Official Journal of the European Union

L 415

Volume 64

English edition

Legislation

22 November 2021

Contents

[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.

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

DECISIONS

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/2026

of 13 September 2021

amending Delegated Regulation (EU) 2020/592 as regards certain temporary derogations from Regulation (EU) No 1308/2013 of the European Parliament and of the Council to address the market disturbance in the wine sector caused by the COVID-19 pandemic and their period of application

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 219(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2020/592 ([2]) introduced a number of derogations from certain provisions of Regulation (EU) No 1308/2013, inter alia, in the wine sector, aimed at providing relief to wine operators and to help them cope with the impact of the COVID-19 pandemic. However, despite the usefulness of those measures, the wine market has not managed to regain its balance between supply and demand.

(2) The COVID-19 pandemic is not under control. Vaccination campaigns in some regions of the Union and across the world are insufficient and movement restrictions and social distancing measure are still applied in most countries. Those measures continue to include restrictions related to travel, size of social gatherings, private parties, public events and to the possibility to eat and drink outside the home. Those restrictions result in a further decrease in the consumption of wine in the Union, larger stocks and more generally in market disturbance. In some Member States, one third of wine consumption is related to tourism. Therefore, wine consumption has continued to decline and stocks remain high. Those effects of the pandemic coupled with the tariffs imposed by the United States and the frost snap in Europe in April 2021 have had a severe negative impact on the income of wine producers in the Union. It is estimated that the combination of all those factors has had the effect of reducing on average by 15 to 20 % the turnover of the Union wine sector, with some companies having reported losses of up to 40 %.

(3) In addition, the uncertainty as to the duration of the crisis, which remains difficult to predict due to the rapid mutability of the virus, further deepens the existing significant disturbance of the Union wine market. This means that the recovery of the sector will take longer than could be foreseen at the beginning of 2021. Consequently, it is appropriate to continue to offer temporary and exceptional support to the Union wine sector to avoid the increase in bankruptcies that has been reported.

([1]) OJ L 347, 20.12.2013, p. 671.

([2]) Commission Delegated Regulation (EU) 2020/592 of 30 April 2020 on temporary exceptional measures derogating from certain provisions of Regulation (EU) No 1308/2013 of the European Parliament and of the Council to address the market disturbance in the fruit and vegetables and wine sectors caused by the COVID-19 pandemic and measures linked to it (OJ L 140, 4.5.2020, p. 6).

(4) Given that harvest insurance is an important instrument to manage risks, including risks linked to adverse climatic events such as the late and particularly long spells of severe frost in April 2021 and risks linked to market disturbances such as those resulting from the COVID-19 pandemic, it is appropriate to provide a stronger incentive for wine growers to contract harvest insurance by increasing the Union support for that measure. It is also appropriate for this incentive to cover more than one marketing year, because experience has shown that the uptake of support for harvest insurance has been very limited in the past. Thus, it is essential to have enough time to inform and encourage Member States and operators in the wine sector to make use of this exceptional rate of support. Therefore, it is necessary to increase the Union financial contribution to the support for harvest insurance as referred to in Article 8 of Delegated Regulation (EU) 2020/592 as of 16 October 2021 until the end of the programming period 2019-2023.

(5) Furthermore, as the Union wine market is not expected to regain its balance between supply and demand in the short term, it is necessary to extend the application of the measures laid down in Articles 5a and 6, Article 7(2) and Article 9 of Delegated Regulation (EU) 2020/592 until 15 October 2022.

(6) Delegated Regulation (EU) 2020/592 should therefore be amended accordingly.

(7) In order to ensure continuity between financial years 2021 and 2022, this Regulation should enter into force on the third day following that of its publication in the *Official Journal of the European Union* and apply from 16 October 2021,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) 2020/592

Delegated Regulation (EU) 2020/592 is amended as follows:

(1) Article 8 is amended as follows:

(a) the introductory phrase is replaced by the following:

'By way of derogation from Article 49(2), point (b), of Regulation (EU) No 1308/2013, for operations selected from 4 May 2020 to 15 October 2021, the Union financial contribution to the support for harvest insurance shall not exceed 70 % of the cost of the insurance premiums paid for by producers for insurance:';

(b) the following paragraph is added:

'For operations selected from 16 October 2021 to 15 October 2023, the Union financial contribution to the support for harvest insurance shall not exceed 80 % of the cost of such insurance premiums.';

(2) in Article 10, the date '15 October 2021' is replaced by '15 October 2022'.

Article 2

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 October 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/2027

of 13 September 2021

amending Delegated Regulation (EU) 2020/884 as regards the derogations from Delegated Regulation (EU) 2016/1149 to address the crisis caused by the COVID-19 pandemic in the wine sector, and amending Delegated Regulation (EU) 2016/1149

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([1]), and in particular Articles 62(1) and 64(6) thereof,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([2]), and in particular Article 53, points (b) and (h), thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2020/884 ([3]) introduced a number of temporary derogations from existing rules, inter alia, from Commission Delegated Regulation (EU) 2016/1149 ([4]) in the wine sector, aimed at providing relief to operators to help them cope with the impact of the COVID-19 pandemic. However, despite the usefulness of those measures, the wine market has not managed to regain its balance between supply and demand.

