coli* BL21(DE3) on the market within the Union during a period of five years from the entry into force of this Regulation.
- (13) However, restricting the authorisation of 3-FL produced with a derivative strain of *E. coli* BL21(DE3) 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.
- (14) In line with the conditions of use of food supplements containing 3-FL as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers with an appropriate label that food supplements containing 3-FL should not be consumed by infants and children under 3 years of age and should not be used if other foods with added 3-FL are consumed the same day.
- (15) It is appropriate that the inclusion of 3-FL produced with a derivative strain of *E. coli* BL21(DE3) 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.
- (16) 3-FL produced with a derivative strain of *E. coli* BL21(DE3) 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.
- (17) 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) 3-Fucosyllactose produced with a derivative strain of *E. coli* BL21(DE3) is authorised to be placed on the market within the Union.

3-Fucosyllactose produced with a derivative strain of *E. coli* BL21(DE3) 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 Chr. Hansen A/S ⁽¹⁵⁾ 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 25 January 2023, 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 Chr. Hansen A/S.

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 Chr. Hansen A/S.

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, 4 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹⁵⁾ Address: Bøge Allé 10-12, 2970 Hørsholm, Denmark.

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
‘3-Fucosyllactose (‘3-FL’) (produced by a derivative strain of <i>E. coli</i> BL21(DE3))	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘3-fucosyllactose’. The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.		Authorised on 25.1.2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: “Chr. Hansen A/S”, Bøge Allé 10-12, 2970 Hørsholm, Denmark. During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the Union only by Chr. Hansen A/S 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 “Chr. Hansen A/S”. End date of the data protection: 25.1.2028.’
	Infant formula as defined under Regulation (EU) No 609/2013	0,90 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	1,20 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	1,20 g/l or 1,20 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Milk based drinks and similar products intended for young children	1,20 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than 0,9 g/l or 0,9 g/kg (if it is intended for infants from 0 until 6 months) and 1,2 g/l or 1,2 g/kg (if it is intended for infants of 6-12 months and/or for young children) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			

	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	3 g/day			

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

Authorised novel food	Specification
‘3-Fucosyllactose (‘3-FL’) (produced by a derivative strain of <i>E. coli</i> BL21(DE3))	Description: 3-Fucosyllactose (3-FL) is a purified, white to off-white powder that is produced by microbial fermentation and contains limited levels of D-Lactose, L-Fucose, D-Galactose, and D-Glucose. Definition: Chemical name: β-D-Galactopyranosyl-(1 $\rightarrow$ 4)- [α-L-fucopyranosyl-(1 $\rightarrow$ 3)]- D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ Molecular mass: 488,44 Da CAS No: 41 312-47-4 Source: A genetically modified strain of <i>Escherichia coli</i> BL21(DE3) Characteristics/Composition: 3-Fucosyllactose (% of dry matter): $\geq 90,0$ % (w/w) D-Lactose (% of dry matter): $\leq 5,0$ % (w/w) D-glucose (% of dry matter): $\leq 3,0$ % (w/w) D-galactose (% of dry matter): $\leq 3,0$ % (w/w) L-Fucose (% of dry matter): $\leq 3,0$ % (w/w) Sum of other carbohydrates (% of dry matter) ^(a): $\leq 5,0$ % (w/w) Moisture: $\leq 9,0$ % (w/w) Ash: $\leq 1,0$ % (w/w) Residual protein: $\leq 0,01$ % (w/w)

Heavy metals and contaminants:Arsenic: $\leq 0,2$ mg/kgAflatoxin M1: $\leq 0,025$ µg/kg**Microbiological criteria:**Standard plate count: $\leq 1\ 000$ CFU (*) /gEnterobacteriaceae: ≤ 10 CFU/g*Salmonella* spp.: Absence in 25 gYeast and mould: ≤ 100 CFU/g*Cronobacter* (*Enterobacter*) *sakazakii*.: Absence in 10 gResidual endotoxins: ≤ 10 EU (**) /mg

([†]) Sum of other carbohydrates = 100 (% (w/w) of dry matter) – quantified carbohydrates (% (w/w) of dry matter) – Ash (% (w/w) of dry matter).

(*) CFU: Colony Forming Units.

