Official Journal of the European Union

L 59

Volume 66

English edition

Legislation

24 February 2023

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.

([1]) Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/409

of 18 November 2022

amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the minimum content of calcium oxide in straight solid inorganic macronutrient fertilisers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 ([1]), and in particular Article 42(1) thereof,

Whereas:

(1) Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products, and repeals Regulation (EC) No 2003/2003 of the European Parliament and of the Council ([2]) as of 16 July 2022.

(2) In accordance with Annex I to Regulation (EU) 2019/1009, a straight solid inorganic macronutrient fertiliser with only calcium as a declared macronutrient is to contain at least 12 % by mass calcium expressed as calcium oxide.

(3) Commission Regulation (EU) 2020/1666 ([3]) amended Regulation (EC) No 2003/2003 by introducing calcium chelate of iminodisuccinic acid (Ca-IDHA) as a new type of EC fertiliser. The minimum content of nutrients in that fertiliser is 9 % calcium oxide.

(4) Ca-IDHA is a fertiliser providing plants with the macronutrient calcium. When assessing the conditions for its inclusion in Regulation (EC) No 2003/2003, this type of EC fertilisers has been found to be agronomically efficient. Regulation (EU) 2019/1009 should be amended to take into account the technical development occurring after its adoption and thus the minimum content of calcium oxide in straight solid inorganic macronutrient fertilisers should be lowered from 12 % to 9 %. Lowering the minimum content of calcium oxide would introduce this type of fertiliser in the scope of the harmonisation rules and thus facilitate its free movement in the single market. This adaptation is linked to the agronomic efficiency criteria of the fertilisers, and is not lowering the high standards of protection of human health and of the environment laid down in Regulation (EU) 2019/1009.

(5) Regulation (EU) 2019/1009 should therefore be amended accordingly,

([1]) OJ L 170, 25.6.2019, p. 1.

([2]) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1).

([3]) Commission Regulation (EU) 2020/1666 of 10 November 2020 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purpose of including a new type of EC fertiliser in Annex I (OJ L 377, 11.11.2020, p. 3).

HAS ADOPTED THIS REGULATION:

Article 1

In Part II, in PFC 1(C)(I)(a)(i), point 2, of Annex I to Regulation (EU) 2019/1009, point (e) is replaced by the following:

'(e) 9 % by mass of total calcium oxide (CaO),'.

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, 18 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2023/410

of 19 December 2022

amending Delegated Regulation (EU) 2016/1675 as regards adding the Democratic Republic of the Congo, Gibraltar, Mozambique, Tanzania and the United Arab Emirates to Table I of the Annex to Delegated Regulation (EU) 2016/1675 and deleting Nicaragua, Pakistan and Zimbabwe from that table

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, amending Regulation (EU) No 648/2012 of the European Parliament and of the Council, and repealing Directive 2005/60/EC of the European Parliament and of the Council and Commission Directive 2006/70/EC ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) The Union has to ensure the effective protection of the integrity and proper functioning of its financial system and the internal market from money laundering and terrorist financing. Directive (EU) 2015/849 therefore provides that the Commission should identify countries which have strategic deficiencies in their regimes on Anti-Money Laundering and Countering Financing of Terrorism (AML/CFT) that pose significant threats to the financial system of the Union.

(2) Commission Delegated Regulation (EU) 2016/1675 ([2]) identifies high-risk third countries with strategic deficiencies.

(3) Considering the high level of integration of the international financial system, the close connection of market operators, the high volume of cross-border transactions to and from the Union, and the degree of market openness, any AML/CFT threat posed to the international financial system also represents a threat to the financial system of the Union.

(4) In line with Article 9(4) of Directive (EU) 2015/849, the Commission takes the recent available information into account, in particular recent Financial Action Task Force (FATF) Public Statements, the FATF list of 'Jurisdictions under Increased Monitoring', and FATF reports of the International Cooperation Review Group in relation to the risks posed by individual third countries.

(5) Since the latest amendments to Regulation (EU) 2016/1675, the FATF has significantly updated its list of 'Jurisdictions under Increased Monitoring'. At its plenary meeting in March 2022, the FATF added the United Arab Emirates (UAE) to its list and deleted Zimbabwe from its list. At its plenary meeting in June 2022, the FATF added Gibraltar to its list. At its plenary meeting in October 2022, the FATF added the Democratic Republic of the Congo (DRC), Mozambique and Tanzania to its list and deleted Nicaragua and Pakistan from its list. All those changes were assessed by the Commission in line with Article 9 of Directive (EU) 2015/849.

(6) In February 2022, the UAE made a high-level political commitment to work with the FATF and the Middle East and North Africa Financial Action Task Force to strengthen the effectiveness of its AML/CFT regime. Since then, the UAE demonstrated positive progress, including by providing additional resources to the Financial Intelligence Unit (FIU) to strengthen the FIU analysis and providing financial intelligence to Law Enforcement Authorities and the Public Prosecutors for combating of high-risk ML threats. The UAE should continue to work to implement its FATF action plan by: (1) demonstrating through case studies and statistics a sustained increase in outbound Mutual Legal

([1]) OJ L 141, 5.6.2015, p. 73.

([2]) Commission Delegated Regulation (EU) 2016/1675 of 14 July 2016 supplementing Directive (EU) 2015/849 of the European Parliament and of the Council by identifying high-risk third countries with strategic deficiencies (OJ L 254, 20.9.2016, p. 1).

Assistance requests to help facilitate investigation of Terrorism Financing (TF), Money-Laundering (ML), and high-risk predicates; (2) enhancing and maintaining a shared understanding of the ML/TF risks between the different DNFBP sectors and institutions; (3) showing an increase in the number and quality of STRs filed by FIs and Designated Non-Financial Businesses and Professions (DNFBPs); (4) ensuring a more granular understanding of the risk of abuse of legal persons and, where applicable, legal arrangements, for ML/TF; (5) demonstrate greater use of financial intelligence to pursue high-risk ML threats; and demonstrating a sustained increase in effective investigations and prosecutions of different types of ML cases consistent with the UAE's risk profile; and (6) proactively identifying and combating sanctions evasion, including by demonstrating a better understanding of sanctions evasion among the private sector. Despite that commitment and progress, the concerns that led to the listing of the UAE by the FATF have not yet been fully addressed. The UAE should therefore be considered as a country that has strategic deficiencies in its AML/CFT regime under Article 9 of Directive (EU) 2015/849.

