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Corrigenda


(*) Text with EEA relevance.

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.

The titles of all other acts are printed in bold type and preceded by an asterisk.
II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/145

of 3 February 2020

amending Implementing Regulation (EU) No 433/2012 laying down detailed rules for the application of Regulation (EU) No 1236/2010 of the European Parliament and of the Council as regards the transmission of reports and information to the North-East Atlantic Fisheries Commission

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1236/2010 of the European Parliament and of the Council of 15 December 2010 laying down a scheme of control and enforcement applicable in the area covered by the Convention on future multilateral cooperation in the North-East Atlantic fisheries and repealing Council Regulation (EC) No 2791/1999 (1), and in particular Articles 9 and 11 thereof,

Whereas:

(1) Regulation (EU) No 1236/2010 lays down certain specific control measures to monitor fishing activities of the Union in the area covered by the North-East Atlantic Fisheries Commission (NEAFC). Detailed rules for the application of Regulation (EU) No 1236/2010 are laid down in Commission Implementing Regulation (EU) No 433/2012 (2).

(2) In accordance with Article 12(2) of Regulation (EU) No 1236/2010 Members states are to ensure that the reports and information transmitted to the NEAFC Secretariat comply with the data exchange formats and data communication systems determined pursuant to Article 16 of Implementing Regulation (EU) No 433/2012.

(3) At its 2018 Annual Meeting the NEAFC has agreed on a new electronic reporting system for the communication of data between the contracting parties and the NEAFC Secretariat based on the UN/FLUX standard (3). NEAFC has decided that the European Union would be the first contracting party to NEAFC to implement the new electronic reporting system. Once the Commission informs NEAFC Secretariat that it is ready to start the implementation of the new reporting system and NEAFC has established that the technical preparations to use the UN/FLUX standard are completed, NEAFC will decide on a date as of which the new standard becomes applicable for data exchanges. The new reporting system will first be used between the EU and the NEAFC Secretariat, and other contracting parties will have to implement the system at the latest within two years of its entry into force.

(4) Implementation of the new electronic reporting system requires preparatory work at Commission and Member States level. To avoid undue delays in implementation of the new reporting system, it is therefore necessary to define the date by which the Member States concerned should be in a position to implement the new data exchange formats and data communication systems.

(5) The Commission will communicate the date for the start of the implementation period of the new electronic reporting system to the Member States once a decision is taken by NEAFC to this effect.

(6) It is therefore necessary to amend Implementing Regulation (EU) No 433/2012.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

Article 16 of Implementing Regulation (EU) No 433/2012 is replaced by the following:

‘Article 16

Communication to the NEAFC Secretary

1. The data exchange formats and data communication systems referred to in Article 12(2) of Regulation (EU) No 1236/2010 to be used for transmission of reports and information to the NEAFC Secretary shall continue to comply with the rules set out in Annex X to this Regulation until the date referred to in paragraph 3; the corresponding codes to be used in communication with the NEAFC Secretary are as set out in Annex XI.

2. Member States shall complete, by 1 November 2020, all necessary technical preparations enabling the utilisation of the following data exchange formats and data communication systems for transmission of reports and information to the NEAFC Secretary:

   (a) To exchange fishing logbook data, prior notification data, transhipment declaration data, and landing declaration data, the format shall be the Fishing Activity Domain XML Schema Definition based on the UN/FLUX P1000-3 standard. The data exchange shall comply with the FLUX Fishing Activities Implementation Document adopted by NEAFC.

   (b) To report vessel monitoring system data, the format shall be the Vessel Position Domain XML Schema Definition based on the UN/FLUX P1000-7 standard. The data exchange shall comply with the FLUX Vessel Position Implementation Document adopted by NEAFC.

3. Member States shall use the data exchange formats and data communication systems referred to in paragraph 2 from the date to be communicated by the Commission following the decision by NEAFC to this effect. The data exchanges shall comply with the FLUX Implementation Documents adopted by NEAFC.

4. By way of derogation from paragraph 1 and 3, Member States may use the data exchange format referred to in paragraph 2 (b) to report vessel monitoring system data as of the entry into force of this Regulation. Member States shall inform the Commission of the date as of which the new data exchange format will be used.’

Article 2

This Regulation shall enter into force on the seventh day following 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, 3 February 2020.

For the Commission
The President
Ursula VON DER LEYEN
COMMISSION IMPLEMENTING REGULATION (EU) 2020/146

of 3 February 2020


(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 13(3) 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 authorisation.


(3) On 31 August 2018, Asahi Calpis Wellness Co. Ltd., represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office, submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003, proposing to modify the minimum content of the additive for use in chickens for fattening from the authorised concentration of $5 \times 10^8$ CFU/kg feed to a concentration of $3 \times 10^8$ CFU/kg feed. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (‘the Authority’).

(4) The Authority concluded in its opinion of 22 January 2019 (8) that the reduced minimum content of the additive with a concentration of $3 \times 10^8$ CFU/kg feed has the potential to be efficacious in chickens for fattening. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) EFSA Journal 2019; 17(3):5605.
On 26 March 2019, Asahi Calpis Wellness Co. Ltd., represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office, submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003, proposing to amend the name of its representative. The applicant claimed that Pen & Tec Consulting S.L.U. is to be considered its representative in the Union for the additive. The application was accompanied by the relevant supporting data.

That proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The Authority was informed of the application.

The assessment of the applications shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.


Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the preparation of Bacillus subtilis C-3102 (DSM 15544), which are in conformity with the provisions applying before the date of entry into force of this Regulation, may continue to be placed on the market and used until they are exhausted.

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

Amendments to Regulation (EU) No 333/2010

Regulation (EU) No 333/2010 is amended as follows:

(1) in the title, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’;

(2) in the second column of the Annex, ‘Name of the holder of authorisation’, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’.

Article 2

Amendments to Regulation (EU) No 184/2011

Regulation (EU) No 184/2011 is amended as follows:

(1) in the title, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’;

(2) in the second column of the Annex, ‘Name of the holder of authorisation’, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’.

Article 3

Amendments to Implementing Regulation (EU) 2016/897

Implementing Regulation (EU) 2016/897 is amended as follows:

(1) in the title, the words ‘Asahi Calpis Wellness Co. Ltd’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’;

(2) in the second column of the Annex, ‘Name of the holder of authorisation’, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’.
Article 4

Amendments to Implementing Regulation (EU) 2017/2312

Implementing Regulation (EU) 2017/2312 is amended as follows:

(1) in the title, the words ‘Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’;

(2) in the second column of the Annex, ‘Name of the holder of authorisation’, the words ‘Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’.

Article 5

Amendments to Implementing Regulation (EU) 2018/1081

Implementing Regulation (EU) 2018/1081 is amended as follows:

(1) in the title, the words ‘Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’;

(2) in the second column of the Annex, ‘Name of the holder of authorisation’, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’.

Article 6

Amendments to Implementing Regulation (EU) 2019/893

Regulation (EU) 2019/893 is amended as follows:

(1) in the title, the words ‘Asahi Calpis Wellness Co. Ltd, represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’;

(2) in the second column of the Annex, ‘Name of the holder of authorisation’ the words ‘Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office’ are replaced by the words ‘Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.’.

(3) in column 7 ‘Minimum content’, the word ‘5 × 10⁸’ is replaced by ‘3 × 10⁸’.

Article 7

Transitional measures

Bacillus subtilis C-3102 (DSM 15544), as set out in Regulation (EU) No 333/2010, Implementing Regulation (EU) 2017/2312, Implementing Regulation (EU) 2018/1081, Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2019/893 and Regulation (EU) No 184/2011, and premixtures containing that substance and compound feed containing that substance, which are produced and labelled before 24 February 2020 in accordance with the rules applicable before 24 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 8

Entry into force

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, 3 February 2020.

For the Commission
The President
Ursula VON DER LEYEN
COMMISSION IMPLEMENTING REGULATION (EU) 2020/147
of 3 February 2020

concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-4407 as a feed additive for weaned piglets, sows (in order to have a benefit for suckling piglets) and dairy cows and amending Regulations (EC) No 2148/2004, (EC) No 1288/2004 and (EC) No 1811/2005 (holder of authorisation S.I. Lesaffre)

(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 authorisation.


(4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, an application was submitted for the re-evaluation of the preparation of Saccharomyces cerevisiae CNCM I-4407 (former Saccharomyces cerevisiaeNCYC Sc 47) as a feed additive for weaned piglets, sows and dairy cows. The applicant requested that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 22 January 2019 (6) that, under the proposed conditions of use, the preparation Saccharomyces cerevisiae CNCM I-4407 does not have an adverse effect on animal health, human health or the environment. The Authority considered that the additive has the potential to improve performance parameters in weaned piglets and sows in order to have a benefit in suckling piglets. It also concluded that the additive showed a positive effect on performance in dairy cows in two studies. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) Since the additive has already demonstrated the capacity to improve the performance parameters in other dairy ruminants, namely dairy goats, dairy sheep and dairy buffalos, it was considered that the conditions for the demonstration of the efficacy for dairy cows are met by the results of the provided two in vivo studies.

(6) EFSA Journal 2019; 17(3):5600.
(7) The assessment of the preparation of *Saccharomyces cerevisiae* CNCM I-4407 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.


(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(10) 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 preparation specified in the Annex, belonging to the additive category ‘zootecnic additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

**Article 2**

In Annex II to Regulation (EC) No 2148/2004, the entry E 1702 on *Saccharomyces cerevisiae* NCYC Sc 47 is deleted.

**Article 3**

In Annex I to Regulation (EC) No 1288/2004, the entry E 1702 on *Saccharomyces cerevisiae* NCYC Sc 47 is deleted.

**Article 4**

In Annex III to Regulation (EC) No 1811/2005, the entry E 1702 on *Saccharomyces cerevisiae* NCYC Sc 47 is deleted.

**Article 5**

The preparation specified in the Annex and feed containing that preparation which are produced and labelled before 24 August 2020 in accordance with the rules applicable before 24 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

**Article 6**

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, 3 February 2020.

*For the Commission*

*The President*

Ursula VON DER LEYEN
### ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
</table>
| 4b1702                              | S.I. Lesaffre                        | Saccharomyces cerevisiae CNCM 1-4407 | Additive composition  
Preparation of Saccharomyces cerevisiae CNCM 1-4407 containing a minimum of 5 × 10⁹ CFU/g of additive  
Solid form  
Characterisation of the active substance  
Viable cells of Saccharomyces cerevisiae CNCM 1-4407  
Analytical method (*)  
Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15789:2009).  

**Category of zootechnical additives. Functional group: gut flora stabilisers**

1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.
2. The additive shall be used in feed for sows in order to have a benefit for suckling piglets.
3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their 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.

(*) 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](https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports)
CORRIGENDA


(Official Journal of the European Union L 280 of 31 October 2019)

On page 1030, the entry for Switzerland, in third column, is replaced with the following:

‘Eidgenössische Zollverwaltung EZV — Sektion Tabak- und Biersteuer

Administration fédérale des douanes AFD — Section Impôts sur le tabac et sur la bière

Amministrazione federale delle dogane AFD — Sezione imposte sul tabacco e sulla birra

Federal Customs Administration FCA — Section Tobacco and Beer Tax’.

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