(**) EU: Endotoxin Units.'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/53

of 4 January 2023

concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for all animal species

(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 nutrition ⁽¹⁾, 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 such an authorisation.
- (2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Pediococcus acidilactici* CNCM I-4622. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for all animal species, to be classified in the additive category 'technological additives' and in the functional groups 'acidity regulators' and 'hygiene condition enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Pediococcus acidilactici* CNCM I-4622 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that it is considered a respiratory sensitiser, but not irritant to eyes/skin or a skin sensitiser. The Authority further concluded that the preparation showed a potential to reduce the pH and the growth of coliforms in liquid feeds. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of *Pediococcus acidilactici* CNCM I-4622 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) 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. The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'acidity regulators', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.
2. The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'hygiene condition enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2022;20(8):7424.

Article 2

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, 4 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU of additive/kg of complete feed with a moisture content of 12 %			
Category: technological additives. Functional group: acidity regulators.								
4d1712	<i>Pediococcus acidilactici</i> CNCM I-4622	<i>Additive composition</i> Preparation of <i>Pediococcus acidilactici</i> CNCM I-4622 containing a minimum of 1 × 10 ¹⁰ CFU/g Solid form <i>Characterisation of the active substance</i> Viable cells of <i>Pediococcus acidilactici</i> CNCM I-4622 <i>Analytical method</i> ⁽¹⁾ Enumeration: Spread plate method using MRS agar (EN 15786) Identification: Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods	All animal species	-	1 x 10 ⁹	-	1. In the directions for use of the additive and pre-mixtures, the storage conditions shall be indicated. 2. The additive shall be used only in mash compound feed intended for the preparation of liquid feed on the farm and/or in solid feed materials intended for the preparation of liquid feed on the farm. 3. May be used in feed containing the following permitted coccidiostats: halofuginone, diclazuril, decoquinate and nicarbazin. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	24.1.2033

(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU of additive/kg of fresh material			

Category: technological additives. Functional group: hygiene condition enhancers (reduction of the growth of coliforms).

4d1712	<i>Pediococcus acidilactici</i> CNCM I-4622	<i>Additive composition</i> Preparation of <i>Pediococcus acidilactici</i> CNCM I-4622 containing a minimum of 1×10^{10} CFU/g Solid form <i>Characterisation of the active substance</i> Viable cells of <i>Pediococcus acidilactici</i> CNCM I-4622 <i>Analytical method</i> ⁽¹⁾ Enumeration: Spread plate method using MRS agar (EN 15786) Identification: Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods	All animal species	-	1×10^9	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. The additive shall be used only in mash compound feeds intended for the preparation of liquid feed on the farm and/or in solid feed materials intended for the preparation of liquid feed on the farm. 3. May be used in feed containing the following permitted coccidiostats: halofuginone, diclazuril, decoquinate and nicarbazin. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	24.1.2033
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

COMMISSION IMPLEMENTING REGULATION (EU) 2023/54
of 4 January 2023
correcting Implementing Regulation (EU) 2022/652 concerning the authorisation of bitter orange
extract as a feed additive for certain animal species

(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 nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) The use of the bitter orange extract as a feed additive was authorised for certain animal species by Commission Implementing Regulation (EU) 2022/652 ⁽²⁾.
- (2) Bitter orange extract is known to contain 10 to 20 % neohesperidin, as detailed in the column 'Composition, chemical formula, description, analytical method' in the Annex to Implementing Regulation (EU) 2022/652.
- (3) An incorrect presumption of a relationship between neohesperidin, identified with CAS number 13241-33-3, and neohesperidin dihydrochalcone, identified with CAS number 20702-77-6, which has a similar name, but is a distinct substance, resulted in point 3 of the column 'Other provisions' in the Annex to Implementing Regulation (EU) 2022/652, which mistakenly provides for the exclusion of the use of bitter orange extract in combination with neohesperidin dihydrochalcone.
- (4) The opinion of the European Food Safety Authority of 23 June 2021 on the safety of bitter orange extract ⁽³⁾ does not mention any risk as regards the use of bitter orange extract in combination with neohesperidin dihydrochalcone.
- (5) It is therefore necessary to correct the Annex to Implementing Regulation (EU) 2022/652 by deleting point 3 of the column 'Other provisions' in that Annex. For the sake of clarity, it is appropriate to replace the whole Annex to that Implementing Regulation.
- (6) In the interest of preventing disruptions to the placing of the feed additive in the market due to the error in Implementing Regulation (EU) 2022/652, this Regulation should enter into force as a matter of urgency.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2022/652 of 20 April 2022 concerning the authorisation of bitter orange extract as a feed additive for certain animal species (OJ L 119, 21.4.2022, p. 74).

