Official Journal of the European Union

L 426

Volume 64

English edition

Legislation

29 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.

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2076

of 26 November 2021

concerning the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80210 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

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

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80210. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80210 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2021 ([2]) that, under the proposed conditions of use, L-tryptophan produced by *Escherichia coli* KCCM 80210 does not have an adverse effect on the health of non-ruminant animals, consumer safety or the environment. To be safe for ruminants, the L-tryptophan should be protected against degradation in the rumen. The Authority stated that the additive under assessment is considered a mild eye irritant. The endotoxin activity of the additive and its dusting potential indicate a risk by inhalation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(5) The Authority considered that L-tryptophan produced by *Escherichia coli* KCCM 80210 is an efficacious source of the essential amino acid tryptophan for non-ruminant animals; for the supplemental L-tryptophan produced by *Escherichia coli* KCCM 80210 to be as efficacious in ruminants as in non-ruminants, it should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021;19(3):6425.

(6) The assessment of L-tryptophan produced by *Escherichia coli* KCCM 80210 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.

(7) 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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

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, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives **Functional group: amino acids, their salts and analogues**									
3c440i	-	L-tryptophan	*Additive composition* Powder with a minimum of 98 % L-tryptophan on a dry matter basis and a maximum moisture content of 1 %. Maximum content of 10 mg/kg 1,1′-ethylidene-bis-L-tryptophan (EBT) *Characterisation of the active substance* L-tryptophan produced by fermentation with *Escherichia coli* KCCM 80210 Chemical formula: $C_{11}H_{12}N_2O_2$ CAS No: 73-22-3 *Analytical methods* (1) For the identification of L-tryptophan in the feed additive: — Food Chemical Codex 'L-tryptophan monograph'. — For the determination of tryptophan in the feed additive and premixtures: — High performance liquid chromatography with fluorescence detection (HPLC-FLD) – EN ISO 13904.	All species	-	-	-	1. The feed business operator placing the additive on the market shall ensure that its endotoxin content and dusting potential result in a maximal endotoxin exposure of 1600 IU endotoxins/m³ air (2). 2. For ruminants, L-tryptophan shall be rumen protected. 3. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, skin or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used	19 December 2031

			For the determination of tryptophan in compound feed and feed materials: — High performance liquid chromatography with fluorescence detection (HPLC-FLD); Commission Regulation (EC) No 152/2009 (3) (Annex III, G).					with personal protective equipment, including eyes, skin and breathing protection.	

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

(2) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (*EFSA Journal* 2015;13(2):4015); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

(3) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2077

of 26 November 2021

concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

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

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-valine. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ([2]) that, under the proposed conditions of use, L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer safety or the environment. With respect to the safety of the user of that additive, the Authority could neither exclude a risk by inhalation, nor that L-valine might be irritant to skin or eyes, or a dermal sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Further, the Authority concluded that it is considered an efficacious source of the essential amino acid L-valine for animal nutrition and that in order to be efficacious in ruminants, the additive should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021;19(4):6521.

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, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives **Functional group: amino acids, their salts and analogues**									
3c371i	-	L-valine	*Additive composition* Powder with a minimum content of L-valine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water. *Characterisation of the active substance* L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by *Corynebacterium glutamicum* CGMCC 7.366 Chemical formula: $C_5H_{11}NO_2$ CAS number: 72-18-4 *Analytical method* (1) For the identification of L-valine in the feed additive: — Food Chemical Codex 'L-valine monograph' — For the quantification of valine in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For the quantification of valine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F)	All species	-			1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 3. The label of the additive and premixture shall indicate the following: 'The supplementation with L-valine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	19 December 2031

			For the quantification of valine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FD)						

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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2078

of 26 November 2021

laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (Eudamed)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([1]), in particular Article 33(8) thereof:

Whereas:

(1) Regulation (EU) 2017/745 requires the Commission to lay down the detailed arrangements necessary for the setting up and maintenance of the European database on medical devices ('Eudamed').

(2) Regulation (EU) 2017/746 of the European Parliament and of the Council ([2]) requires the Commission to set up, maintain and manage Eudamed, in accordance with the conditions and detailed arrangements established by Regulation (EU) 2017/745.

(3) As provided for in Regulations (EU) 2017/745 and (EU) No 2017/746, the Commission, competent authorities, authorities responsible for notified bodies, notified bodies, manufacturers, authorised representatives, importers, natural or legal persons referred to in Article 22(1) of Regulation (EU) 2017/745 (system or procedure pack producers) and sponsors of clinical investigations and performance studies should have access to and use Eudamed for the purpose of complying with their obligations and carrying out their tasks under those Regulations. It is, therefore, necessary to provide for the accessibility of Eudamed via a restricted website. In addition, Eudamed should provide the public with adequate information about devices placed on the market, the corresponding certificates issued by notified bodies, the relevant economic operators and clinical investigations. It is, therefore, also necessary to make Eudamed accessible via a public website. Moreover, in order to allow for the exchange of data between Eudamed and national databases, it is necessary to make Eudamed accessible through machine-to-machine data exchange services.

(4) As regards natural and legal persons that need to be able to access Eudamed via the restricted website, it is necessary to specify the conditions and the procedure for granting such access.

(5) The Commission has established the European Medical Device Nomenclature (EMDN) as provided for in Regulations (EU) 2017/745 and (EU) No 2017/746. The EMDN should therefore be made available in Eudamed free of charge and used for providing information on medical devices in Eudamed.

(6) In order to ensure that users of Eudamed receive the support needed when using the database, the Commission should provide them with timely technical and administrative assistance on Eudamed.

(7) In case of technical unavailability or malfunction of Eudamed, authorised users should still be able to fulfil their obligations. It is therefore necessary to specify alternative mechanisms to be used to exchange data in such events and to lay down contingency rules for such mechanisms.

([1]) OJ L 117, 5.5.2017, p. 1.

([2]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

(8) Rules on IT security set out in Commission Decision (EU, Euratom) 2017/46 ([3]) apply to Eudamed. In order for Eudamed to function in a secure manner, protected against threats to the availability, integrity and confidentiality of its functions and data, additional security rules should be laid down.

(9) In order to mitigate risks and address potential fraudulent use of Eudamed, specific provisions on fraudulent user activity in Eudamed should be laid down.

(10) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council ([4]) and delivered an opinion on 9 July 2021.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'actor' means the Commission, a competent authority, an authority responsible for notified bodies, a notified body, a manufacturer, an authorised representative, an importer, a system or procedure pack producer or a sponsor, who has been registered in Eudamed in accordance with Article 3 of this Regulation in order to fulfil its obligations set out in Regulations (EU) 2017/745 and (EU) No 2017/746;

(2) 'authorised user' means a natural person who has been granted access to Eudamed via the restricted website to act on behalf of an actor;

(3) 'local actor administrator' (LAA) means an authorised user who has the right to manage certain information regarding the details of the actor and to grant access to Eudamed via the restricted website to other natural persons to act on behalf of that actor;

(4) 'local user administrator' (LUA) means an authorised user who has the right to grant access to Eudamed via the restricted website to other natural persons to act on behalf of an actor;

(5) 'malfunction' means a significant failure of the functioning of Eudamed, including any failure caused by unforeseeable circumstances or by force majeure, that could adversely affect the IT security or hinder the availability of any of the functionalities of Eudamed's electronic systems referred to in Article 33(2) of Regulation (EU) 2017/745.

Article 2

Modes of access

1. Eudamed shall be accessible for authorised users via a restricted website ('the restricted website') and for non-identified users via a public website ('the public website').

2. Eudamed shall be accessible through machine-to-machine data exchange services to competent authorities as referred to in Article 101 of Regulation (EU) 2017/745 and Article 96 of Regulation EU 2017/746 ('competent authorities') and notified bodies registered in Eudamed in accordance with Article 3 of this Regulation. The Commission shall provide each Member State and notified body with data exchange access points enabling them to use such data exchange services upon their request.