(7) In June 2022, Gibraltar made a high-level political commitment to work with the FATF and MONEYVAL, the Committee of Experts on the Evaluation of Anti-Money Laundering Measures and the Financing of Terrorism of the Council of Europe, to strengthen the effectiveness of its AML/CFT regime. Since the adoption of its MER in December 2019, Gibraltar has made progress on a significant number of its MER's recommended actions, such as completing a new national risk assessment, addressing the technical deficiencies in relation to Beneficial Owner-related recordkeeping, introducing transparency requirements for nominee shareholders and directors, strengthening the financial intelligence unit, and refining its ML investigation policy in line with risks. Gibraltar should work on implementing its action plan, including by (1) ensuring that supervisory authorities for non-bank financial institutions and DNFBPs use a range of effective, proportionate, and dissuasive sanctions for AML/CFT breaches; and (2) demonstrating that it is more actively and successfully pursuing final confiscation judgements, through criminal or civil proceedings based on financial investigations. Despite that commitment and progress, the concerns that led to the listing of Gibraltar by the FATF have not yet been fully addressed. Gibraltar should therefore be considered as a third-country jurisdiction that has strategic deficiencies in its AML/CFT regime under Article 9 of Directive (EU) 2015/849.

(8) In October 2022, the Democratic Republic of the Congo made a high-level political commitment to work with the FATF and the '*Groupe d'Action contre le Blanchiment d'Argent en Afrique Centrale*' (GABAC), a FATF-style regional body, to strengthen the effectiveness of its AML/CFT regime. Since the adoption of its MER in October 2020, the DRC has made progress on some of the MER's recommended actions including making confiscation of proceeds of crime a policy priority. The DRC will work to implement its FATF action plan by: (1) finalising the National Risk Assessment on ML and TF and adopting an AML/CFT national strategy; (2) designating supervisory authorities for all DNFBP sectors, and developing and implementing a risk-based supervision plan; (3) adequately resourcing the FIU, and build its capacity to conduct operational and strategic analysis; (4) strengthening the capabilities of authorities involved in the investigation and prosecution of ML and TF; and (5) demonstrating effective implementation of TF and Proliferation Financing-related Targeted Financial Sanctions. Despite that commitment and progress, the concerns that led to the listing of the DRC by the FATF have not yet been fully addressed. The DRC should therefore be considered as a country that has strategic deficiencies in its AML/CFT regime under Article 9 of Directive (EU) 2015/849.

(9) In October 2022, Mozambique made a high-level political commitment to work with the FATF and the Eastern and Southern Africa AML Group (ESAAMLG) to strengthen the effectiveness of its AML/CFT regime. Since the adoption of its MER in April 2021, Mozambique has made progress on some of the MER's recommended actions to improve its system including by finalising its National Risk Assessment and strengthening its asset confiscation efforts. Mozambique will work to implement its FATF action plan by: (1) ensuring cooperation and coordination amongst relevant authorities to implement risk-based AML/CFT strategies and policies; (2) conducting training for all Law Enforcement Authorities (LEAs) on mutual legal assistance to enhance the gathering of evidence or seizure/confiscation of proceeds of crime; (3) providing adequate financial and human resources to supervisors, developing and implementing a risk-based supervision plan; (4) providing adequate resources to the authorities to commence the collection of adequate, accurate and up-to-date beneficial ownership information of legal persons; (5) increasing

the human resources of the FIU as well as increasing financial intelligence sent to authorities; (6) demonstrating LEAs' capability to effectively investigate ML/TF cases using financial intelligence; (7) conducting a comprehensive TF Risk Assessment and beginning to implement a comprehensive national CFT strategy; (8) increasing awareness on TF and Proliferation Financing-related Targeted Financial Sanctions; and (9) carrying out the TF risk assessment for Non-Profit Organizations in line with the FATF Standards and using it as a basis to develop an outreach plan. Despite that commitment and progress, the concerns that led to the listing of Mozambique by the FATF have not yet been fully addressed. Mozambique should therefore be considered as a country that has strategic deficiencies in its AML/CFT regime under Article 9 of Directive (EU) 2015/849.

(10) In October 2022, Tanzania made a high-level political commitment to work with the FATF and ESAAMLG to strengthen the effectiveness of its AML/CFT regime. Since the adoption of its MER in April 2021, Tanzania has made progress on some of the MER's recommended actions to improve its system including by developing legal framework for TF and Targeted Financial Sanctions (TFS) and disseminating FIU strategic analysis. Tanzania will work to implement its FATF action plan by: (1) improving risk-based supervision of Financial Institutions and DNFBPs, including by conducting inspections on a risk-sensitive basis and applying effective, proportionate, and dissuasive sanctions for non-compliance; (2) demonstrating authorities' capability to effectively conduct a range of investigations and prosecutions of ML in line with the country's risk profile; (3) demonstrating that Law Enforcement Authorities are taking measures to identify, trace, seize, and confiscate proceeds and instrumentalities of crime; (4) conducting a comprehensive TF Risk Assessment and beginning to implement a comprehensive national CFT strategy as well as demonstrating capability to conduct TF investigations and pursue prosecutions in line with the country's risk profile; (5) increasing awareness of the private sector and competent authorities on TF and PF-related TFS; and (6) carrying out the TF risk assessment for Non-Profit Organizations in line with the FATF Standards and using it as a basis to develop an outreach plan. Despite that commitment and progress, the concerns that led to the listing of Tanzania by the FATF have not yet been fully addressed. Tanzania should therefore be considered as a country that has strategic deficiencies in its AML/CFT regime under Article 9 of Directive (EU) 2015/849.

(11) The Commission's assessment therefore concludes that the Democratic Republic of the Congo, Gibraltar, Mozambique, Tanzania, and the UAE should be considered as third-country jurisdictions which have strategic deficiencies in their AML/CFT regimes that pose significant threats to the financial system of the Union, in accordance with the criteria set out in Article 9 of Directive (EU) 2015/849.

(12) The Commission has reviewed progress in addressing the strategic deficiencies of the countries that were listed in Regulation (EU) 2016/1675 but were delisted in March, June and October 2022 by the FATF. In order to update the Annex to Delegated Regulation (EU) 2016/1675 as required by Article 9 of Directive (EU) 2015/849, the Commission has reviewed the progress made by Nicaragua, Pakistan and Zimbabwe.