⁽³⁾ EFSA Journal 2021;19(7):6709.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2022/652 is replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 4 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

Identifica- tion number of the additive	Name of the holder of author- isation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maxi- mum age	Mini- mum content	Maxi- mum content	Other provisions	End of period of authorisa- tion
						mg active substance/kg of complete feed with a moisture content of 12 %			

Category: Sensory additives. Functional group: Flavouring compounds

2b136-ex	-	Bitter orange extract	<i>Additive composition</i> Bitter orange extract from the fruit of <i>Citrus x aurantium</i> L. Solid form <i>Characterisation of the active substance</i> Bitter orange extract from the fruit of <i>Citrus x aurantium</i> L. as defined by the Council of Europe ⁽¹⁾. Flavonoids: 45-55 % of which — Naringin: 20-30 % — Neohesperidin: 10-20 % 5- methoxypsoralen (also known as bergapten): ≤ 0,03 % (-)-Synephrine: ≤ 1 % CoE number: 136 <i>Analytical method</i> ⁽²⁾ For the quantification of naringin (phytochemical marker) in the feed additive: — High performance liquid chromatography (HPLC) with spectrophotometric (UV) detection	Chickens for fattening Laying hens Turkeys for fattening Piglets Pigs for fattening Sows Dairy cows Calves Cattle for fattening Sheep/goats Horses Rabbits Salmonids Ornamental fish Dogs Cats	-	-		- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — Chickens for fattening: 102 mg. — Laying hens: 151 mg. — Turkeys for fattening: 136 mg. — Piglets: 182 mg. — Pigs for fattening: 217 mg. — Sows: 268 mg. — Dairy cows: 259 mg. — Calves (milk replacer), cattle for fattening, sheep/goats, horses, salmonids, dogs and ornamental fish: 400 mg. — Cats: 80 mg. — Rabbits: 161 mg.'	11 May 2032
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								4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3. 5. The mixture of bitter orange extract from the fruit of <i>Citrus x aurantium</i> L with other authorised additives obtained from <i>Citrus aurantium</i> L. shall not be allowed in feedingstuffs. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	
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(¹) Natural sources of flavourings – Report No 2 (2007)

(²) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

DECISIONS

DECISION (EU) 2023/55 OF THE EUROPEAN CENTRAL BANK

of 16 December 2022

amending Decision (EU) 2019/1743 on the remuneration of holdings of excess reserves and of certain deposits (ECB/2019/31) and Decision (EU) 2022/1521 on temporary adjustments to the remuneration of certain non-monetary policy deposits held with national central banks and the European Central Bank (ECB/2022/30) (ECB/2022/47)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first indent of Article 127(2) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular the first indent of Article 3.1 and Articles 17 and 18 thereof,

Whereas:

- (1) As stated in the proposal for a regulation of the European Parliament and of the Council, establishing an Instrument for providing support to Ukraine for 2023 (macro-financial assistance+) ⁽¹⁾ and in the proposal for a regulation of the European Parliament and the Council amending Regulation (EU, Euratom) 2018/1046 as regards the establishment of a diversified funding strategy as a general borrowing method ⁽²⁾, the funding needs for the Union's support to Ukraine require mobilisation and disbursement in a cost-effective and financially sound manner, integrating all funding needs including those for NextGenerationEU ('NGEU'). Funding should therefore be organised using a single funding method in order to allow different policy needs of the Union to be met concurrently, ensuring parallel financing of all Union programmes relying on borrowing.
- (2) Article 13(2) of Commission Implementing Decision of 14 April 2021 establishing the necessary arrangements for the administration of the borrowing operations under Council Decision (EU, Euratom) 2020/2053 and for the lending operations related to loans granted in accordance with Article 15 of Regulation (EU) 2021/241 of the European Parliament and of the Council ⁽³⁾ provides that a dedicated account is maintained with the European Central Bank (ECB) for prudential cash holdings. Following the establishment of a single funding method ensuring parallel financing of all Union programmes that rely on borrowing, the dedicated account maintained with the ECB is also to be used in the context of this single funding method for the purposes of prudential cash holdings related to the Instrument for providing support to Ukraine for 2023 (macro-financial assistance+).
- (3) The Governing Council has decided that it is appropriate that the dedicated account maintained with the ECB, which is currently used for prudential holdings related to NGEU and which will be extended to be used also for prudential holdings related to the Instrument for providing support to Ukraine for 2023 (macro-financial assistance+), continues to be remunerated on the basis of the rules and provisions laid down in Decision (EU) 2019/1743 of the European Central Bank (ECB/2019/31) ⁽⁴⁾ and Decision (EU) 2022/1521 of the European Central Bank (ECB/2022/30) ⁽⁵⁾.