([3]) Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission (OJ L 6, 11.1.2017, p. 40).

([4]) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Eudamed shall be accessible through machine-to-machine data exchange services to actors other than the competent authorities and notified bodies, provided that the LAA of the actor concerned submits a request for such access as referred to in Article 3(8), first subparagraph. The Commission shall approve that request under the condition set out in Article 3(8), second subparagraph.

Article 3

Registration in Eudamed and access to Eudamed via the restricted website

1. In order to be granted access to Eudamed via the restricted website, a natural person shall create an account on the Commission authentication service website.

2. The Commission shall register the competent authorities and the authorities responsible for the notified bodies and shall grant access to the restricted website to a first natural person to act on their behalf. For that purpose, the Member States shall provide to the Commission information on their competent authorities, the authorities responsible for notified bodies and the natural persons to become the first authorised users of those authorities.

3. The Commission shall register the notified bodies in Eudamed on the basis of the information in the database of notified bodies developed and managed by the Commission (NANDO).

In order to be granted access to Eudamed via the restricted website, the first natural person acting on behalf of an actor that is a notified body shall submit an access request via the restricted website. The authority responsible for the notified body shall approve the request.

4. In order for other entities than the ones mentioned in paragraphs 2 and 3 to be registered in Eudamed, a natural person acting on behalf of the prospective actor shall submit an actor registration request, via the restricted website. The actor registration request shall include the signed declaration on information security responsibilities referred to in Article 10(1). A national competent authority shall approve the actor registration request, except when the request concerns a sponsor of a clinical investigation or a performance study.

Upon approval of the actor registration request or, in case of a sponsor, when the actor registration request has been submitted, the natural person who submitted that request as referred to in the first subparagraph shall be automatically granted access to the restricted website and become the first authorised user, provided that the conditions in paragraph 6 are fulfilled.

For the purposes of this paragraph, the national competent authority shall be the authority of the place of establishment of the prospective actor. As regards manufacturers established outside of the Union, the national competent authority shall be the authority responsible for the authorised representative mentioned in the actor registration request. As regards system or procedure pack producers established outside of the Union, the national competent authority shall be the authority of the Member State, where the first system or procedure pack of that producer is to be placed on the market.

5. In order for a natural person to be granted access to the restricted website to act on behalf of an actor, he or she shall submit an access request via the restricted website. A LAA or LUA of that actor shall approve the access request.

6. In order to become authorised users, natural persons shall accept the user rights and obligations as set out in the document referred to in Article 10(1), point (a), and consult the privacy statement referred to in point (c) of that Article.

7. The first authorised user of an actor shall automatically be the first LAA of that actor.

8. A LAA may via the restricted website make a request to the Commission for a machine-to-machine connection for performing data exchanges between the actor's database and Eudamed.

The Commission may approve the request referred to in the first subparagraph provided that the LAA has confirmed that the actor complies with the information security requirements for data exchange referred to in Article 10(1).

Article 4

Nomenclature

Authorised users shall use the open access codes of the European Medical Device Nomenclature (EMDN) when providing information on medical devices in Eudamed.

The Commission shall make the EMDN available in Eudamed free of charge.

Article 5

Technical and administrative support

1. The Commission shall set up an application support team to provide timely assistance to users of Eudamed, reachable via a dedicated functional mailbox.

2. The Commission shall make available to the users of Eudamed the relevant technical documentation on Eudamed, Frequently Asked Questions regarding Eudamed and the documentation in support of machine-to-machine data exchange services.

Article 6

Ownership and processing of personal data

1. The Commission shall be the owner of Eudamed and shall have full administration rights.

2. Personal data shall be processed in Eudamed for the purpose of complying with the obligations set out in Regulations (EU) 2017/745 and (EU) No 2017/746.

3. The following categories of personal data shall be processed:

(a) names of actors and authorised users;

(b) contact details of actors and authorised users;

(c) identification and contact details, and data on professional qualifications of other natural or legal persons, which shall be reported in Eudamed for the purpose of complying with the obligations set out in Regulations (EU) 2017/745 and (EU) No 2017/746.

Article 7

Functioning rules

1. The submission of data in Eudamed shall be deemed executed at the date and time when the data is successfully registered in Eudamed. The date and time of submission shall be determined based on Central European Time (CET) or Central European Summer Time (CEST), as applicable.

2. Eudamed shall be accessible at all times, except during necessary and previously announced downtime periods due to maintenance activities, including new releases. The Commission shall display in advance a notice to that regard on the restricted website or the public website, as applicable.

Article 8

Malfunction

1. The Commission shall take all necessary measures to prevent any malfunction and to identify it, without undue delay, when it occurs.

2. Where an actor or an authorised user suspects a malfunction, it shall immediately inform the Commission thereof.

3. Where the Commission identifies a malfunction, it shall take the following measures:

(a) display, without delay, a notice to that regard ('malfunction notice') on the restricted website or the public website, as applicable, unless the nature of the malfunction prevents the Commission from doing so, in which case it shall, to the extent possible, display the notice on the Commission's dedicated website for medical devices;

(b) suspend the periods for submission of data in Eudamed set out in Regulations (EU) 2017/745 and (EU) No 2017/746, where the malfunction hinders entering of the relevant data.

Where the Commission suspends the periods for submission of data to Eudamed as provided for in the first subparagraph, point (b), the malfunction notice shall specify the time of the display of that notice and the likely duration of the suspension.

4. In addition to the suspension of periods referred to in paragraph 3, first subparagraph, point (b), of this Article, where a malfunction hinders compliance with any of the obligations referred to in Article 80, Article 87(1), Article 89(5), (7), (8) and (9), Article 95(2), (4) and (6), or Article 98(2) of Regulation (EU) 2017/745, or in Article 76, Article 82(1), Article 84(5), (7), (8) and (9), Article 90(2), (4) and (6) or Article 93(2) of Regulation (EU) 2017/746, either of the following procedure shall apply:

(a) where the malfunction lasts more than 12 hours following the display of the malfunction notice, the actor shall without delay provide general information about the relevant data and an indication that the submission of data is pending due to the malfunction to the Commission, to the national competent authorities concerned and to the notified body that issued the certificate of conformity referred to in Article 56 of Regulation (EU) 2017/745 or Article 51 of Regulation (EU) 2017/746, as applicable;

(b) where the malfunction lasts more than 24 hours following the display of the malfunction notice, or where the malfunction lasts less than 24 hours and it is requested by the national competent authorities concerned after receiving the information referred to in point (a) of this paragraph, the actor shall without delay provide the relevant data to those authorities, in the manner prescribed by them.

5. In addition to the suspension of periods referred to in paragraph 3, first subparagraph, point (b) of this Article, in the event of a malfunction that hinders compliance with one of the obligations set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746 other than the obligations referred to in paragraph 4 of this Article, the following procedure shall apply:

(a) where the malfunction lasts more than 36 hours following the display of the malfunction notice, the actor shall without delay provide general information about those data and an indication that the submission of data is pending due to the malfunction to the Commission, to the national competent authorities concerned and to the notified body that issued the certificate of conformity referred to in Article 56 of Regulation (EU) 2017/745 or Article 51 of Regulation (EU) 2017/746, as applicable;

(b) where the malfunction lasts more than five days following the display of the malfunction notice, the actor shall inform the national competent authorities concerned thereof and shall, if they so request, provide them with the relevant data, in the manner prescribed by them.

6. When the Commission has established that the malfunction has ceased, it shall communicate that information to the competent authorities. In addition, the Commission shall display a notice to that regard on the restricted website and/or the public website, as applicable. Both the communication and the notice shall indicate the duration of the malfunction and of the suspension of periods referred to in paragraph 3, point (b).

7. When the Commission has displayed the notice referred to in paragraph (6), actors shall without delay enter the data that they were hindered to submit during the malfunction in Eudamed.

Article 9

Websites for testing and training purposes

1. The Commission shall make available to the actors websites for the purposes of testing and training with regard to using Eudamed ('websites for testing and training').