(2) The COVID-19 pandemic is not under control. Vaccination campaigns in some regions of the Union and across the world are insufficient and movement restrictions and social distancing measure are still applied in most countries. Those measures continue to include restrictions related to travel, size of social gatherings, private parties, public events and to the possibility to eat and drink outside the home. Those restrictions result in a further decrease in the consumption of wine in the Union, larger stocks and more generally in market disturbance. In some Member States, one third of wine consumption is related to tourism. Therefore, wine consumption has continued to decline and stocks remain high. Those effects of the pandemic coupled with the tariffs imposed by the United States and the frost snap in Europe in April 2021 have had a severe negative impact on the income of wine producers in the Union. It is estimated that the combination of all those factors has had the effect of reducing on average by 15 to 20 % the turnover of the Union wine sector, with some companies having reported losses of up to 40 %.

(3) In addition, the uncertainty as to the duration of the crisis, which remains difficult to predict due to the rapid mutability of the virus, further deepens the existing significant disturbance of the Union wine market. This means that the recovery of the sector will take longer than could be foreseen at the beginning of 2021. Consequently, it is appropriate to continue to offer temporary and exceptional support to the Union wine sector to avoid the increase in bankruptcies that has been reported.

([1]) OJ L 347, 20.12.2013, p. 549.
([2]) OJ L 347, 20.12.2013, p. 671.
([3]) Commission Delegated Regulation (EU) 2020/884 of 4 May 2020 derogating in respect of the year 2020 from Delegated Regulation (EU) 2017/891 as regards the fruit and vegetables sector and from Delegated Regulation (EU) 2016/1149 as regards the wine sector in connection with the COVID-19 pandemic (OJ L 205, 29.6.2020, p. 1).
([4]) Commission Delegated Regulation (EU) 2016/1149 of 15 April 2016 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector and amending Commission Regulation (EC) No 555/2008 (OJ L 190, 15.7.2016, p. 1).

(4) As the COVID-19 pandemic and its effects on the wine market are expected to continue beyond the year 2021 and thus during a considerable part of the financial year 2022, it is necessary to extend the application of the measures laid down in Article 2(1), (3), (4) and (6) of Delegated Regulation (EU) 2020/884 for the duration of the financial year 2022.

(5) Article 25(1) of Delegated Regulation (EU) 2016/1149 provides that the support for mutual funds referred to in Article 48 of Regulation (EU) No 1308/2013 are to be limited to 10 %, 8 % and 4 % of the contribution of the producers to the mutual fund respectively in the first, second and third year of its implementation. However, experience to date has shown that such support rates do not encourage Member States to include that measure in their support programmes in the wine sector and operators to apply for support thereunder. Given that mutual funds are an important instrument to manage risks, including risks linked to adverse climatic events such as the late and particularly long spells of severe frost that occurred in April 2021 and those linked to market disturbances such as those resulting from the COVID-19 pandemic, it is appropriate to double the support rates provided for in Article 25(1) of Delegated Regulation (EU) 2016/1149 to increase the incentive for operators in the wine sector to set up mutual funds and provide the tool and support for them to protect themselves against future risks.

(6) It is also appropriate for that increased incentive to cover more than one marketing year, because experience has shown that the uptake of support for the setting up of mutual funds has been very limited in the past. Thus, it is essential to have enough time to inform and encourage Member States and operators in the wine sector to make use of that exceptional rate of support. Furthermore, setting up mutual funds can take more than one year. Therefore the increased support should cover at least two years. For all these reasons, it is necessary to increase the Union financial contribution to the support for mutual funds until the end of the programming period 2019-2023.

(7) Delegated Regulations (EU) 2020/884 and (EU) No 2016/1149 should therefore be amended accordingly.

(8) In order to ensure continuity between financial years 2021 and 2022, this Regulation should enter into force on the third day following that of its publication in the *Official Journal of the European Union* and apply from 16 October 2021,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) 2020/884

Article 2 of Delegated Regulation (EU) 2020/884 is amended as follows:

(1) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 22 of Delegated Regulation (EU) 2016/1149, during the years 2020, 2021 and 2022, green harvesting may be applied on the same parcel for two or more consecutive years.’;

(2) in paragraphs 3, 4 and 6, the date ‘15 October 2021’ is replaced by ‘15 October 2022’.

Article 2

Amendment to Delegated Regulation (EU) 2016/1149

In Article 25 of Delegated Regulation (EU) 2016/1149, paragraph 1 is replaced by the following:

‘1. Where the support referred to in Article 48 of Regulation (EU) No 1308/2013, is used to finance the administrative cost of setting up mutual funds, it shall be limited to the following proportion of the contribution of the producers to the mutual fund in the first, second and third year of its implementation: 20 %, 16 % and 8 %.’.

Article 3

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 October 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2028

of 15 November 2021

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Cerezas de la Montaña de Alicante' (PGI))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Spain's application for the approval of amendments to the specification for the protected geographical indication 'Cerezas de la Montaña de Alicante', registered under Commission Regulation (EC) No 1107/96 ([2]), as amended by Commission Regulation (EU) No 106/2011 ([3]) and Commission Implementing Regulation (EU) 2018/123 ([4]). These amendments include changing the name 'Cerezas de la Montaña de Alicante' to 'Cerezas de la Montaña de Alicante'/'Cireres de la Muntanya d'Alacant'.

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ([5]) as required by Article 50(2)(a) of that Regulation.

(3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Cerezas de la Montaña de Alicante' (PGI) are hereby approved.

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*.

([1]) OJ L 343, 14.12.2012, p. 1.