(13) The FATF has welcomed the significant progress made by Nicaragua, Pakistan and Zimbabwe in improving their respective AML/CFT regimes. It has noted that Nicaragua, Pakistan and Zimbabwe have established the legal and regulatory frameworks to meet the commitments in their respective action plans regarding the strategic deficiencies that the FATF had identified. Nicaragua, Pakistan and Zimbabwe are therefore no longer subject to the FATF's monitoring process under its ongoing global AML/CFT compliance process. Nicaragua should continue to work with the '*Grupo de Acción Financiera de Latinoamérica*' (GAFILAT), the FATF-style regional body, to improve further its AML/CFT regime, including by ensuring its oversight of non-profit organisations (NPOs) is risk-based and in line with the FATF Standards. Pakistan will continue to work with the Asia Pacific Group, the FATF-style Regional Body, to further improve its AML/CFT system. Zimbabwe should continue to work with ESAAMLG to improve further its AML/CFT system, including by ensuring its oversight of NPOs is risk-based and in line with the FATF Standards.

(14) The Commission's assessment of the information available leads it to conclude that Nicaragua, Pakistan and Zimbabwe no longer have strategic deficiencies in their AML/CFT regimes. Nicaragua, Pakistan and Zimbabwe have strengthened the effectiveness of their AML/CFT regimes and addressed related technical deficiencies to meet the commitments in their action plans regarding the strategic deficiencies that the FATF had identified.

(15) Delegated Regulation (EU) 2016/1675 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The table in point I of the Annex to Delegated Regulation (EU) 2016/1675 is replaced by the table in 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 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

'No	High-risk third country ([1])
1	Afghanistan
2	Barbados
3	Burkina Faso
4	Cambodia
5	Cayman Islands
6	Democratic Republic of the Congo
7	Gibraltar
8	Haiti
9	Jamaica
10	Jordan
11	Mali
12	Morocco
13	Mozambique
14	Myanmar
15	Panama
16	Philippines
17	Senegal
18	South Sudan
19	Syria
20	Tanzania
21	Trinidad and Tobago
22	Uganda
23	United Arab Emirates
24	Vanuatu
25	Yemen

([1]) Without prejudice to the legal position of the Kingdom of Spain with regard to sovereignty and jurisdiction in relation to the territory of Gibraltar.'

COMMISSION REGULATION (EU) 2023/411

of 23 February 2023

amending Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), and in particular Article 18 thereof,

Whereas:

(1) Nitrofurans and their metabolites are antimicrobial agents which are prohibited for use in food of animal origin in the Union and therefore nitrofurans are listed in Table 2 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) on prohibited substances, for which maximum residue limits cannot be established.

(2) Commission Regulation (EU) 2019/1871 ([3]) established reference points for action ('RPA') for certain non-allowed pharmacologically active substances present in food of animal origin, for which no maximum residue limits have been laid down. From 28 November 2022, a reference point of action of 0,5 µg/kg shall be applied for nitrofurans and their metabolites.

(3) Based on the opinion of the European Food Safety Authority ([4]), semicarbazide ('SEM'), a metabolite of the nitrofuran nitrofurazone, can be present in food either as a metabolite occurring due to illegal treatment with nitrofurazone or as a metabolite produced during food processing, arising from the use of disinfecting agents or from reactions of various food components. Therefore, the presence of SEM cannot be considered as an unequivocal marker of abuse of nitrofurazone during animal products production.

(4) Based on data provided by industry and available occurrence data ([5]), higher levels of SEM can be found in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder as a result of high temperature processing, even when no treatment with nitrofurans has been applied to those processed products.

(5) Therefore, as an exception, the RPA for SEM should not be applied for gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder unless other nitrofurans or their metabolites are found together with SEM in those processed products.

([1]) OJ L 152, 16.6.2009, p. 11.

([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([3]) Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC (OJ L 289, 8.11.2019, p. 41).

([4]) EFSA (European Food Safety Authority), O'Keeffe M, Christodoulidou A and Nebbia C, 2021. Scientific report on the presence of nitrofurans and their metabolites in gelatine. *EFSA Journal* 2021;19(10):6881, 22 pp, https://doi.org/10.2903/j.efsa.2021.6881.

([5]) Richard H. Stadler et al. 2015. Why semicarbazide (SEM) is not an appropriate marker for the usage of nitrofurazone on agricultural animals. Food Additives & Contaminants: Part A, Vol. 32, No 11, p. 1842–1850, http://dx.doi.org/10.1080/19440049.2015.1086028

(6) Infants and young children are vulnerable group of consumers. Bearing in mind that their diet consists in particular of milk-powdered food, that exemption should not apply to infant formulae and follow-on formulae.

(7) In order to enable the Commission to establish specific regulatory measures as regards the presence of SEM in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder, food business operators and other interested parties should provide within a defined time period necessary data and information on investigations on the parameters and factors in the processing steps resulting in the formation of SEM during processing in those processed products. Food business operators should also take measures to reduce the presence of SEM in these products at levels as low as reasonably achievable. In the absence of those data and information, the exemption can no longer be maintained.

(8) Regulation (EU) 2019/1871 should be amended accordingly.

(9) The reference point of action at level 0,5 µg/kg for nitrofurans and their metabolites applies as from 28 November 2022. In order to avoid unnecessary withdrawals from the market of the processed products concerned with SEM content at the level above the RPA because of wrong assumption of illegal use of nitrofurans, it is necessary to apply the exemption retroactively from the same date.

(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 Annex to Regulation (EU) 2019/1871 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*.

It shall apply from 28 November 2022.