Data entered in the websites for testing and training shall be considered fictitious and shall not be made available to the public.

2. Before using for the first time machine-to-machine data exchange services, an actor shall make at least one successful attempt of submission of data through machine-to-machine using a website for testing and training.

3. Any changes that the Commission intends to introduce to the Eudamed machine-to-machine data exchange services shall first be introduced by it in the websites for testing and training and shall be available on those websites for a period to be defined in advance by the Commission in collaboration with the Medical Device Coordination Group established under Article 103 of Regulation (EU) 2017/745.

The Commission shall inform the concerned actors via Eudamed in advance of the envisaged changes and of the period of their availability on the websites for testing and training.

Article 10

IT Security

1. The Commission shall make the following documents available on the restricted website:

(a) a document on user rights and obligations;

(b) the declaration on information security responsibilities;

(c) the privacy statement;

(d) the information security requirements for data exchange.

2. Actors shall comply with the terms and conditions set out in the documents referred to in paragraph 1, point (b), and, where applicable, point (d) of that paragraph.

3. Where the Commission suspects that an IT security incident, IT security risk or IT security threat, as defined in Article 2, points (15), (22) and (25), of Decision (EU, Euratom) 2017/46, which it considers as potentially harmful for Eudamed, its data or their confidentiality ('IT security incident, IT security threat or IT security risk') has occurred or is present, the Commission may suspend all access to Eudamed.

4. The Commission may suspend all or part of the functionalities of Eudamed's electronic systems, where it identifies an IT security incident, IT security threat or IT security risk.

If the suspension referred to in the first subparagraph hinders the entering of data in Eudamed, Article 8(3), (4) and (5) shall apply *mutatis mutandis*.

5. Any actor or authorised user who becomes aware of or suspects an IT security incident, IT security threat or IT security risk, shall immediately inform the Commission and the concerned Member States thereof.

Article 11

Fraudulent user activity within Eudamed

1. Where a competent authority, an LAA or an LUA suspects a fraudulent request for access to Eudamed, they shall refuse the request and immediately inform the Commission of such refusal via the application support team referred to in Article 5(1), specifying that it concerns a suspected fraudulent access request.

2. Where the Commission has a reasonable suspicion of fraudulent activity by an authorised user affecting the IT security of Eudamed, it shall temporarily suspend that authorised user's access to Eudamed. In that case, the Commission shall without delay inform all Member States and the concerned actors of the suspension and its justification.

3. Any actor or authorised user who suspects a fraudulent activity by an authorised user shall without delay inform the Commission and the Member States of the suspected fraudulent activity via the application support team referred to in Article 5(1).

4. Where the Commission establishes a fraudulent activity in Eudamed, it shall immediately terminate the relevant authorised users' access to Eudamed and take the necessary measures, including, where appropriate, preventing any future access to Eudamed from the related accounts created on the Commission authentication service website. The Commission shall without delay inform the relevant national competent authorities and the concerned actors of any measures taken pursuant to this paragraph.

Article 12

Entry into force

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

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

Done at Brussels, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2079

of 26 November 2021

authorising the placing on the market of vitamin D_2 mushroom powder 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 29 July 2019, the company MBio, Monaghan Mushrooms ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 to place vitamin D_2 mushroom powder on the Union market as a novel food. The applicant requested vitamin D_2 mushroom powder to be used in number of foods intended for the general population. The applicant also requested the novel food to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), excluding in food supplements for infants, and in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]), excluding foods for special medical purposes intended for infants. During the application process, the applicant agreed to exclude children under 3 years of age from the request for authorisation of the novel food in food supplements.

([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]) 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]) 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) The applicant also submitted a request to the Commission for the protection of proprietary data for a number of original data submitted in support of the application, namely, data concerning the production process ([5]); compositional data: particle size ([6]), physico-chemical properties ([7]), vitamin D analysis ([8]), nutritional analysis ([9]), vitamin D_2 analysis ([10]), vitamin D analysis validation ([11]), stability studies ([12]), toxicological analysis ([13]), data concerning tachysterol and lumisterol ([14]), ergosterol ratio analysis ([15]), vitamin D ratio analysis ([16]), data concerning ergosterol ([17]); specifications of fresh mushrooms ([18]); data concerning allergenicity ([19]).

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 24 January 2020, requesting it to provide a scientific opinion by carrying out an assessment of the safety of vitamin D_2 mushroom powder as a novel food.

(6) On 24 February 2021, the Authority adopted its scientific opinion on the 'Safety of Vitamin D_2 mushroom powder (*Agaricus bisporus*) as a novel food pursuant to Regulation (EU) 2015/2283' ([20]). That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In that opinion, the Authority concluded that vitamin D_2 mushroom powder is safe at the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that vitamin D_2 mushroom powder under the specific conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.

(8) A labelling requirement should be provided in order to properly inform the consumers that infants and children under 3 years of age should not consume food supplements containing vitamin D_2 mushroom powder.

(9) In its opinion, the Authority considered that the data concerning the production process and compositional data served as a basis to establish the safety of the novel food. On this basis, the Commission considers that the conclusions on the safety of vitamin D_2 mushroom powder could not have been reached without that data.

(10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those data and to clarify their claim to an exclusive right of reference to those data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to those data under national law, and that therefore third parties cannot lawfully access or use those data or refer to those data.

(12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data concerning the production process; compositional data: particle size, physico-chemical properties, vitamin D analysis, nutritional analysis, vitamin D_2 analysis, vitamin D analysis validation, stability

([5]) 2.3.1 Production Process Confidential_Final.
([6]) Annex 1 Particle Size Report.
([7]) Annex 3 NIZO Report physico-chemical properties.
([8]) Annex 4 COA vitamin D analysis.
([9]) Annex 5 COA nutritional analysis.
([10]) Annex 7 MBio SOP Vitamin D_2 analysis.
([11]) Annex 8 MBio Vit. D analysis validation report.
([12]) Annex 9 Stability Study Report UCC; Annex 14 COA Vit. D stability study; Annex 24 Stability study Report CampdenBRI; Annex 25 Stability study report meat free product; Annex 29 COAs Stability Meat free.
([13]) Annex 16 COA Toxicological analysis.
([14]) Annex 17 Report Tachysterol and lumisterol.
([15]) Annex 20 COA Ergosterol ratio analysis.
([16]) Annex 21 COA Vitamin D ratio analysis.
([17]) Annex 22 MBio Ergosterol.
([18]) Annex 13 COA fresh mushrooms analysis.
([19]) Annex 12 MBio Allergen Policy.
([20]) EFSA Journal 2021;19(4):6516.

studies, toxicological analysis, data concerning tachysterol and lumisterol, ergosterol ratio analysis, vitamin D ratio analysis, data concerning ergosterol contained in the applicant's file, on which the Authority based its conclusion on the safety of the novel food and without which it could not have assessed the novel food, 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, only the applicant should be authorised to place vitamin D_2 mushroom powder on the market within the Union during that period.

(13) However, restricting the authorisation of vitamin D_2 mushroom powder and the reference to the data contained in the applicant's file for the sole use of 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 an authorisation under Regulation (EU) 2015/2283.

(14) 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. The vitamin D_2 mushroom powder as specified in the Annex 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 19 December 2021 only the initial applicant:

Company: MBio, Monaghan Mushrooms,

Address: Tullygony, Tyholland, Co. Monaghan, Ireland,

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 the novel food without reference to the data protected pursuant to Article 2 or with the agreement of MBio, Monaghan Mushrooms.

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 data 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 19 December 2021 without the agreement of MBio, Monaghan Mushrooms.