([2]) Commission Regulation (EC) No 1107/96 of 12 June 1996 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation (EEC) No 2081/92 (OJ L 148, 21.6.1996, p. 1).

([3]) Commission Regulation (EU) No 106/2011 of 7 February 2011 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Cerezas de la Montaña de Alicante (PGI)] (OJ L 32, 8.2.2011, p. 3).

([4]) Commission Implementing Regulation (EU) 2018/123 of 15 January 2018 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Cerezas de la Montaña de Alicante' (PGI)) (OJ L 22, 26.1.2018, p. 8).

([5]) OJ C 272, 8.7.2021, p. 35.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 November 2021.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

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

(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 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]) establishing a Union list of authorised novel foods, was adopted.

(3) On 1 October 2019, the company DuPont Nutrition & Biosciences ApS ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 3-Fucosyllactose (3-FL), obtained by microbial fermentation with a genetically modified strain of *Escherichia coli,* strain K12 MG1655, on the Union market as a novel food. The applicant requested for 3-FL to be used as a novel food in unflavoured pasteurised and unflavoured sterilised (including Ultra High Temperature, 'UHT') milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, dairy analogues and non-dairy yoghurts, beverages (flavoured drinks, energy drinks, sports drinks), infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]), processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013, 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 ([4]) intended for the general population, excluding infants. During the application process, the applicant agreed to also exclude young children (under 3 years of age) from the scope of the request for authorisation of the novel food in food supplements. The applicant also proposed that food supplements containing 3-FL should not be used if other foods with added 3-FL are consumed on the same day.

([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]) 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).

([4]) 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).

(4) On 1 October 2019, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, the detailed characterisation data on the production bacterial strain ([5]); the novel food production process ([6]); the analyses of the various 3-FL batches ([7]); the analytical reports on the characterisation via nuclear magnetic resonance ('NMR') of 3-FL and of the 3-FL naturally present in human milk ([8]); the 3-FL stability reports ([9]); the 3-FL intake assessment reports ([10]); a bacterial reverse mutation test ([11]); an *in vitro* mouse micronucleus test ([12]); an *in vitro* micronucleus test with Chinese hamster ovary cells ([13]); an *in vitro* mammalian cell chromosomal aberration test in human lymphocytes ([14]); an acute oral toxicity test in rats ([15]); a 90-day oral toxicity study in the rat including serum and urine analysis ([16]); a 6-day oral toxicity study in piglets ([17]); and a 3-week oral toxicity study in neonatal piglets ([18]).

(5) On 29 January 2020, the Commission, in accordance with Article 10(3) of Regulation (EU) 2015/2283 requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3-FL as a novel food.

(6) On 25 May 2021, the Authority adopted its scientific opinion on the safety of 3-FL as a novel food pursuant to Regulation (EU) 2015/2283 ([19]).

(7) 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 unflavoured pasteurised and unflavoured sterilised (including UHT) milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, dairy analogues and non-dairy yoghurts, beverages (flavoured drinks, energy drinks, sports drinks), infant formula and follow-on formula as defined in Regulation (EU) No 609/2013, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013, milk based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC intended for the general population, with limitations for infants and young children complies with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the 3-FL without the data from the detailed characterisation data on the production bacterial strain; the novel food production process; the analyses of the various 3-FL batches; the analytical reports on the characterisation via NMR of 3-FL and of the 3-FL naturally present in human milk; the 3-FL stability reports; the 3-FL intake assessment reports; a bacterial reverse mutation test; an *in vitro* mouse micronucleus test; an *in vitro* micronucleus test with Chinese hamster ovary cells; an *in vitro* mammalian cell chromosomal aberration test in human lymphocytes; an acute oral toxicity test in rats; a 90-day oral toxicity study in the rat including serum and urine analysis; a 6-day oral toxicity study in piglets; and a 3-week oral toxicity study in neonatal piglets.

(9) Following the receipt of the Authority's scientific opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the data from the detailed characterisation data on the production bacterial strain; the novel food production process; the analyses of the various 3-FL batches; the analytical reports on the characterisation via NMR of 3-FL and of the 3-FL naturally present in human milk; the 3-FL stability reports; the 3-FL intake assessment reports; a bacterial reverse mutation test; an *in vitro* mouse micronucleus test; an *in vitro* micronucleus test with Chinese hamster ovary cells; an *in vitro* mammalian cell chromosomal aberration test in human lymphocytes; an acute oral toxicity test in rats; a 90-day oral toxicity study in the rat including serum and urine analysis; a 6-day oral toxicity study in piglets; and a 3-week oral toxicity study in neonatal piglets.

([5]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([6]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([7]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([8]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([9]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([10]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([11]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([12]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([13]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([14]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([15]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([16]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished); J. Pitt et al., 2019 Food and Chemical Toxicology, 134.
([17]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([18]) DuPont Nutrition & Biosciences ApS, 2019 (unpublished).
([19]) Safety of 3-Fucosyllactose (3-FL) as a novel food pursuant to Regulation (EU) 2015/2283; *EFSA Journal* 2021;19(6):6662.

(10) The applicant declared that, at the time the application was made, they held proprietary and exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use those studies.

(11) 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 data contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and to reach its conclusions on the safety of 3-FL, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of 3-FL should be restricted to the applicant for that period.

(12) However, restricting the authorisation of 3-FL and of the reference to the data contained in the applicant's file for the sole use by the applicant, does not prevent other 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 authorisation under Regulation (EU) 2015/2283.