⁽¹⁾ COM(2022) 597 final.

⁽²⁾ COM(2022) 596 final.

⁽³⁾ C(2021) 2502 final.

⁽⁴⁾ Decision (EU) 2019/1743 of the European Central Bank of 15 October 2019 on the remuneration of holdings of excess reserves and of certain deposits (ECB/2019/31) (OJ L 267, 21.10.2019, p. 12).

⁽⁵⁾ Decision (EU) 2022/1521 of the European Central Bank of 12 September 2022 on temporary adjustments to the remuneration of certain non-monetary policy deposits held with national central banks and the European Central Bank (ECB/2022/30) (OJ L 2361, 13.9.2022, p. 1).

- (4) Decision (EU) 2022/1521 (ECB/2022/30) will remain in force until 30 April 2023. Until that date, pursuant to Article 3 of that Decision, in the event of a conflict between it and, inter alia, Article 2 of Decision (EU) 2019/1743 (ECB/2019/31), Decision (EU) 2022/1521 (ECB/2022/30) prevails. Therefore, Decision (EU) 2019/1743 (ECB/2019/31) and Decision (EU) 2022/1521 (ECB/2022/30) are to be read in conjunction.
- (5) In light of the current situation in Ukraine, this Decision should enter into force and apply as a matter of urgency.
- (6) Therefore, Decision (EU) 2019/1743 (ECB/2019/31) and Decision (EU) 2022/1521 (ECB/2022/30) should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Amendment to Decision (EU) 2019/1743 (ECB/2019/31)

In Article 2 of Decision (EU) 2019/1743 (ECB/2019/31), paragraph 2 is replaced by the following:

‘2. The dedicated account maintained with the ECB in accordance with Article 13(2) of Commission Implementing Decision of 14 April 2021 establishing the necessary arrangements for the administration of the borrowing operations under Council Decision (EU, Euratom) 2020/2053 and for the lending operations related to loans granted in accordance with Article 15 of Regulation (EU) 2021/241 of the European Parliament and of the Council (*) and used for the purposes of prudential cash holdings in relation to NextGenerationEU (‘NGEU’) and in relation to the Instrument for providing support to Ukraine for 2023 (macro-financial assistance+) shall be remunerated at zero per cent or the euro short-term rate (€STR), whichever is higher, except where the aggregate amount of deposits held in that dedicated account exceeds EUR 20 billion, in which case the amount in excess shall be remunerated as follows:

- (a) if the deposit facility rate on the relevant calendar day is zero or higher (positive), at zero per cent or the euro short-term rate (€STR), whichever is lower;
- (b) if the deposit facility rate on the relevant calendar day is lower than zero (negative), at the deposit facility rate or the euro short-term rate (€STR), whichever is lower.

(*) C(2021) 2502 final.’.

Article 2

Amendment to Decision (EU) 2022/1521 (ECB/2022/30)

In Article 2 of Decision (EU) 2022/1521 (ECB/2022/30), paragraph 3 is replaced by the following:

‘3. The dedicated account maintained with the ECB in accordance with Article 13(2) of Commission Implementing Decision of 14 April 2021 establishing the necessary arrangements for the administration of the borrowing operations under Council Decision (EU, Euratom) 2020/2053 and for the lending operations related to loans granted in accordance with Article 15 of Regulation (EU) 2021/241 of the European Parliament and of the Council (*) and used for the purposes of prudential cash holdings in relation to NextGenerationEU (‘NGEU’) and in relation to the Instrument for providing support to Ukraine for 2023 (macro-financial assistance+) shall be remunerated at zero per cent or the euro short-term rate (€STR), whichever is higher, except where the aggregate amount of deposits held in that dedicated account exceeds EUR 20 billion, in which case the amount in excess of EUR 20 billion shall be remunerated at the deposit facility rate or the euro short-term rate (€STR), whichever is lower.

(*) C(2021) 2502 final.’.

*Article 3***Entry into force**

1. This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply from 9 January 2023.

Done at Frankfurt am Main, 16 December 2022.

The President of the ECB
Christine LAGARDE

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