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, 26 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
'Vitamin D_2 mushroom powder	*Specified food category*	*Maximum levels of vitamin D_2*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'UV-treated mushroom powder containing vitamin D_2' 2. The labelling of food supplements containing vitamin D_2 mushroom powder shall bear a statement that they should not be consumed by infants and children under 3 years of age.		Authorised on 19 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: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland. During the period of data protection, the novel food vitamin D_2 mushroom powder is authorised for placing on the market within the Union only by MBio, Monaghan Mushrooms, 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 MBio, Monaghan Mushrooms. End date of the date protection: 19 December 2026.'
	Breakfast cereals	2,1 µg/100 g			
	Yeast leavened bread and similar pastries	2,1 µg/100 g			
	Grain products and pasta and similar products	2,1 µg/100 g			
	Fruit/vegetable juices and nectars	1,1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and analogues other than beverages	2,1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and analogues as beverages	1,1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Milk and dairy powders	21,3 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
	Meat analogues	2,1 µg/100 g			
	Soups	2,1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Extruded vegetable snack	2,1 µg/100 g			
	Meal replacement for weight control	2,1 µg/100 g			

	Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 excluding those intended for infants	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 intended for infants and young children	15 µg of vitamin D_2/day			

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

Authorised Novel Food	Specifications
'**Vitamin D_2 mushroom powder**	**Description/Definition:** The novel food is mushroom powder produced from the dried whole *Agaricus bisporus* mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to UV irradiation. UV radiation: A process of radiation in ultraviolet light within a range of wavelength similar to those UV-treated novel foods authorised under Regulation (EU) 2015/2283. **Characteristics/composition:** Vitamin D_2 content: 580-595 µg/g of mushroom powder Ash: ≤ 13,5 % Water activity: < 0,5 Moisture content: ≤ 7,5 % Carbohydrates: ≤ 35,0 % Total Dietary Fibre: ≥ 15 % Crude protein (N × 6,25): ≥ 22 % Fat: ≤ 4,5 % **Heavy metals:** Lead: ≤ 0,5 mg/kg Cadmium: ≤ 0,5 mg/kg Mercury: ≤ 0,1 mg/kg Arsenic: ≤ 0,3 mg/kg **Mycotoxins:** Aflatoxin B1: ≤ 0,10 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg **Microbiological criteria:** Total plate count: ≤ 5 000 CFU ([a]) Total yeast and mould count: < 100 CFU/g *E. coli*: < 10 CFU/g

	Salmonella spp.: Absence in 25 g *Staphylococcus aureus*: ≤ 10 CFU/g Coliforms: ≤ 10 CFU/g *Listeria* spp.: Absence in 25 g Enterobacteriaceae: < 10 CFU/g'

([a]) CFU: colony forming units.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2080

of 26 November 2021

concerning the authorisation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive for all animal species except finfish

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

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

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the extension of use of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive from finfish to all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the extension of use of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive from finfish to all animal species to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues', and in the additive category 'sensory additives', functional group 'flavouring compounds'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 ([2]) that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia co*li NITE SD 00268 does not have an adverse effect on animal health, consumers safety or the environment. The Authority also concluded for the additive in question that it was not possible to conclude on the potential for the additive to be toxic if inhaled, an irritant to eyes or a skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive is an efficacious source of the essential amino acid histidine and efficacious as a flavouring compound.

(5) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021; 19(5):6622.

HAS ADOPTED THIS REGULATION:

Article 1

1. The substance L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

2. The substance L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds' is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

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, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives									
Functional group: amino acids, their salts and analogues									
3c351i	-	L-histidine monohydrochloride monohydrate	*Additive composition* Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine *Characterisation of the active substance* L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 Chemical formula: $C_3H_3N_2$-CH_2-CH(NH_2)-COOH·HCl·H_2O CAS number: 5934-29-2 Einecs number 211-438-9 *Analytical method* (1) For the quantification of histidine in the feed additive: — high performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV),	All animal species except finfish	-	-	-	1. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 2. Declaration to be made on the label of the additive and premixture: — 'The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depend on the species, the physiological state of the animal, the performance level, the environmental conditions, the level of other amino acids in the diet and the level of essential trace elements, such as copper and zinc.' — 'Histidine content'. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and	19 December 2031

			— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD). For the quantification of histidine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of histamine in the feed additive: — high performance liquid chromatography coupled to a spectrophotometric detection (HPLC-UV).					measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	
Category: Sensory additives									
Functional group: Flavouring compounds									
3c351i	-	L-histidine monohydrochloride monohydrate	*Additive composition* Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine *Characterisation of the active substance* L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feed with a moisture content of 12 %: 25 mg/kg.	19 December 2031

			Chemical formula: $C_3H_3N_2$-CH_2-CH(NH_2)-COOH·HCl·H_2O CAS number: 5934-29-2 Einecs number 211-438-9 *Analytical method* (1) For the quantification of histidine in the feed additive: — performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV), — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD). For the quantification of histidine in premixtures: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of histamine in the feed additive: — high performance liquid chromatography coupled to a spectrophotometric detection (HPLC-UV).					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture, where the use level on the label of the premixture would result in exceeding the level of active substance in complete feed referred to in point 3. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	

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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2081

of 26 November 2021

concerning the non-renewal of approval of the active substance indoxacarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 20(1)(b) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2006/10/EC ([2]) included indoxacarb as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance indoxacarb, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2022.

(4) An application for the renewal of the approval of indoxacarb was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 28 November 2016.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 15 December 2017, the Authority communicated to the Commission its conclusion ([6]) on whether indoxacarb can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The ecotoxicology section of this conclusion was amended in 2018 to clarify the risk assessment for bees according to the relevant European Commission Guidance (SANCO/10329/2002-rev.2). On 15 May 2019, the Commission

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2006/10/EC of 27 January 2006 amending Council Directive 91/414/EEC to include forchlorfenuron and indoxacarb as active substances (OJ L 25, 28.1.2006, p. 24).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

([6]) *EFSA Journal* 2018;16(1):5140, 36 pp. doi:10.2903/j.efsa.2018.5140. Available online: www.efsa.europa.eu.

requested the Authority for an updated peer review concerning the risk to mammals and bees of indoxacarb. On 28 October 2019, the Authority adopted a statement on the updated peer review concerning the risk to mammals and bees posed by the active substance indoxacarb ([7]) which was reflected in a second update of the Authority's conclusion on whether indoxacarb can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) A critical area of concern was identified by the Authority in relation to the high long-term risk to wild mammals, in particular the long-term risk to small herbivorous mammals.

(10) Additionally, a high risk to consumers and workers was identified for the representative use in lettuce and a high risk to bees was identified for the representative use in maize, sweet corn and lettuce for seed production.

(11) Furthermore, several areas of the risk assessment could not be finalised due to insufficient data in the dossier. In particular, the consumer risk assessment could not be finalised due to lack of data on rotational crop metabolism, data regarding the metabolism in poultry, the magnitude of residues in primary and rotational crops and data on the effect of water treatment processes on the nature of residues in drinking water. In addition, the assessment concerning groundwater exposure for soil metabolite IN-U8E24 could not be finalised due to lack of data on soil degradation and adsorption. Similarly, the ecotoxicological risk assessment for several metabolites could not be finalised.

(12) On 14 November 2018, the applicant informed the Commission of its decision to withdraw from the renewal application the representative use in lettuce.

(13) The Commission invited the applicant to submit its comments on the conclusion of the Authority, the revised conclusion and the statement. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

(14) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

(15) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance indoxacarb in accordance with Article 20(1)(b) of that Regulation.

(16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(17) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing indoxacarb.

(18) For plant protection products containing indoxacarb, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should be as short as possible.

([7]) EFSA (European Food Safety Authority), 2019. Statement on the updated peer review concerning the risk to mammals and bees for the active substance indoxacarb. *EFSA Journal* 2019;17(10):5866, 10 pp.

(19) Commission Implementing Regulation (EU) 2021/1449 ([8]) extended the expiry date of indoxacarb to 31 October 2022 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

(20) This Regulation does not prevent the submission of a further application for the approval of indoxacarb in accordance with Article 7 of Regulation (EC) No 1107/2009.