(13) 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 through the use of an appropriate label that food supplements containing 3-FL should not be consumed on the same day with other foods containing added 3-FL.

(14) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(15) 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 (3-FL) as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of 5 years from the date of entry into force of this Regulation only the initial applicant:

Company: DuPont Nutrition & Biosciences ApS;

Address: Langebrogade 1, 1001 Copenhagen K, Denmark,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected pursuant to Article 2 or with the agreement of the applicant.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of DuPont Nutrition & Biosciences ApS.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

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, 19 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

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

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
3-Fucosyllactose (3-FL) (microbial source)	*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 they should not be consumed: a) if foods containing added 3-Fucosyllactose are consumed on the same day; b) by infants and children under 3 years of age.		Authorised on 12 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: DuPont Nutrition & Biosciences ApS Langebrogade 1, 1001 Copenhagen K, Denmark. During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the Union only by DuPont Nutrition & Biosciences ApS, 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 DuPont Nutrition & Biosciences ApS. End date of the data protection: 12 December 2026.'
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,85 g/L			
	Unflavoured and flavoured fermented milk-based products including heat-treated products	0,5 g/L (beverages)			
		5,0 g/kg (products other than beverages)			
	Dairy analogues	0,85 g/L (beverages)			
		8,5 g/kg (products other than beverages)			
	Flavoured drinks, energy and sports drinks	1,0 g/L			
	Cereal bars	30,0 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,85 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	0,85 g/L 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	0,85 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

	Processed cereal-based food and baby food for infants and young children as defined under Regulation (EU) No 609/2013	0,3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		3,0 g/kg for products other than beverages			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages)			
		30,0 g/kg (products other than beverages)			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013	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, excluding food supplements for infants and young children	5,0 g/day			

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

'Authorised Novel Food	Specification
3-Fucosyllactose ('3-FL') (microbial source)	**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. **Source:** Genetically modified strain of *Escherichia coli* K-12. **Definition:** Chemical formula: $C_{18}H_{32}O_{15}$ Chemical name: β-D-galactopyranosyl-(1 → 4)[-α-L-fucopyranosyl-(1 → 3)]-D-glucopyranose Molecular mass: 488,44 Da CAS No 41312-47-4 **Characteristics/Composition:** 3-Fucosyllactose (% of dry matter): ≥ 90,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) L-Fucose (% of dry matter): ≤ 3,0 % (w/w) Sum of D-Galactose/D-Glucose (% of dry matter): ≤ 3,0 % (w/w) Sum of other carbohydrates[a] (% of dry matter): ≤ 3,0 % (w/w)

	Moisture: ≤ 5,0 % (w/w) pH (20 °C, 5 % solution): 3,0-7,5 Residual protein: ≤ 0,01 % (w/w) Ash (%): ≤ 0,5 **Heavy metals/Contaminants:** Arsenic: ≤ 0,2 mg/kg Cadmium: ≤ 0,05 mg/kg Lead: ≤ 0,05 mg/kg Mercury: ≤ 0,1 mg/kg Aflatoxin M1: ≤ 0,025 µg/kg Aflatoxin B1: ≤ 0,1 µg/kg Residual endotoxins: ≤ 0,3 EU/mg **Microbiological criteria:** Total plate count: ≤ 1 000 CFU/g Enterobacteriaceae: Absence in 10 g *Salmonella* sp.: Absence in 25 g *Cronobacter (Enterobacter) sakazakii*: Absence in 10 g *Listeria monocytogenes*: Absence in 25 g *Bacillus cereus*: ≤ 10 CFU/g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g CFU: Colony Forming Units; EU: Endotoxin Units; [a]Sum of other carbohydrates: 3-Fucosyllactose isomer, difucosyllactose isomer, and oligomers.’

COMMISSION REGULATION (EU) 2021/2030

of 19 November 2021

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards *N,N*-dimethylformamide

(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([1]), and in particular Article 68(1) thereof,

Whereas:

(1) *N,N*–dimethylformamide is an aprotic medium polar organic solvent classified as toxic to reproduction 1B, acute toxicant 4 (inhalation and dermal route) and as an eye irritant 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]). *N,N*–dimethylformamide is a high production volume substance used in many industrial settings and professional activities across Europe.

(2) On 5 October 2018, Italy (hereinafter 'the dossier submitter') submitted to the European Chemicals Agency ('the Agency') a dossier ([3]) pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'), in order to initiate the restriction process set out in Articles 69 to 73 of that Regulation. The Annex XV dossier demonstrated that action on a Union-wide basis was necessary and proposed to restrict the industrial and professional use, as well as the placing on the market of *N,N*–dimethylformamide on its own or in mixtures.

(3) The dossier submitter based its hazard assessment of *N,N*–dimethylformamide on the systemic effects of the substance on several endpoints. This resulted in a long-term inhalation derived no-effect level ('DNEL') and a long-term dermal DNEL based on animal data on decreased body weights, clinical chemistry changes and liver injury.

(4) On 20 September 2019, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion ([4]) concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks arising from exposure to *N,N*–dimethylformamide in terms of its effectiveness in reducing the risk, its practicality and monitorability.

(5) As the dossier submitter's assessment considered several contributing scenarios for *N,N*–dimethylformamide containing substances at low concentrations, RAC proposed to clarify the wording of the scope by including the presence of the substance, regardless of whether *N,N*–dimethylformamide is a constituent, a main constituent, an impurity or a stabiliser.