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

Done at Brussels, 23 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Regulation (EU) 2019/1871 is replaced by the following:

'*ANNEX*

Reference points for action (RPA)

Substance	RPA (µg/kg)	Other provisions
Chloramphenicol	0,15	
Malachite green	0,5	0,5 µg/kg for the sum of malachite green and leucomalachite green
Nitrofurans and their metabolites	0,5 ([1]) ([2])	0,5 µg/kg for each of the metabolites of furazolidone (AOZ or 3-amino-2-oxazolidinone), furaltadone (AMOZ or 3-amino-5-methylmorpholino-2-oxazolidinone), nitrofurantoin (AHD or 1-aminohydantoin), nitrofurazone (SEM or semicarbazide) and nifursol (DNSH or 3,5-dinitrosalicylic acid hydrazide)

([1]) Due to the natural occurrence of SEM in crayfish at levels above the RPA, only levels of AOZ, AMOZ, AHD and DNSH above the RPA are a clear indication of the illegal use of nitrofurans and their metabolites. The RPA of 0,5 µg/kg for SEM in crayfish shall only be applied when the illegal use of nitrofurazone or SEM on crayfish has been established, i.e. at least one of the other nitrofuran metabolites has been detected.

([2]) Due to the occurrence of SEM at levels above the RPA as the consequence of processing in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) only levels of AOZ, AMOZ, AHD and DNSH above the RPA are a clear indication of the illegal use of nitrofurans and their metabolites. The RPA of 0,5 µg/kg for SEM in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) shall only be applied, when the illegal use of nitrofurazone or SEM has been established, i.e. at least one of the other nitrofuran metabolites has been detected.

Food business operators and other interested parties shall communicate by 1 March 2024 to the Commission the results of investigations on the parameters and factors in the processing steps resulting in the formation of SEM in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) during processing. They shall also communicate the measures taken to ensure that the levels of SEM in these products are kept as low as reasonably achievable. In the absence of satisfactory data and information, measures shall be taken to end this exemption.'

DECISIONS

COUNCIL DECISION (EU) 2023/412

of 21 February 2023

as regards the extension of the period of entitlement for audiovisual co-productions as provided for in Article 5 of the Protocol on Cultural Cooperation to the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Decision (EU) 2015/2169 of 1 October 2015 on the conclusion of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part ([1]), and in particular Article 3(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) On 1 October 2015, the Council adopted Decision (EU) 2015/2169.

(2) The Protocol on Cultural Cooperation ([2]) (the 'Protocol') annexed to the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part ([3]) (the 'Free Trade Agreement'), sets up the framework within which the Parties are to cooperate for the facilitation of exchanges regarding cultural activities, goods and services, including in the audiovisual sector.

(3) The Protocol exceptionally includes provisions on the entitlement for audiovisual co-productions to benefit from the respective schemes that is in principle reserved for developing countries with developing audiovisual industries.

(4) Pursuant to those provisions of the Protocol, following the initial period of 3 years, that period of entitlement is to be renewed for further successive periods of the same duration, unless a Party terminates the entitlement by giving notice in writing at least 3 months before the expiry of the initial or any subsequent period. In accordance with those provisions, the period of entitlement was last extended until 30 June 2023, no Party having terminated it. The actual effects of the Protocol in relation to audiovisual co-productions are to be assessed in due time by the Committee on Cultural Cooperation (the 'Committee') and to serve as the basis for the Union's decision on whether or not to extend the period of entitlement for a further period of 3 years until 2023.

(5) In accordance with Decision (EU) 2015/2169, the Commission is to provide notice to the Republic of Korea of the Union's intention not to extend the period of entitlement to co-production, following the procedure set out in the Protocol unless, on a proposal from the Commission, the Council agrees 4 months before the end of such period of entitlement to continue the entitlement. If the Council agrees to continue the entitlement, that procedure is to become applicable again at the end of the renewed period of entitlement.

(6) On 17 October 2019, the Union Domestic Advisory Group provided for in the Protocol was consulted on the extension of the period of entitlement, as provided for in the provisions on the entitlement for audiovisual co-productions of the Protocol.

([1]) OJ L 307, 25.11.2015, p. 2.
([2]) OJ L 127, 14.5.2011, p. 1418.
([3]) OJ L 127, 14.5.2011, p. 6.

(7) In view of the close, historical and unique relationship between the Union and the Republic of Korea, the Council agreed with the extension of the period of entitlement for audiovisual co-productions to benefit from the respective schemes of the Parties for the promotion of local/regional cultural content as provided for in the Protocol.

(8) Council Decision (EU) 2020/470 ([4]) therefore extended the period of entitlement for audiovisual co-productions for a duration of 3 years, from 1 July 2020 to 30 June 2023. However, by means of a judgment of 1 March 2022 in the case *Commission* v *Council* ([5]), the Court of Justice annulled Decision (EU) 2020/470. In its judgment, the Court also maintained the effects of that Decision until the grounds for annulment established have been remedied.

(9) On 28 November 2022, the Council adopted Decision (EU) 2022/2335 ([6]), which amended Decision (EU) 2015/2169 in conformity with that judgment.

(10) In order to remove any doubt as to the commitment of the Union regarding the extension of the period of the entitlement for a duration of 3 years, from 1 July 2020 to 30 June 2023, and thus to ensure the proper implementation of the Protocol, a new decision should be adopted on the basis of Decision (EU) 2015/2169, and apply as of 1 July 2020, in conformity with that judgment.

(11) This Decision should not affect the respective competences of the Union and the Member States. In particular, it should not affect the competence of Member States to conclude co-production agreements,

HAS ADOPTED THIS DECISION:

Article 1

The period of entitlement for audiovisual co-productions to benefit from the respective schemes of the Parties for the promotion of local/regional cultural content, as provided for in Article 5, paragraphs (4) to (7), of the Protocol, shall be extended for a duration of 3 years, from 1 July 2020 to 30 June 2023.

Article 2

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

It shall apply from 1 July 2020.

Done at Brussels, 21 February 2023.

For the Council
The President
J. ROSWALL

([4]) Council Decision (EU) 2020/470 of 25 March 2020 as regards the extension of the period of entitlement for audiovisual co-productions as provided for in Article 5 of the Protocol on Cultural Cooperation to the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part (OJ L 101, 1.4.2020, p. 1).

([5]) Judgment of the Court of Justice of 1 March 2022, *Commission* v *Council*, C-275/20, ECLI:EU:C:2022:142.

([6]) Council Decision (EU) 2022/2335 of 28 November 2022 amending Decision (EU) 2015/2169 on the conclusion of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part (OJ L 309, 30.11.2022, p. 6).