(21) 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

Non-renewal of approval of active substance

The approval of the active substance indoxacarb is not renewed.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 119, on indoxacarb, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing indoxacarb as an active substance by 19 March 2022 at the latest.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 19 September 2022.

Article 5

Entry into force

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

([8]) Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron (OJ L 313, 6.9.2021, p. 20).

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

Done at Brussels, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2082

of 26 November 2021

laying down the arrangements for the implementation of Regulation (EU) No 376/2014 of the European Parliament and of the Council as regards the common European risk classification scheme

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 ([1]), and in particular Article 7(7) thereof,

Whereas:

(1) In accordance with Regulation (EU) No 376/2014 Member States and the European Union Aviation Safety Agency ('the Agency') are each required to establish a mechanism to independently collect, evaluate, process, analyse and store details of aviation safety occurrences. The competent authorities of the Member States have to draw up occurrence reports on the basis of details of occurrences and store them in a national database. The same obligation exists for the Agency to draw up occurrence reports on the basis of details of occurrences and store them in a database.

(2) In accordance with Article 9(1) of Regulation (EU) No 376/2014, Member States and the Agency are to participate in an exchange of information by making all information relating to safety stored in their respective reporting databases available through the European Central Repository (ECR).

(3) Pursuant to Regulation (EU) No 376/2014, occurrence reports are to contain a safety risk classification that is subject to review by the competent authorities of the Member States or the Agency, and are to be transferred into the ECR.To ensure that the occurrence reports contained in the ECR are all classified in a harmonised manner, the competent authorities of the Member States and the Agency should ensure that the classification in those reports is determined in accordance with the common European risk classification scheme (ERCS) as set out in Commission Delegated Regulation (EU) 2020/2034 ([2]).

(4) It is now necessary to lay down the arrangements for a harmonised and consistent implementation of the ERCS by the Agency and Member States.

(5) When occurrence reports contain a risk classification determined by using methodologies other than the ERCS, the competent authorities of the Member States or the Agency should classify the risk of the occurrence concerned in accordance with the ERCS as defined in Commission Delegated Regulation (EU) 2020/2034.

(6) In cases where the competent authorities of the Member States or the Agency decide to use a conversion procedure to convert the risk classifications referred to in recital 5 into an ERCS classification, and where such methodologies are ARMS-ERC 4x4 or RAT 'ATM Overall', the competent authorities of the Member States or the Agency should use the direct conversion procedure provided in this Regulation.

(7) Where the direct conversion procedure set out in the Annex is not applicable, the competent authorities of the Member States and the Agency should be allowed to use other conversion procedures as long as an equivalent ERCS classification is achieved.

([1]) OJ L 122, 24.4.2014, p. 18.

([2]) Commission Delegated Regulation (EU) 2020/2034 of 6 October 2020 supplementing Regulation (EU) No 376/2014 of the European Parliament and of the Council as regards the common European risk classification scheme (OJ L 416, 11.12.2020, p. 1).

(8) Continuous monitoring and improvement of the ERCS is necessary to ensure its effective application. It is necessary to lay down detailed rules for such monitoring and improvement and the Agency should assist the Commission in that review and monitoring. For that purpose, Member States should report regularly and within prescribed deadlines to the Agency and the Commission on the use of the ERCS and its assessment.

(9) The competent authorities of the Member States, and the Agency need to prepare for the application of the ERCS, in particular by adjusting their internal processes and possibly allocating additional resources. However, Article 24(3) of Regulation (EU) No 376/2014 provides that Article 7(2) of that Regulation, which mandates the use of the ERCS by the Member States and the Agency, is to apply once the delegated and implementing acts specifying and developing the ERCS enter into force. Commission Delegated Regulation (EU) 2020/2034 defining the ERCS already entered into force on 31 December 2020. Therefore, it is not possible to delay the applicability of the obligation to use the ERCS beyond the date of the entry into force of this Regulation. Moreover, for the purposes of the annual safety review published by the Agency in accordance with Article 72(7) of Regulation (EU) 2018/1139 of the European Parliament and of the Council ([3]), it is essential that occurrence reports uploaded to the ECR within a 1 year period are scored in a harmonised way. The obligation to classify the occurrences in accordance with the ERCS should start to apply as of the date of entry into force of this Regulation. Therefore, this Regulation should enter into force on 1 January 2023.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down the arrangements for the implementation of the common European risk classification scheme ('ERCS') set out in Delegated Regulation (EU) 2020/2034.

Article 2

Definitions

For the purposes of this Regulation, the definitions in Article 2 of Delegated Regulation (EU) 2020/2034 apply.

The following definitions also apply:

(1) 'ARMS-ERC methodology' means the methodology developed by the industry working group 'Airline Risk Management Solutions' (ARMS) for assessing operational risks;

(2) 'ATM' means air traffic management as defined in Article 2(10) of Regulation (EC) No 549/2004 of the European Parliament and of the Council ([4]);

(3) 'ATM airborne severity score' means the part of the RAT methodology that assesses the air operation performance of the occurrence;

(4) 'ATM ground severity score' means the part of the RAT methodology that assesses the system performance (procedures, equipment and human) of the ATM system;

([3]) Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

([4]) Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) (OJ L 96, 31.3.2004, p. 1).

(5) 'ATM overall severity score' means the ATM ground severity score and ATM airborne severity score combined into one single score;

(6) 'RAT methodology' means the Risk Analysis Tool methodology developed by Eurocontrol used to classify safety related occurrences in the ATM domain;

(7) 'Eurocontrol' is the European Organisation for the Safety of Air Navigation set up by the International Convention of 13 December 1960 relating to Cooperation for the Safety of Air Navigation ([5]).

Article 3

Review, amendment, and endorsement of the safety risk classification

1. The competent authority of the Member State or the Agency shall review and, if necessary, amend, and endorse the safety risk classification contained in the occurrence report of the occurrence concerned in accordance with the ERCS as set out in Commission Delegated Regulation (EU) 2020/2034.

2. Without prejudice to paragraph 1, the competent authority of the Member State or the Agency shall use the direct conversion procedure set out in the Annex when converting the safety risk classification determined through ARMS/ERC 4x4 or RAT 'ATM Overall' methodologies. For safety risk classifications determined through other methodologies, the competent authority of the Member State or the Agency may use the manual conversion procedure set out in point 2 of the Annex, or other conversion procedures as deemed appropriate, as long as an equivalent ERCS classification is achieved.

Article 4

Monitoring and improvement of the ERCS

1. On 31 March 2026 and every 5 years thereafter, each Member State shall provide the Commission and the Agency with a report on the use of the ERCS.

2. The Agency shall review the information received from Member States in accordance with paragraph 1 of this Article, as well as other information that the Agency may receive regarding the implementation of the ERCS. The review by the Agency may take account of the expertise of the network of aviation safety analysts (NoA) referred to in Article 14(2) of Regulation (EU) No 376/2014 and relevant expert groups if established by the Agency.

Article 5

Monitoring of compatibility with other risk classification schemes

1. The conversion procedures set out in the Annex shall be subject to regular review by the Agency to ensure its continuing relevance. The review may take account of the expertise of the NoA and relevant expert groups if established by the Agency.

2. When applicable, Member States shall notify to the Commission and the Agency the use of the manual conversion procedure set out in point 2 of the Annex and other conversion procedures referred to in Article 3(2) of this Regulation.

Article 6

Entry into force

This Regulation shall enter into force on 1 January 2023.

([5]) Convention modified by the protocol of 12 February 1981 and revised by the protocol of 27 June 1997.

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

Done at Brussels, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Conversion procedures from the Risk Analysis Tool (RAT) and Aviation Risk Management Solutions – Event Risk Classification (ARMS-ERC) scores into the European Risk Classification Scheme (ERCS) scores

This Annex lays down conversion procedures from RAT and ARMS ERC scores to the ERCS score ([1]) defined in Step 2 of the Annex to Commission Delegated Regulation (EU) 2020/2034.