(6) The dossier submitter proposed a long-term inhalation DNEL of 3,2 mg/m^3 based on hepatic effects in animals. However, RAC recommended a long-term inhalation DNEL of 6 mg/m^3 based on a combination of human data and animal data, taking into account liver toxicity and developmental toxicity, respectively.

([1]) OJ L 396, 30.12.2006, p. 1.

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([3]) https://echa.europa.eu/documents/10162/d3feb838-3c17-bcf9-db88-92b83f5a43fc

([4]) https://echa.europa.eu/documents/10162/44ad5cd9-1143-0072-0550-5860846ffbb4

(7) For the long-term dermal DNEL, RAC recommended a DNEL based on a dermal study rather than making a route-to-route extrapolation from an oral 28-day study as proposed by the dossier submitter. Therefore, RAC proposed to use the value of 1,1 mg/kg/day as the long-term dermal DNEL.

(8) On 5 December 2019, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion ([5]), concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to reduce the risk to the health of workers arising from *N,N*–dimethylformamide, taking into account its socioeconomic benefits and costs. SEAC recommended a 24-month deferral of application of the restriction for all sectors, in line with the Annex XV dossier, to provide sufficient time to stakeholders to fully implement the restriction requirements.

(9) The Forum for Exchange of Information on Enforcement was consulted on the proposed restriction and its recommendations have been taken into account.

(10) On 1 April 2020, the Agency submitted the opinions of RAC and SEAC to the Commission. The said opinions confirmed that the risk to the health of workers in all occupational settings during the manufacture and use of *N, N*–dimethylformamide is not adequately controlled.

(11) Taking into account the Annex XV dossier and the RAC and SEAC opinions, the Commission considers that there is an unacceptable risk to workers arising from exposure to *N,N*–dimethylformamide above specific DNEL values and that the proposed restriction establishing a DNEL for exposure of workers to *N,N*–dimethylformamide via both the inhalation and the dermal routes is the most appropriate Union-wide measure to address that risk.

(12) The Commission considers that the proposed restriction, as modified by RAC and SEAC, is appropriate for the following reasons: the overall risk characterisation ratio is based on quantified DNELs for inhalation and dermal exposure to *N,N*–dimethylformamide; harmonisation of chemical safety reports in the registration dossiers via harmonised DNELs can only be achieved under Regulation (EC) No 1907/2006; the safety data sheets will include those DNELs in the appropriate specific sections.

(13) Stakeholders should be allowed sufficient time to comply with the proposed restriction, and downstream users, in particular, should have the same time period as manufacturers and importers to implement the appropriate risk management measures and operational conditions in order to ensure that exposure of workers to *N,N*–dimethylformamide is below the DNELs. The Commission therefore considers, in line with the Annex XV dossier and the opinion of SEAC, that the application of the restriction should be deferred for 24 months.

(14) It is expected that, to comply with the DNELs for exposure of workers to *N,N*–dimethylformamide, the polyurethane coatings and membranes and the synthetic fibre manufacturing sectors will require more time. Therefore, longer transitional periods are suggested for the polyurethane coatings and membranes sector, where *N,N*–dimethylformamide is used as a solvent in direct or transfer polyurethane coating processes on textiles and paper material or in the production of polyurethane membranes (36 months) and, for the synthetic fibre manufacturing, where *N,N*–dimethylformamide is used as a solvent in the dry and wet spinning processes of synthetic fibres (48 months).

(15) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

([5]) https://echa.europa.eu/documents/10162/b6644298-54a4-052a-9bbc-6824966d151e (compiled version of final RAC and SEAC opinions)

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

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, 19 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:

'76. *N*,*N*-dimethylformamide CAS No 68-12-2 EC. No 200-679-5	1. Shall not be placed on the market as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 % after 12 December 2023 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of 6 mg/m^3 for exposure by inhalation and 1,1 mg/kg/day for dermal exposure. 2. Shall not be manufactured, or used, as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 % after 12 December 2023 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1. 3. By way of derogation from paragraphs 1 and 2, the obligations laid down therein shall apply from 12 December 2024 in relation to placing on the market for use, or use, as a solvent in direct or transfer polyurethane coating processes of textiles and paper material or the production of polyurethane membranes, and from 12 December 2025 in relation to placing on the market for use, or use, as a solvent in the dry and wet spinning processes of synthetic fibres.'

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2031

of 19 November 2021

amending Annexes V and XIV to Implementing Regulation (EU) 2021/404 as regards the entries for the United Kingdom in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry and fresh meat of poultry and game birds

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ([1]), and in particular Article 230(1) thereof,

Whereas:

(1) Regulation (EU) 2016/429 requires that consignments of animals, germinal products and products of animal origin must come from a third country or territory, or zone or compartment thereof, listed in accordance with Article 230(1) of that Regulation in order to enter the Union.

(2) Commission Delegated Regulation (EU) 2020/692 ([2]) lays down the animal health requirements with which consignments of certain species and categories of animals, germinal products and products of animal origin from third countries or territories, or zones thereof, or compartments thereof, in the case of aquaculture animals, must comply with in order to enter the Union.

(3) Commission Implementing Regulation (EU) 2021/404 ([3]) establishes the lists of third countries, or territories, or zones or compartments thereof, from which the entry into the Union of the species and categories of animals, germinal products and products of animal origin falling within the scope of Delegated Regulation (EU) 2020/692 is permitted.