COUNCIL DECISION (EU) 2023/413

of 21 February 2023

as regards the extension of the period of entitlement for audiovisual co-productions as provided for in Article 5 of the Protocol on Cultural Cooperation to the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Decision (EU) 2015/2169 of 1 October 2015 on the conclusion of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part ([1]), and in particular Article 3(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) On 1 October 2015, the Council adopted Decision (EU) 2015/2169.

(2) The Protocol on Cultural Cooperation ([2]) (the 'Protocol') annexed to the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part ([3]) (the 'Free Trade Agreement'), sets up the framework within which the Parties are to cooperate for the facilitation of exchanges regarding cultural activities, goods and services, including in the audiovisual sector.

(3) The Protocol exceptionally includes provisions on the entitlement for audiovisual co-productions to benefit from the respective schemes that is in principle reserved for developing countries with developing audiovisual industries.

(4) Pursuant to those provisions of the Protocol, following the initial period of three years, that period of entitlement is to be renewed for further successive periods of the same duration, unless a Party terminates the entitlement by giving notice in writing at least three months before the expiry of the initial or any subsequent period. In accordance with those provisions, the period of entitlement was last extended until 30 June 2023, no Party having terminated it. The actual effects of the Protocol in relation to audiovisual co-productions are to be assessed in due time by the Committee on Cultural Cooperation (the 'Committee') and to serve as the basis for the Union's decision on whether or not to extend the period of entitlement for a further period of three years until 2026.

(5) In accordance with Decision (EU) 2015/2169, the Commission is to provide notice to the Republic of Korea of the Union's intention not to extend the period of entitlement to co-production following the procedure set out in the Protocol unless, on a proposal from the Commission, the Council agrees four months before the end of such period of entitlement to continue the entitlement. If the Council agrees to continue the entitlement, that procedure is to become applicable again at the end of the renewed period of entitlement.

(6) On 22 December 2022, the Union Domestic Advisory Group provided for in the Protocol was consulted on the extension of the period of entitlement, as provided for in the provisions on the entitlement for audiovisual co-productions of the Protocol.

(7) On 7 December 2022, the Committee assessed the results of the implementation of the entitlement in terms of enhancement of cultural diversity and mutually beneficial cooperation on co-produced works as provided for in the Protocol.

([1]) OJ L 307, 25.11.2015, p. 2.
([2]) OJ L 127, 14.5.2011, p. 1418.
([3]) OJ L 127, 14.5.2011, p. 6.

(8) In view of the close, historical and unique relationship between the Union and the Republic of Korea, and as EU-Republic of Korea co-productions are potentially mutually beneficial both economically and culturally, the Council agrees with the extension of the period of entitlement for audiovisual co-productions to benefit from the respective schemes of the Parties for the promotion of local/regional cultural content as provided for in the Protocol. The audiovisual entitlement can create additional opportunities for all Member States, including those who have so far been unable to develop co-productions bilaterally.

(9) This Decision should not affect the respective competences of the Union and the Member States. In particular, it should not affect the competence of Member States to conclude co-production agreements,

HAS ADOPTED THIS DECISION:

Article 1

The period of entitlement for audiovisual co-productions to benefit from the respective schemes of the Parties for the promotion of local/regional cultural content, as provided for in Article 5, paragraphs (4) to (7), of the Protocol, shall be extended for a duration of three years, from 1 July 2023 to 30 June 2026.

Article 2

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

Done at Brussels, 21 February 2023.

For the Council
The President
J. ROSWALL

COMMISSION IMPLEMENTING DECISION (EU) 2023/414

of 17 February 2023

amending Implementing Decision (EU) 2022/2333 concerning certain emergency measures relating to sheep pox and goat pox in Spain

(notified under document C(2023) 1270)

(Only the Spanish text is authentic)

(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 259(1) thereof,

Whereas:

(1) Sheep pox and goat pox is an infectious viral disease affecting caprine and ovine animals and can have a severe impact on the concerned animal population and the profitability of farming causing disturbance to movements of consignments of those animals and products thereof within the Union and exports to third countries. In the event of an outbreak of that disease in caprine and ovine animals, there is a serious risk that it may spread to other establishments keeping those animals.

(2) Sheep pox and goat pox is defined as a category A disease in Commission Implementing Regulation (EU) 2018/1882 ([2]). In addition, Commission Delegated Regulation (EU) 2020/687 ([3]) supplements the rules for the control of the listed diseases referred to in Article 9(1), points (a), (b) and (c), of Regulation (EU) 2016/429, and defined as category A, B and C diseases in Implementing Regulation (EU) 2018/1882. In particular, Articles 21 and 22 of Delegated Regulation (EU) 2020/687 provide for the establishment of a restricted zone in the event of an outbreak of a category A disease, including sheep pox and goat pox, and for certain disease control measures to be applied therein. In addition, Article 21(1) of that Delegated Regulation provides that the restricted zone is to comprise a protection zone and a surveillance zone, and if necessary further restricted zones around or adjacent to the protection and surveillance zones.

(3) Commission Implementing Decision (EU) 2022/2333 ([4]) was adopted within the framework of Regulation (EU) 2016/429 and it lays down emergency measures for Spain in relation to outbreaks of sheep pox and goat pox, that were detected in the regions of Andalusia and Castilla-La Mancha, where they form two distinct clusters, one in each region.

(4) More particularly, Implementing Decision (EU) 2022/2333 provides that the protection, surveillance and further restricted zones, to be established by Spain following outbreaks of sheep pox and goat pox, in accordance with Delegated Regulation (EU) 2020/687, are to comprise at least the areas listed in the Annex to that Implementing Decision.

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

([2]) Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

([3]) Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

([4]) Commission Implementing Decision (EU) 2022/2333 of 23 November 2022 concerning certain emergency measures relating to sheep pox and goat pox in Spain and repealing Implementing Decision (EU) 2022/1913 (OJ L 308, 29.11.2022, p. 22).

(5) Furthermore, in the Annex to Implementing Decision (EU) 2022/2333, the areas listed as protection and surveillance zones, are grouped together with the same date of duration during which the measures apply, for each cluster, which takes into account the date when the last preliminary cleaning and disinfection was completed so that all outbreaks within the same area have been subjected to preliminary cleaning and disinfection.

(6) In addition to the protection and surveillance zones, a further restricted zone was established, in accordance with Article 21(1), point (c), of Delegated Regulation (EU) 2020/687, in both the region of Andalusia as well as the region of Castilla-La Mancha, where Spain is required to apply certain measures regarding restrictions on the movements of sheep and goats outside that zone, with a view to preventing the spread of the disease to the rest of its territory and the rest of the Union.