The following conversion procedures provide either a direct or a manual conversion to obtain an ERCS classification equivalent to the RAT and/or ARMS – ERC scores in accordance with Article 3 of this Regulation.

1. **DIRECT CONVERSION**

The mandatory conversion procedure consists of the following two workflows:

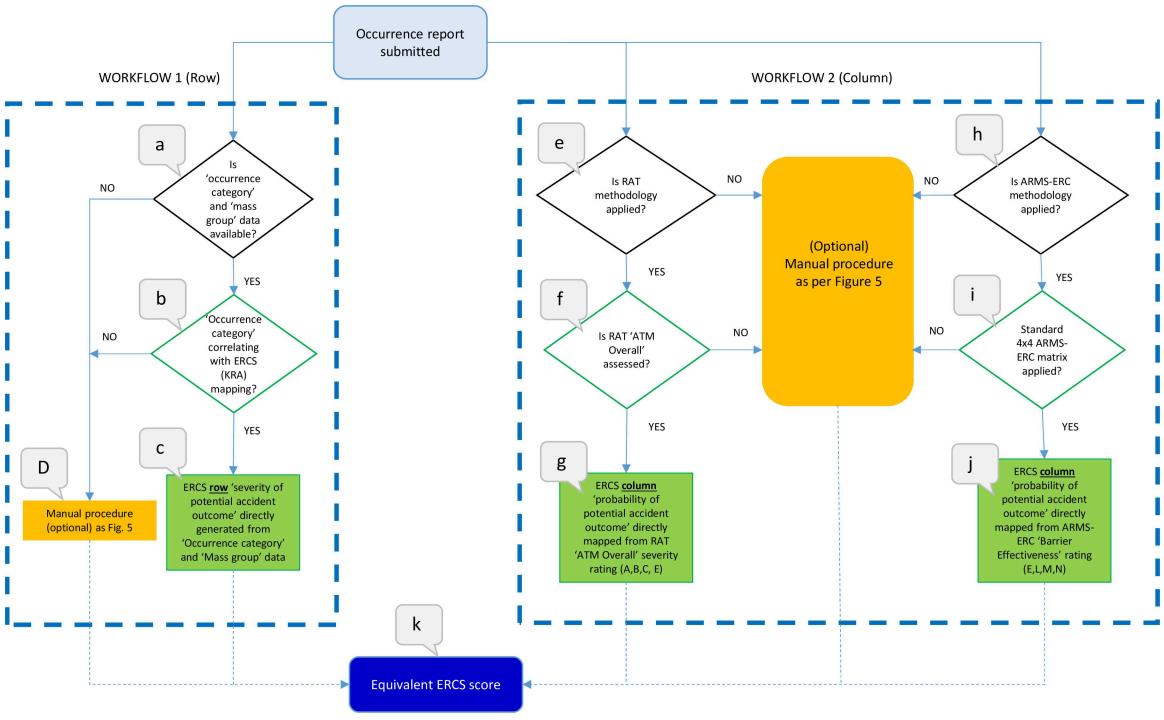
— Workflow 1 - provides a direct conversion to obtain the ERCS severity score,

— Workflow 2 - provides direct conversion to obtain the ERCS probability score.

Figure 1 shows an overview of the procedures. The starting point of the process is the 'occurrence report submitted' box and the output the 'Equivalent ERCS score' box. The dotted lines in Figure 1 indicate that only one source for each process result is required.

Figure 1

Conversion procedures



1.1. ***WORKFLOW 1 – ERCS severity score***

a. **'Occurrence category' and 'Mass group' information**

— If the occurrence report contains information on the 'occurrence category' of the occurrence and the 'mass group', then these can be converted into the 'Severity of potential accident outcome' ERCS score. The next step is (b) of Figure 1.

([1]) The ERCS score is a two-digit value where the first digit corresponds to the alphabetic value resulting from the calculation of the severity of the occurrence (severity score A to X) and the second digit represents the numerical value from the calculation of the corresponding score of the occurrence (probability).

— If the occurrence report contains no information about the 'occurrence category' or the 'mass group', or both, direct conversion is not possible. If the manual conversion described in point 2 of this Annex is used, then next step is (D) of Figures 1 and 5.

b. **'Occurrence category' and ERCS Key Risk Area (KRA) conversion**

— If the 'occurrence category' of the occurrence report corresponds directly to the one of the ERCS Key Risk Areas defined in point 1.2 of Annex to Delegated Regulation (EU) 2020/2034 then the next step is (c) of Figure 1.

— For occurrence reports with 'occurrence categories' different from the ERCS Key Risk Areas, there is no direct conversion. If the manual conversion described in point 2 of this Annex is used, then the next step is (D) of Figures 1 and 5.

c. **ERCS 'Severity of potential accident outcome' score – direct conversion**

— If the occurrence report contains information about 'occurrence category' and 'mass group' then the severity score is directly converted into an appropriate ERCS 'severity of potential accident outcome' score. The result is (k), which gives the first digit corresponding to the alphabetic value resulting from the calculation of the severity of the occurrence (severity score A to X).

1.2. ***WORKFLOW 2 – ERCS probability score***

e. **Occurrence report scored using RAT**

If the occurrence report has been scored using the RAT methodology ([2]):

— Occurrence reports that have a RAT 'ATM overall' severity score classification can be mapped directly to the ERCS probability columns as explained in step (g) of Figure 2,

— Occurrence reports that only have a RAT 'ATM ground' severity ([3]) score have to be manually converted to provide the ERCS probability score. If the manual conversion described in point 2 of this Annex is used, then next step is (L) of figure 5,

— In the case of occurrence reports coded as 'ATM-specific occurrence', conversion between the RAT and ERCS scores is not possible.

f. **RAT 'ATM overall' severity score**

— If an occurrence report contains the 'ATM overall' severity score, then the next step is (g) of Figure 1.

g. **ERCS column 'Probability of potential accident outcome' converted from RAT 'ATM Overall' value (relevant only for A, B, C, E values)**

For the occurrence reports with an 'ATM Overall' severity score (A, B, C, E) classification, the following direct conversion into ERCS probability categories applies:

([2]) The RAT methodology classifies Air Traffic Management related occurrences.RAT methodology does not score accidents, as it measures only how close the ATM occurrence was to becoming an accident. The RAT methodology is divided into several main elements (i.e. 'ATM ground', 'ATM airborne'), in which each delivers a part of the input for the final RAT 'ATM overall' severity score. In order to achieve 'ATM Overall' severity score, both 'ATM ground' and 'ATM airborne' severity scores must be available.

([3]) The 'severity' under the RAT methodology indicates how bad the actual occurrence was in comparison to other occurrences. The RAT methodology determines 'severity' through an assessment of the defences/barriers.

Figure 2

RAT 'ATM overall' severity score conversion onto the ERCS probability score

ERCS Probability categories

			E		C		B		A	
Corresponding Barrier Score	9	8	7	6	5	4	3	2	1	0
Barrier Weight Sum	17-18	15-16	13-14	11-12	9-10	7-8	5-6	3-4	1-2	0
Probability	10^{-9}	10^{-8}	10^{-7}	10^{-6}	10^{-5}	10^{-4}	10^{-3}	10^{-2}	10^{-1}	1
Description	Remaining barriers preedicted to fail 1 in 1,000M times	Remaining barriers preedicted to fail 1 in 100M times	Remaining barriers preedicted to fail 1 in 10M times	Remaining barriers preedicted to fail 1 in 1M times	Remaining barriers preedicted to fail 1 in 100,000 times	Remaining barriers preedicted to fail 1 in 10,000 times	Remaining barriers preedicted to fail 1 in 1,000 times	Remaining barriers preedicted to fail 1 in 100 times	Remaining barriers preedicted to fail 1 in 10 times	Realised accidents

h. **Occurrence reports classified using the ARMS-ERC methodology**

— For the occurrence reports that have been scored according to the ARMS-ERC, the next step is (i) of Figure 1.