(4) More particularly, Annexes V and XIV to Implementing Regulation (EU) 2021/404 set out the lists of third countries, or territories, or zones thereof authorised for the entry into the Union, respectively, of consignments of poultry, germinal products of poultry, and of fresh meat from poultry and game birds.

(5) On 12 November 2021, the United Kingdom notified the Commission of an outbreak of highly pathogenic avian influenza in poultry. The outbreak is located near Frinton-on-Sea, Tendring, Essex in England and was confirmed on 12 November 2021 by laboratory analysis (RT-PCR).

(6) On 14 November 2021, the United Kingdom notified the Commission of outbreaks of highly pathogenic avian influenza in poultry. The outbreaks are located near Leeming Bar, Hambleton, North Yorkshire in England and near Salwick, Fylde, Lancashire in England and were confirmed on 14 November 2021 by laboratory analysis (RT-PCR).

([1]) OJ L 84, 31.3.2016, p. 1.

([2]) Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

([3]) Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).

(7) The veterinary authorities of the United Kingdom established a 10 km control zone around the affected establishments and implemented a stamping-out policy in order to control the presence of highly pathogenic avian influenza and limit the spread of that disease.

(8) The United Kingdom has submitted information to the Commission on the epidemiological situation on its territory and the measures it has taken to prevent the further spread of highly pathogenic avian influenza. That information has been evaluated by the Commission. On the basis of that evaluation, the entry into the Union of consignments of poultry, germinal products of poultry, and fresh meat from poultry and game birds from the areas under restrictions established by the veterinary authorities of the United Kingdom due to the recent outbreaks of highly pathogenic avian influenza. should no longer be authorised.

(9) Annexes V and XIV to Implementing Regulation (EU) 2021/404 should be therefore amended accordingly.

(10) Taking into account the current epidemiological situation in the United Kingdom as regards highly pathogenic avian influenza, the amendments to be made to Implementing Regulation (EU) 2021/404 by this Regulation should take effect as a matter of urgency.

(11) 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

Annexes V and XIV to Implementing Regulation (EU) 2021/404 are amended in accordance with 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, 19 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes V and XIV to Implementing Regulation (EU) 2021/404 are amended as follows:

(1) Annex V is amended as follows:

(a) in Part 1, in the entry for the United Kingdom, the following rows for zones GB-2.20, GB-2.21 and GB-2.22 are inserted after the row for zone GB-2.19:

‘**GB** United Kingdom	GB-2.20	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		12.11.2021	
		Breeding ratites and productive ratites	BPR	N, P1		12.11.2021	
		Poultry intended for slaughter other than ratites	SP	N, P1		12.11.2021	
		Ratites intended for slaughter	SR	N, P1		12.11.2021	
		Day-old chicks other than ratites	DOC	N, P1		12.11.2021	
		Day-old chicks of ratites	DOR	N, P1		12.11.2021	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		12.11.2021	
		Hatching eggs of poultry other than ratites	HEP	N, P1		12.11.2021	
		Hatching eggs of ratites	HER	N, P1		12.11.2021	
		Less than 20 heads of poultry other than ratites	HE-LT20	N, P1		12.11.2021	
	GB-2.21	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		14.11.2021	
		Breeding ratites and productive ratites	BPR	N, P1		14.11.2021	
		Poultry intended for slaughter other than ratites	SP	N, P1		14.11.2021	
		Ratites intended for slaughter	SR	N, P1		14.11.2021	
		Day-old chicks other than ratites	DOC	N, P1		14.11.2021	
		Day-old chicks of ratites	DOR	N, P1		14.11.2021	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		14.11.2021	
		Hatching eggs of poultry other than ratites	HEP	N, P1		14.11.2021	
		Hatching eggs of ratites	HER	N, P1		14.11.2021	
		Less than 20 heads of poultry other than ratites	HE-LT20	N, P1		14.11.2021	

	GB-2.22	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		14.11.2021	
		Breeding ratites and productive ratites	BPR	N, P1		14.11.2021	
		Poultry intended for slaughter other than ratites	SP	N, P1		14.11.2021	
		Ratites intended for slaughter	SR	N, P1		14.11.2021	
		Day-old chicks other than ratites	DOC	N, P1		14.11.2021	
		Day-old chicks of ratites	DOR	N, P1		14.11.2021	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		14.11.2021	
		Hatching eggs of poultry other than ratites	HEP	N, P1		14.11.2021	
		Hatching eggs of ratites	HER	N, P1		14.11.2021	
		Less than 20 heads of poultry other than ratites	HE-LT20	N, P1		14.11.2021’	

(b) in Part 2, in the entry for the United Kingdom, the following descriptions of the zones GB-2.20, GB-2.21 and 2.22 are inserted after the description of the zone GB-2.19:

‘United Kingdom	GB-2.20	Near Frinton-on-Sea, Tendring, Essex, England: The area contained within a circle of a radius of 10km, centred on WGS84 dec, coordinates N51.84 and W1.22
	GB-2.21	Near Leeming Bar, Hambleton, North Yorkshire, England: The area contained within a circle of a radius of 10km, centred on WGS84 dec, coordinates N54.30 and W1.50
	GB-2.22	Near Salwick, Fylde, Lancashire, England: The area contained within a circle of a radius of 10km, centred on WGS84 dec, coordinates N53.79 and W2.80’