(7) After the adoption of Implementing Decision (EU) 2022/2333, Spain notified the Commission of two additional outbreaks of sheep pox and goat pox in establishments where ovine and/or caprine animals were kept, located in the region of Castilla – La Mancha. As a result, the areas listed as protection and surveillance zones, as well as further restricted zones for Spain, in the Annex to this Decision, were amended by Commission Implementing Decision (EU) 2023/10 ([5]).

(8) Since the date of adoption of Implementing Decision (EU) 2023/10, Spain has notified the Commission of three additional outbreaks of sheep pox and goat pox in establishments where ovine and/or caprine animals were kept, all located in the region of Castilla – La Mancha, inside the further restricted zone already established in this region. Two of these outbreaks are located in the Province of Cuenca, while the third one is located in the Province of Ciudad Real and is the first outbreak reported in this province.

(9) In the region of Andalusia, no new outbreaks of sheep pox and goat pox have been reported to date, since the confirmation of the last ones, on 7 November 2022. As a result, all restricted zones in that region have been lifted since 16 January 2023.

(10) The competent authority of Spain has taken the necessary disease control measures required in accordance with Delegated Regulation (EU) 2020/687, including the establishment of protection and surveillance zones around those three new outbreaks and the expansion of the further restricted zone around them.

(11) Spain has also provided the Commission, with regular updates, on the epidemiological situation of sheep pox and goat pox in its territory. These updates include the disease control measures taken by Spain that the Commission reviews in order to assess their effectiveness, taking into account the evolution of the disease.

(12) Therefore, the areas listed as protection, surveillance and further restricted zones for Spain in the Annex to Implementing Decision (EU) 2022/2333, should be amended, spatially and/or temporally, taking into account the current epidemiological situation in the region of Castilla-La Mancha. Furthermore, in view of the current epidemiological situation, it is necessary to put in place stricter measures in relation to movements of sheep and goats from the further restricted zone to establishments outside that zone, in order to prevent the spread of the disease to the rest of the territory of Spain and the rest of the Union. To this end, movements of sheep and goats outside the further restricted zone should only be allowed to a slaughterhouse for immediate slaughter.

(13) Given the urgency of the epidemiological situation in the Union as regards the spread of sheep pox and goat pox, it is important that the measures laid down in this Implementing Decision apply as soon as possible.

(14) In addition, taking into account the current epidemiological situation in the Union as regards sheep pox and goat pox, this Decision should apply until 31 July 2023.

(15) Implementing Decision (EU) 2022/2333 should therefore be amended accordingly.

([5]) Commission Implementing Decision (EU) 2023/10 of 20 December 2022 amending Implementing Decision (EU) 2022/2333 concerning certain emergency measures relating to sheep pox and goat pox in Spain (OJ L 2, 4.1.2023, p. 126).

(16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2022/2333 is amended as follows:

(1) paragraph 2 of Article 3 is replaced by the following:

'2. The following movements of sheep and goats kept in the further restricted zone outside that zone within the territory of Spain may be authorised by the competent authority:

— Movements of sheep and goats directly to a slaughterhouse for immediate slaughter.';

(2) Article 5 is replaced by the following:

'*Article 5*

Application

This Decision shall apply until 31 July 2023.';

(3) the Annex to Implementing Decision (EU) 2022/2333 is replaced by the text set out in the Annex to this Decision.

Article 2

Addressee

This Decision is addressed to the Kingdom of Spain.

Done at Brussels, 17 February 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

'*ANNEX*

A. **Protection and surveillance zones established around confirmed outbreaks**

Region and ADIS reference number of the outbreak	Areas established as protection and surveillance zones, part of the restricted zones in Spain as referred to in Article 1	Date until applicable
Region of Castilla – La Mancha ES-CAPRIPOX-2023-00001 ES-CAPRIPOX-2023-00002 ES-CAPRIPOX-2023-00003	Protection zone: Those parts of the provinces of Cuenca and Ciudad Real, contained within a circle of a radius of 5 kilometres, centred on UTM 30, ETRS89 coordinates Lat. 39.5105823, Long. -2.4881244 (2023/01); Lat. 39.4754483, Long. -2.1693509 (2023/2); Lat 39.3779337, Long -3.2065384 (2023/3)	22.3.2023
	Surveillance zone: Those parts of the provinces of Cuenca, Ciudad Real, Toledo and Albacete, beyond the area described in the protection zone and contained within a circle of a radius of 20 kilometres centred on UTM 30, ETRS89 coordinates Lat. 39.5105823, Long. -2.4881244 (2023/01); Lat. 39.4754483, Long. -2.1693509 (2023/2); Lat 39.3779337, Long -3.2065384 (2023/3)	7.4.2023
	Surveillance zone: Those parts of the provinces of Cuenca and Ciudad Real, contained within a circle of a radius of 5 kilometres, centred on UTM 30, ETRS89 coordinates Lat. 39.5105823, Long. -2.4881244 (2023/01); Lat. 39.4754483, Long. -2.1693509 (2023/2); Lat 39.3779337, Long -3.2065384 (2023/3)	23.3.2023 – 7.4.2023

B. **Further restricted zones**

Region	Areas established as further restricted zones, part of the restricted zones in Spain as referred to in Article 1	Date until applicable
Region of Castilla – La Mancha	A further restricted zone that comprises the following provinces: — Albacete — Ciudad Real — Cuenca — Toledo	17.5.2023'

COMMISSION IMPLEMENTING DECISION (EU) 2023/415

of 22 February 2023

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 1126)

(Only the German text is authentic)

(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Implementing Decision 2012/81/EU ([2]) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean A5547-127. The scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of genetically modified soybean A5547-127, for the same uses as any other soybean, with the exception of cultivation.

(2) On 10 December 2020, BASF SE, based in Germany, submitted an application on behalf of BASF Agricultural Solutions Seed US LLC, based in the United States, to the Commission for the renewal of that authorisation.

(3) On 20 June 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]). It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified soybean A5547-127, adopted by the Authority in 2011 ([4]).

(4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

(6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean A5547-127 and of products containing it or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Implementing Decision 2012/81/EU of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 40, 14.2.2012, p. 10).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on the assessment on genetically modified soybean A5547-127 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-020). *EFSA Journal* 2022; 20(6):7340, 12 pp.; https://doi.org/10.2903/j.efsa.2022.7340

([4]) EFSA GMO Panel, 2011. Scientific Opinion on application (EFSA-GMO-NL-2008-52) for the placing on the market of herbicide tolerant genetically modified soybean A5547-127 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. *EFSA Journal* 2011; 9(5):2147, 27 pp.; https://doi.org/10.2903/j.efsa.2011.2147

(7) A unique identifier has been assigned to genetically modified soybean A5547-127, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Implementing Decision 2012/81/EU. That unique identifier should continue to be used.

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([6]), appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified soybean A5547-127 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([7]).

(10) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified soybean A5547-127, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([8]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max*) A5547-127, as specified in the Annex to this Decision, is assigned the unique identifier ACS-GMØØ6-4, in accordance with Regulation (EC) No 65/2004.

([5]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([6]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([7]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([8]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

Article 2

Renewal of the authorisation

The authorisation for placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified soybean ACS-GMØØ6-4;

(b) feed containing, consisting of or produced from genetically modified soybean ACS-GMØØ6-4;

(c) products containing or consisting of genetically modified soybean ACS-GMØØ6-4, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean as referred to in Article 1, with the exception of products referred to in point (a) of Article 2.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean ACS-GMØØ6-4.

Article 5

Monitoring plan for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, United States, represented in the Union by BASF SE, Germany.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to BASF Agricultural Solutions Seed US LLC, 100 Park Avenue, Florham Park, New Jersey 07932, United States, represented in the Union by BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

Done at Brussels, 22 February 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States

represented in the Union by: BASF SE, Carl-Bosch-Str. 38, D-67063, Ludwigshafen, Germany.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean ACS-GMØØ6-4;

(2) feed containing, consisting of or produced from genetically modified soybean ACS-GMØØ6-4;

(3) products containing or consisting of genetically modified soybean ACS-GMØØ6-4 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean ACS-GMØØ6-4 expresses the *pat* gene, which confers tolerance to glufosinate ammonium-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified soybean ACS-GMØØ6-4, with the exception of the products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event-specific method for the quantification of genetically modified soybean ACS-GMØØ6-4 using real-time PCR

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

(3) Reference Material: AOCS 0707-C8 is accessible via the American Oil Chemists Society at https://aocs.org/tech/crm

(e) **Unique identifier:**

ACS-GMØØ6-4

(f) **Information required pursuant to Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council ([1]).

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

([1]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

COMMISSION IMPLEMENTING DECISION (EU) 2023/416

of 22 February 2023

authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100 (MON-941ØØ-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 1135)

(Only the Dutch text is authentic)

(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 29 October 2020, Bayer Agriculture BV, based in Belgium, submitted, on behalf of Bayer CropScience LP, based in the United States, an application to the national competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified oilseed rape MON 94100, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also concerned the placing on the market of products containing or consisting of genetically modified oilseed rape MON 94100 for uses other than food and feed, with the exception of cultivation.

(2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([2]). It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.

(3) On 22 July 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. The Authority concluded that genetically modified oilseed rape MON 94100, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified oilseed rape reference varieties with respect to the potential effects on human and animal health and the environment. The Authority also concluded that the consumption of food and feed from genetically modified oilseed rape MON 94100 does not represent any nutritional concern for humans and animals.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on assessment of genetically modified oilseed rape MON 94100 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-169). EFSA Journal 2022; 20(7):7411, 29 pp. https://doi.org/10.2903/j.efsa.2022.7411.

(4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

(6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100 should be authorised for the uses listed in the application.

(7) A unique identifier should be assigned to genetically modified oilseed rape MON 94100 in accordance with Commission Regulation (EC) No 65/2004 ([4]).

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([5]), appear to be necessary. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified oilseed rape MON 94100, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([6]).

(10) The opinion of the Authority does not justify the imposition of other specific conditions or restrictions for the placing on the market, for the use and handling or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e), of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([7]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([5]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([6]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([7]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified oilseed rape (*Brassica napus* L.) MON 94100, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-941ØØ-2, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003, in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified oilseed rape MON-941ØØ-2;

(b) feed containing, consisting of or produced from genetically modified oilseed rape MON-941ØØ-2;

(c) products containing or consisting of genetically modified oilseed rape MON-941ØØ-2, for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified oilseed rape MON-941ØØ-2, as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified oilseed rape MON-941ØØ-2.

Article 5

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 22 February 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States.

Represented in the Union by: Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified oilseed rape MON-941ØØ-2;

(2) feed containing, consisting of or produced from genetically modified oilseed rape MON-941ØØ-2;

(3) products containing or consisting of genetically modified oilseed rape MON-941ØØ-2 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified oilseed rape MON-941ØØ-2 expresses the *dmo* gene, which confers tolerance to dicamba-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of oilseed rape MON-941ØØ-2, with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based method for detection of the genetically modified oilseed rape MON-941ØØ-2;

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx;

(3) Reference Material: AOCS 0421-A is accessible via the American Oil Chemists Society at https://www.aocs.org/crm?SSO=True

(e) **Unique identifier:**

MON-941ØØ-2

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring plan:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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of 22 February 2023

accepting a request submitted by the Netherlands and Germany, pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council, not to apply temporarily point 4.2.5.1. 'Radio communications with the train' and point 4.2.8. 'Key Management' of the Annex to Commission Regulation (EU) 2016/919 for the eight trainsets FLIRT3 EMU3 Limburg MS (L-435)

(notified under document C(2023) 1154)

(Only the Dutch and German texts are authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union ([1]), and in particular Article 7(4) thereof,

Whereas:

(1) On 15 and 20 July 2022, respectively, the Netherlands and Germany submitted to the Commission a request for temporary non-application of point 4.2.5.1. 'Radio communications with the train' and point 4.2.8. 'Key Management' of the Annex to Commission Regulation (EU) 2016/919 ([2]) to eight vehicles FLIRT3 EMU3 Limburg MS (L-435) (the 'trainsets') supplied by the manufacturer Stadler to the operator Arriva. The requests are based on Article 7(1), point (c), of Directive (EU) 2016/797 providing for a possibility of non-application due to the risk of compromising the economic viability of the project. Those trainsets are used to perform services between Maastricht (the Netherlands), Heerlen (the Netherlands) and Aachen (Germany).

(2) The same eight trainsets FLIRT3 EMU3 Limburg MS (L-435) have already been the object of Commission Implementing Decision C(2020) 5081 final ([3]). By that implementing decision, the Commission accepted the request of the Netherlands to temporarily not apply point 7.4.2.1 of the Annex to Regulation (EU) 2016/919, which provides for the installation of European Train Control System (ETCS) Baseline 3 equipment ([4]) in vehicles intended for operations on TEN-T core network corridors. The temporary non-application was accepted on the basis of Article 7(1), point (c), of Directive (EU) 2016/797 which refers to the lack of economic viability of performing the upgrade to install European Rail Traffic Management System (ERTMS) on-board equipment in full compliance with Regulation (EU) 2016/919.

(3) Implementing Decision C(2020) 5081 final granted the temporary non-application until 31 March 2022, with the possibility for the Dutch national safety authority to extend the period of non-application until 31 December 2022, if needed for reasons outside the responsibility of the trainsets' owner or manufacturer, and upon a request by either of them.

(4) On the basis of the obligation of the Dutch authorities under Implementing Decision C(2020) 5081 final to monitor progress of the trainsets' owner and manufacturer as regards their obligation to bring the eight trainsets in full compliance with on-board ERTMS, the Dutch national safety authority authorised the extension of the period of non-application until 31 December 2022.

([1]) OJ L 138, 26.5.2016, p. 44.

([2]) Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union (OJ L 158, 15.6.2016, p. 1).

([3]) Commission Implementing Decision C(2020) 5081 final of 29 July 2020 accepting a request submitted by the Netherlands, pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council, not to apply point 7.4.2.1 of the Annex to Commission Regulation (EU) 2016/919 to eight trainsets of FLIRT3 EMU3 Limburg MS (L-435).

([4]) Table A 2.2 and Table A 2.3 of Annex A to the Annex of Commission Regulation (EU) 2016/919.

(5) Thus, the eight trainsets concerned are currently equipped with class B systems, as the owner decided to postpone the installation of Baseline 2 and directly update to Baseline 3 by the end of 2022, on the basis of Implementing Decision C(2020) 5081 final.

(6) As regards the current request for temporary non-application of point 4.2.5.1. and point 4.2.8. of the Annex to Regulation (EU) 2016/919, the information provided by the Dutch and German authorities in accordance with Article 7(4) of Directive (EU) 2016/797 enabled the Commission to carry out its analysis.

(7) The project of updating the eight trainsets with ETCS Baseline 3 on-board equipment faced delays in the first year of the project, mainly due to external factors with only limited leverage by the manufacturer. The reasons for the delays include the lack of upgrading of the infrastructure to ETCS Baseline 3, vagueness regarding the requirements of the implementation of the type of Class B system, and the impact of COVID-19 on decision-making and communication between stakeholders.

(8) In order to compensate for the delays and continue operating the trains, the Dutch and German authorities accepted the request from the manufacturer to temporarily remove the two functions 'GPRS packet switching' and 'online key management' from the specifications of the trainsets and explore the possibility of applying a restriction or condition of use to compensate for the two functions. However, GPRS packet switching and online key management are two technical functions inherently part of ETCS Baseline 3. GPRS packet switching is part of the requirements under point 4.2.5.1. 'Radio communications with the train' and online key management is part of the requirements under point 4.2.8. 'Key management' of the Annex to Regulation (EU) 2016/919. Thus, removal of those two functions constitutes non-compliance with Regulation (EU) 2016/919.

(9) Therefore, without a derogation from full ETCS Baseline 3 application, the operation of the trainsets would need to be ceased. The trainsets are equipped with specific characteristics, namely three power supply systems (1,5 kV, 3 kV and 15 kV) and three Class B train control systems (ATB, TBL1+, and PZB). Trainsets with these or similar characteristics, authorised for running in the Netherlands and Germany, are currently not available on the market. Temporary replacement by leased trainsets is therefore impossible. As a result, the trainsets would need to be replaced by buses, which would not only have an economic impact in the missing income and high direct costs of an alternative road transportation service, but also have a negative socioeconomic impact on Arriva customers and loss of passenger trust in the operator due to the disruption of the service.

(10) In accordance with Article 7(4) of Directive (EU) 2016/797, the applicants informed the Commission that the delay of implementation of the two functions will not affect safety and interoperability, as the trackside introduction of the two functions is not foreseen before 2026 and ETCS Baseline 3 on-board is fully compatible with the trackside signalling. Furthermore, the impact of the non-application of the two functions is limited, as the trainsets will only travel between Aachen and Maastricht.

(11) Therefore, in order to avoid disruption of interregional rail services pending installation of the lacking ERTMS equipment, the condition set out in Article 7(1), point (c) of Directive (EU) 2016/797 should be considered as fulfilled and the derogation from point 4.2.5.1. and point 4.2.8. of the Annex to Regulation (EU) 2016/919 should be granted until 31 December 2024.

(12) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 51(1) of Directive (EU) 2016/797,

HAS ADOPTED THIS DECISION:

Article 1

The request of the Kingdom of the Netherlands and of the Federal Republic of Germany not to apply point 4.2.5.1. 'Radio communications with the train' and point 4.2.8. 'Key Management' of the Annex to Regulation (EU) 2016/919 to eight trainsets 'FLIRT3 EMU3 Limburg MS (L-435)', is accepted, subject to the conditions set out in Article 2.

Article 2

The Kingdom of the Netherlands and the Federal Republic of Germany shall inform the Commission by 31 March 2023 of the works scheduled for the implementation of point 4.2.5.1. and point 4.2.8. of the Annex to Regulation (EU) 2016/919 and notify the Commission of the actual implementation thereof by 31 December 2024.

Article 3

This Decision shall apply within the geographic limits of the Dutch and German railway networks.

Article 4

This Decision is addressed to the Kingdom of the Netherlands and the Federal Republic of Germany.

It shall apply until 31 December 2024.

Done at Brussels, 22 February 2023.

For the Commission
Adina-Ioana VĂLEAN
Member of the Commission

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

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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