— For the occurrence reports that have not been scored according to the ARMS-ERC methodology, the next step is (M) of Figure 5.

i. **Standard 4x4 ARMS-ERC matrix**

If the 4x4 ARMS-ERC matrix depicted in Figure 3 is used to score the occurrence report, then the next step is (j) of Figure 1.

Figure 3

Standard 4x4 ARMS-ERC matrix

Question 2

What was the effectiveness of the remaining barriers between this event and the most probable accident scenario?

Effective	Limited	Minimal	Not effective
50	102	502	2500
10	21	101	500
2	4	20	100
1			

Question 1

If this event had escalated into an accident, what would have been the most probable outcome?

		Typical accident scenarios
Catastrophic Accident	Loss of aircraft or multiple fatalities (3 or more)	Loss of control, mid air collision, uncontrollable fire on board, explosions, total structural failure of the aircraft, collision with terrain
Major Accident	1 or 2 fatalities, multiple serious injuries, major damage to the aircraft	High speed taxiway collision, major turbulence injuries
Minor Injuries or damage	Minor injuries, minor damage to aircraft	Pushback accident, minor weather damage
No accident outcome	No potential damage or injury could occur	Any event which could not escalate into an accident, even if it may have operational consequences (e.g. diversion, delay, individual sickness)

j. **ERCS 'Probability of the potential accident outcome' score – direct conversion**

If the occurrence report contains an ARMS 'Barrier Effectiveness' rating, then to determine the ERCS 'Probability of potential accident outcome' score a following direct conversion to the ERCS matrix is used.

Figure 4

Conversion of ARMS-ERC to ERCS probability categories.

ERCS Probability categories			Effective		Limited		Minimal		Not effective	
Corresponding Barrier Score	9	8	7	6	5	4	3	2	1	0
Barrier Weight Sum	17-18	15-16	13-14	11-12	9-10	7-8	5-6	3-4	1-2	0
Probability	10^{-9}	10^{-8}	10^{-7}	10^{-6}	10^{-5}	10^{-4}	10^{-3}	10^{-2}	10^{-1}	1
Description	Remaining barriers preedicted to fail 1 in 1,000M times	Remaining barriers preedicted to fail 1 in 100M times	Remaining barriers preedicted to fail 1 in 10M times	Remaining barriers preedicted to fail 1 in 1M times	Remaining barriers preedicted to fail 1 in 100,000 times	Remaining barriers preedicted to fail 1 in 10,000 times	Remaining barriers preedicted to fail 1 in 1,000 times	Remaining barriers preedicted to fail 1 in 100 times	Remaining barriers preedicted to fail 1 in 10 times	Realised accidents

k. **Equivalent ERCS Score**

The combination of the ERCS 'Severity of potential accident outcome' and 'Probability of potential accident outcome' scores are combined in the ERCS matrix to generate an equivalent ERCS score as laid down in Step 2 of Annex to Delegated Regulation (EU) 2020/2034.

2. **MANUAL CONVERSION**

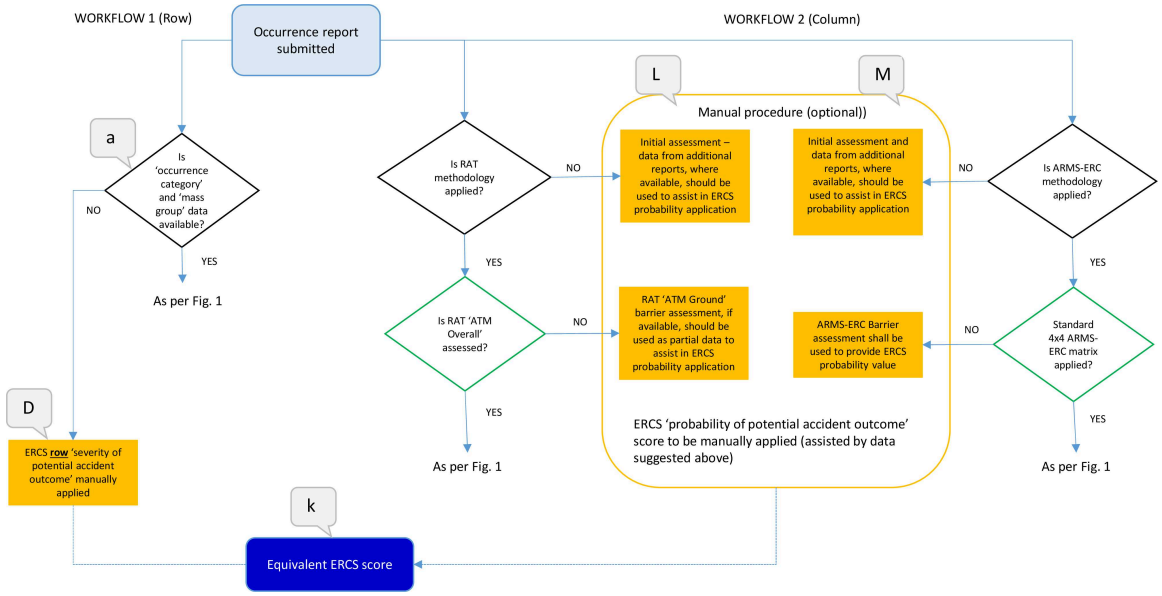
This manual conversion consists of the following two workflows:

— Workflow 1 - provides a manual conversion to obtain the ERCS severity score,

— Workflow 2 - provides a manual conversion to obtain the ERCS probability score.

Figure 5

Manual conversion



2.1. ***WORKFLOW 1***

D. **ERCS 'Severity of potential accident outcome' score – manual conversion**

— If the occurrence report contains no information about the 'occurrence category' or 'mass group', or both, then the ERCS methodology defined in Annex to Delegated Regulation (EU) 2020/2034 applies to determine the 'Potential Accident Outcome' or Key Risk Area. The final result is (k), which gives the first digit corresponding to the alphabetic value resulting from the calculation of the severity of the occurrence (severity score A to X).

2.2. ***WORKFLOW 2***

L. **ERCS column 'Probability of potential accident outcome' – manual procedure**

— For the occurrence reports containing no 'ATM overall' severity there is no direct conversion to the ERCS 'Probability of potential accident outcome' score.

The 'ATM ground' severity can however provide for a partial conversion by mapping the 'ATM ground' barrier assessment and the ERCS barrier assessment process defined in point 2.1.3 of Annex to Delegated Regulation (EU) 2020/2034.

M. **ERCS 'Probability of potential accident outcome' score – manual process**

If the occurrence reports do not use the 4x4 ARMS-ERC matrix to score the occurrence, to generate an ERCS 'Probability of potential accident outcome' score the ARMS-ERC barrier assessment value is converted into the ERCS barrier assessment laid down in point 2.1.3 of Annex to Delegated Regulation (EU) 2020/2034.

k. **Equivalent ERCS Score**

The combination of the ERCS 'Severity of potential accident outcome' and 'Probability of potential accident outcome' scores are combined in the ERCS matrix to generate an equivalent ERCS score as laid down in Step 2 of Annex to Delegated Regulation (EU) 2020/2034.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2083

of 26 November 2021

suspending commercial policy measures concerning certain products originating in the United States of America imposed by Implementing Regulations (EU) 2018/886 and (EU) No 2020/502

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 654/2014 of the European Parliament and of the Council of 15 May 2014 concerning the exercise of the Union's rights for the application and enforcement of international trade rules and amending Council Regulation (EC) No 3286/94 laying down Community procedures in the field of common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization (WTO) ([1]), and in particular Article 7(3) thereof,

Whereas:

(1) On 20 June 2018, the Commission adopted Implementing Regulation (EU) 2018/886 ([2]) on certain commercial policy measures concerning certain products originating in the United States of America that provides for the application of additional customs duties on imports into the Union of a number of products originating in the United States as follows:

(a) at the first stage, the additional ad valorem duties of a rate of 10 % and 25 % on imports of the products listed in Annex I to that Regulation, as specified therein, entered into force on 21 June 2018 and were set to apply until the United States ceases to apply its safeguard measures to products from the Union;

(b) at the second stage, further additional ad valorem duties of a rate of 10 %, 25 %, 35 % and 50 % on imports of the products listed in Annex II to that Regulation, as specified therein, would apply from 1 June 2021 or upon the adoption by, or notification to, the WTO Dispute Settlement Body of a ruling that the United States' safeguard measures are inconsistent with the relevant provisions of the Agreement establishing the World Trade Organization ('WTO Agreement'), if that is earlier, until the United States ceases to apply its safeguard measures to products from the Union.