(2) in Annex XIV, in Part 1, in the entry for the United Kingdom, the following rows for zones GB-2.20, GB-2.21 and GB-2.22 are inserted after the row for zone GB-2.19:

‘**GB** United Kingdom	GB-2.20	Fresh meat of poultry other than ratites	POU	N, P1		12.11.2021	
		Fresh meat of ratites	RAT	N, P1		12.11.2021	
		Fresh meat of game birds	GBM	N, P1		12.11.2021	

	GB-2.21	Fresh meat of poultry other than ratites	POU	N, P1		14.11.2021	
		Fresh meat of ratites	RAT	N, P1		14.11.2021	
		Fresh meat of game birds	GBM	N, P1		14.11.2021	
	GB-2.22	Fresh meat of poultry other than ratites	POU	N, P1		14.11.2021	
		Fresh meat of ratites	RAT	N, P1		14.11.2021	
		Fresh meat of game birds	GBM	N, P1		14.11.2021’	

DECISIONS

COUNCIL DECISION (CFSP) 2021/2032

of 19 November 2021

on an assistance measure under the European Peace Facility to support military units trained by the EU Training Mission in Mozambique

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 41(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) In accordance with Council Decision (CFSP) 2021/509 ([1]), a European Peace Facility (EPF) was established for the financing by Member States of Union actions under the Common Foreign and Security Policy to preserve peace, prevent conflicts and strengthen international security in accordance with Article 21(2), point (c), of the Treaty. In particular, pursuant to Article 1(2), point (b)(i), of Decision (CFSP) 2021/509, the EPF may finance actions to strengthen the capacities of third States and regional and international organisations relating to military and defence matters.

(2) The current crisis in Mozambique's northern Cabo Delgado province is multidimensional, with a severe risk of spillover to other provinces of the country and to neighbouring countries. The Mozambican government has welcomed the deployment of a non-executive military European Union Training Mission as part of the EU Integrated Approach to the crisis in Cabo Delgado.

(3) On 12 July 2021, the Council adopted Decision (CFSP) 2021/1143 ([2]), establishing a European Union military training mission in Mozambique (EUTM Mozambique). The strategic objective of EUTM Mozambique is to support capacity building for the units of the Mozambican armed forces selected to compose a future Quick Reaction Force, in order for those units to develop the necessary sustainable capacities to restore safety and security in Cabo Delgado.

(4) On 30 July 2021, the Council approved a concept note for an assistance measure under the EPF to support military units trained by EUTM Mozambique, including an urgent measure to provide the most urgently required equipment and supplies needed to properly train the two Mozambican companies scheduled to be the first to benefit from training by EUTM Mozambique.

(5) In her letter of 27 August 2021 addressed to the High Representative of the Union for Foreign Affairs and Security Policy (the 'High Representative'), the Minister of Foreign Affairs of the Republic of Mozambique requested the Union to provide equipment not designed to deliver lethal force and supplies to all Mozambican companies to be trained by EUTM Mozambique.

([1]) Council Decision (CFSP) 2021/509 of 22 March 2021 establishing a European Peace Facility, and repealing Decision (CFSP) 2015/528 (OJ L 102, 24.3.2021, p. 14).

([2]) Council Decision (CFSP) 2021/1143 of 12 July 2021 on a European Union Military Training Mission in Mozambique (EUTM Mozambique) (OJ L 247, 13.7.2021, p. 93).

(6) This assistance measure is to be implemented taking into account the principles and requirements set out in Decision (CFSP) 2021/509, and in particular compliance with Council Common Position 2008/944/CFSP ([3]), and in accordance with the rules for the implementation of revenue and expenditure financed under the EPF.

(7) The Council reaffirms its determination to protect, promote and fulfil human rights, fundamental freedoms and democratic principles and to strengthen the rule of law and good governance, in compliance with the United Nations Charter, with the Universal Declaration of Human Rights and with international law, in particular international human rights and international humanitarian law,

HAS ADOPTED THIS DECISION:

Article 1

Establishment, objectives, scope and duration

1. An assistance measure benefiting the Republic of Mozambique (the 'beneficiary') to be financed under the European Peace Facility (EPF) (the 'Assistance Measure') is hereby established.

2. The objective of the Assistance Measure is to support capacity building for and the deployment of the units of the Mozambican armed forces to be trained by EUTM Mozambique in order to allow those units to develop the necessary sustainable capacities to restore safety and security in Mozambique's northern Cabo Delgado province, thereby enabling the presence of accountable law enforcement agencies, subject to the rule of law, to protect the civilian population and the return of accountable State structures that deliver services across Cabo Delgado.

3. To achieve the objective set out in paragraph 2, the Assistance Measure shall finance the provision of the following equipment not designed to deliver lethal force and supplies to the Mozambican units referred to in that paragraph:

(a) individual equipment for soldiers;

(b) collective equipment at company level;

(c) ground and amphibious mobility assets;

(d) technical devices; and

(e) a field hospital.

4. The duration of the Assistance Measure shall be 30 months from the date of conclusion of the contract between the Administrator for Assistance Measures acting as authorising officer and the entity referred to in Article 4(2) in accordance with Article 32(2), point (a), of Decision (CFSP) 2021/509.

Article 2

Financial arrangements

1. The financial reference amount intended to cover the expenditure related to the Assistance Measure shall be EUR 40 000 000.

([3]) Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment (OJ L 335, 13.12.2008, p. 99).

2. All expenditure shall be managed in accordance with Decision (CFSP) 2021/509 and the rules for the implementation of revenue and expenditure financed under the EPF.

Article 3

Arrangements with the beneficiary

1. The High Representative shall make the necessary arrangements with the beneficiary to ensure its compliance with the requirements and conditions established by this Decision as a condition for the provision of support under the Assistance Measure and by the urgent measure approved by the Council on 30 July 2021.

2. The arrangements referred to in paragraph 1 shall include provisions obliging the beneficiary to ensure:

(a) compliance of the units of the Mozambican armed forces trained by EUTM Mozambique with relevant international law, in particular international human rights and international humanitarian law;

(b) proper and efficient use of any assets provided under the Assistance Measure for the purposes for which they were provided;

(c) sufficient maintenance of any assets provided under the Assistance Measure to ensure their usability and their operational availability over their life cycle;

(d) that any assets provided under the Assistance Measure will not be lost, or be transferred without the consent of the Facility Committee established under Decision (CFSP) 2021/509 to persons or entities other than those identified in those arrangements, at the end of their life-cycle.

3. The arrangements referred to in paragraph 1 shall include provisions on the suspension and termination of support under the Assistance Measure in the event of the beneficiary being found in breach of the obligations set out in paragraph 2.

Article 4

Implementation

1. The High Representative shall be responsible for ensuring the implementation of this Decision in accordance with Decision (CFSP) 2021/509 and with the rules for the implementation of revenue and expenditure financed under the EPF, consistently with the Integrated Methodological Framework for assessing and identifying the required measures and controls for assistance measures under the EPF.

2. The implementation of the activities referred to in Article 1(3) shall be carried out by the Ministry of Defence of the Portuguese Republic.

Article 5

Monitoring, control and evaluation

1. The High Representative shall ensure that the respect of the obligations established in accordance with Article 3 by the beneficiary is monitored. This monitoring shall provide awareness of the context and risks of breaches of the obligations established in accordance with Article 3, and shall contribute to the prevention of such breaches, including violations of international human rights and international humanitarian law and acts of sexual and gender-based violence by units of the Mozambican armed forces supported under the Assistance Measure.

2. The post-shipment control of equipment and supplies shall be organised as follows:

(a) delivery verification, whereby delivery certificates are to be signed by the end-user forces upon transfer of ownership;

(b) reporting on the inventory, whereby the beneficiary is to report annually on the inventory of designated items; reporting is to continue until it is no longer deemed necessary by the Political and Security Committee (PSC);

(c) on-site control, whereby the beneficiary is to grant the High Representative access to conduct on-site control upon request.

3. The High Representative shall conduct an evaluation, in the form of a first assessment of the Assistance Measure, 6 months after the first two companies trained by EUTM Mozambique are deployed to the Cabo Delgado region. This will entail on-site visits to check the equipment and supplies delivered under the Assistance Measure, or any other effective forms of independently provided information. A final evaluation shall be conducted upon completion of the delivery of equipment under the Assistance Measure.

Article 6

Reporting

During the period of implementation, the High Representative shall provide the PSC with six monthly reports on the implementation of the Assistance Measure, in accordance with Article 63 of Decision (CFSP) 2021/509. The administrator for assistance measures shall regularly inform the Facility Committee established by Decision (CFSP) 2021/509 on the implementation of revenue and expenditure in accordance with Article 38 of that Decision, including by providing information on the suppliers and subcontractors involved.

Article 7

Suspension and termination

The PSC may decide to suspend wholly or partially the implementation of the Assistance Measure in accordance with Article 64 of Decision (CFSP) 2021/509.

The PSC may also recommend that the Council terminate the Assistance Measure.

Article 8

Entry into force

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 19 November 2021.

For the Council
The President
J. BORRELL FONTELLES

COUNCIL DECISION (CFSP) 2021/2033

of 19 November 2021

amending Decision (CFSP) 2019/97 in support of the Biological and Toxin Weapons Convention in the framework of the EU Strategy against Proliferation of Weapons of Mass Destruction

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 31(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 21 January 2019, the Council adopted Decision (CFSP) 2019/97 ([1]), which provides for a 36-month implementation period from the date of the conclusion of the financing agreement referred to in Article 3(3) of that Decision, for the projects referred to in Article 1 thereof.

(2) The implementation period of the financing agreement ends on 4 February 2022.

(3) On 8 July 2021, the United Nations Office for Disarmament Affairs (UNODA), which is responsible for the technical implementation of the projects referred to in Article 1 of Decision (CFSP) 2019/97, requested a 12-month no-cost extension of the implementation period of that Decision. This extension allows UNODA to carry out the implementation of several of the projects referred to in Article 1 of Decision (CFSP) 2019/97 the implementation of which was delayed due to the COVID-19 pandemic.

(4) The extension of the implementation period of the projects referred to in Article 1 of Decision (CFSP) 2019/97 until 4 February 2023 does not have any implication as regards financial resources.

(5) Decision (CFSP) 2019/97 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Article 5(2) of Decision (CFSP) 2019/97 is replaced by the following:

'2. This Decision shall expire on 4 February 2023.'

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 19 November 2021.

For the Council
The President
J. BORRELL FONTELLES

([1]) Council Decision (CFSP) 2019/97 of 21 January 2019 in support of the Biological and Toxin Weapons Convention in the framework of the EU Strategy against Proliferation of Weapons of Mass Destruction (OJ L 19, 22.1.2019, p. 11).

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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