(2) On 7 April 2020, the Commission adopted Implementing Regulation (EU) 2020/502 ([3]) that provides for the application of additional customs duties on imports into the Union of certain products originating in the United States, as follows:

(a) at the first stage, the additional ad valorem duties of a rate of 20 % and 7 % on imports of the products specified in Article 1(2), point (a), of that Regulation, entered into force on 8 May 2020 and were set to apply until the United States ceases to apply its safeguard measures to products from the Union;

([1]) OJ L 189, 27.6.2014, p. 50; amended by Regulation (EU) 2015/1843 of the European Parliament and of the Council of 6 October 2015 (OJ L 272, 16.10.2015, p. 1) and by Regulation (EU) 2021/167 of the European Parliament and the Council of 10 February 2021 (OJ L 49, 12.2.2021, p. 1).

([2]) Commission Implementing Regulation (EU) 2018/886 of 20 June 2018 on certain commercial policy measures concerning certain products originating in the United States of America and amending Implementing Regulation (EU) 2018/724 (OJ L 158, 21.6.2018, p. 5).

([3]) Commission Implementing Regulation (EU) 2020/502 of 6 April 2020 on certain commercial policy measures concerning certain products originating in the United States of America (OJ L 109, 7.4.2020, p. 10).

(b) at the second stage, a further additional ad valorem duty of 4,4 % on imports of the product specified in Article 1(2), point (b), of that Regulation, should be applied as from 8 February 2023 or upon the adoption by, or notification to, the WTO Dispute Settlement Body of a ruling that the United States' safeguard measures are inconsistent with the relevant provisions of the WTO Agreement, if that is earlier, until the United States' safeguard measures cease to apply.

(3) On 31 May 2021, following the EU-US Joint Statement published on 17 May 2021, the Commission adopted Implementing Regulation (EU) 2021/866 ([4]) on commercial policy measures concerning certain products originating in the United States of America, which suspended the application of the additional ad valorem duties on products listed in Annex II to Implementing Regulation (EU) 2018/886 until 30 November 2021.

(4) The Commission, on behalf of the Union, may amend Implementing Regulations (EU) 2018/886 ([5]) and (EU) 2020/502 ([6]), should it deem that appropriate, to account for any modification of or amendment to the United States' safeguard measures.

(5) On 31 October 2021, the United States announced the following amendments to their respective safeguard measures, to take effect from 1 January 2022:

(i) the United States '*will replace the existing 25 percent tariff on EU steel products under Section 232 with a tariff-rate quota (TRQ).*' The quota is based on historical import volumes of the respective steel products originating in the Union;

(ii) the United States '*will replace the existing 10 percent tariff on EU aluminum products under Section 232 with a tariff-rate quota (TRQ)*'. The quota is based on historical import volumes of the respective aluminium products originating in the Union;

(iii) the United States '*will extend the application of exclusions granted for and utilized in U.S. fiscal year 2021 for steel products imported from the EU for a period of two calendar years without the need to reapply, i.e., until 31 December 2023i*';

(iv) the United States will not apply Section 232 duties on imports from the Union of derivative articles of steel and of derivative articles of aluminium.

(6) Accordingly, the Union should suspend the application of the additional ad valorem duties imposed by Implementing Regulations (EU) 2018/886 and (EU) No 2020/502 for a period until 31 December 2023. The suspension should take place as follows:

(i) the additional ad valorem duties on products listed in Annex I to Implementing Regulation (EU) 2018/886 should be suspended from 1 January 2022;

(ii) the additional ad valorem duties on products listed in Annex II to Implementing Regulation (EU) 2018/886, which are suspended until 30 November 2021, should continue to be suspended from 1 December 2021;

(iii) the additional ad valorem duties on products listed in Article 1(2), points (a) and (b), of Implementing Regulation (EU) 2020/502 should be suspended from 1 January 2022;

(iv) the additional ad valorem duty on the product listed in Article 1(2), point (b), of Implementing Regulation (EU) 2020/502, which are due to apply from 8 February 2023, should be suspended from 8 February 2023.

(7) This suspension would allow the Union and the United States to significantly advance their ongoing cooperation, including with a view of eliminating the respective tariffs. However, it should be noted that the application of the exclusions from the US measures would last only until 31 December 2023. Such exclusions granted to importers in the United States when importing Union products significantly reduce the negative impact of the United States' safeguard measures. Therefore, a suspension until 31 December 2023 is considered as a sufficient and reasonable period and takes due account of the United States' announcements of 31 October 2021.

([4]) Commission Implementing Regulation (EU) 2021/866 of 28 May 2021 suspending commercial policy measures concerning certain products originating in the United States of America imposed by Implementing Regulation (EU) 2018/886 (OJ L 190, 31.5.2021, p. 94).

([5]) Recital 7 of Implementing Regulation (EU) 2018/886.

([6]) Recital 19 of Implementing Regulation (EU) 2020/502.

(8) Article 4(2)(c) of Regulation (EU) No 654/2014 requires the Union's action to be substantially equivalent to the level of concessions or other obligations affected by the safeguard measures of the third country.

(9) The Commission should keep the suspension under review in light of new developments, for instance developments that could deteriorate the situation for the Union exports that remain subject to the safeguard measures of the United States, including any impediments affecting the Union exports. The Commission may amend this Regulation to account for such developments, any modification of or amendment to the United States' safeguard measures.

(10) The suspension is without prejudice to the Union's position that the safeguard measures by the United States remain incompatible with the WTO Agreement.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Trade Barriers Committee, established by Regulation (EU) 2015/1843 of the European Parliament and of the Council ([7]),

HAS ADOPTED THIS REGULATION:

Article 1

The application of the additional ad valorem duties of a rate of 10 % and 25 % on imports of the products listed in Annex I to Implementing Regulation (EU) 2018/886 shall be suspended from 1 January 2022 until 31 December 2023.

The application of additional ad valorem duties of a rate of 10 %, 25 %, 35 % and 50 % on imports of the products listed in Annex II to Implementing Regulation (EU) 2018/886 shall be suspended from 1 December 2021 until 31 December 2023.

Without prejudice to any further suspension, modification, including earlier reinstatement, the duties provided for in Implementing Regulation (EU) 2018/886 shall apply with effect from and including 1 January 2024.

Article 2

The application of Implementing Regulation (EU) 2020/502 shall be suspended until 31 December 2023, as follows:

(a) the additional ad valorem duties of a rate of 20 % and 7 % on imports of the products specified in Article 1(2), point (a), of Implementing Regulation (EU) 2020/502 from 1 January 2022;

(b) the additional ad valorem duty of a rate of 4,4 % on imports of the product specified in Article 1(2), point (b), of Implementing Regulation (EU) 2020/502 from 8 February 2023.

Without prejudice to any further suspension, modification, including earlier reinstatement, the duties provided for in Implementing Regulation (EU) 2020/502 shall apply with effect from and including 1 January 2024.

Article 3

This Regulation shall enter into force on 30 November 2021.

([7]) Regulation (EU) 2015/1843 of the European Parliament and of the Council of 6 October 2015 laying down Union procedures in the field of the common commercial policy in order to ensure the exercise of the Union's rights under international trade rules, in particular those established under the auspices of the World Trade Organization(OJ L 272, 16.10.2015, p. 1).

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

Done at Brussels, 26 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

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

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN