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DECISIONS

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⁽¹⁾ Text with EEA relevance.

EN

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

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

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/1422

of 26 April 2021

amending Delegated Regulation (EU) 2019/624 as regards certification in case of slaughter at the holding of provenance*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 18(7)(d) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States in order to verify compliance with the rules to apply Union legislation in the areas of food and food safety at all stages of the production, processing and distribution process. These official controls include ante-mortem inspection of animals intended for slaughter.
- (2) Commission Delegated Regulation (EU) 2019/624 ⁽²⁾ lays down criteria and conditions to determine when ante-mortem inspections may be performed at the holding of provenance.
- (3) Commission Delegated Regulation (EU) 2021/1374 ⁽³⁾, amending Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽⁴⁾ allows the slaughter of domestic bovine and porcine animals, and domestic solipeds on the holding of provenance under certain conditions. These conditions include that animals are to undergo ante-mortem inspection prior to slaughter and the result of such inspection is to be attested in an official certificate accompanying the bodies of the slaughtered animals to an approved slaughterhouse in accordance with Article 6 of Delegated Regulation (EU) 2019/624.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

⁽³⁾ Commission Delegated Regulation (EU) 2021/1374 of 12 April 2021 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin (OJ L 297, 20.8.2021, p. 1).

⁽⁴⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

- (4) The scope of Article 6 of Delegated Regulation (EU) 2019/624 should be extended to cover also to domestic bovine and porcine animals, and domestic solipeds to ensure that in case of their slaughter at the holding of provenance, the safety of the meat is not jeopardised.
- (5) Delegated Regulation (EU) 2019/624 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Article 6 of Delegated Regulation (EU) 2019/624 is amended as follows:

- (1) paragraph 1 is replaced by the following:

‘1 The competent authorities shall apply the specific criteria and conditions laid down in this Article in the relevant cases of poultry, farmed game, domestic bovine and porcine animals and domestic solipeds.’;

- (2) point 3 is replaced by the following:

‘3 In the case of domestic bovine and porcine animals, domestic solipeds and farmed game, slaughtered at the holding of provenance in accordance with Chapter VIa of section I or point 3 of Section III of Annex III to Regulation (EC) No 853/2004, the official certificate completed in accordance with the model official certificate set out in Chapter 3 of Annex IV to Commission Implementing Regulation (EU) 2020/2235 * shall accompany the animals to the slaughterhouse or be sent in advance in any format, instead of the certificate referred to in Article 5(2)(f) to this Regulation.

* Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).’

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 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/1423**of 21 May 2021****laying down the detailed arrangements under Directive (EU) 2021/555 of the European Parliament and of the Council for the systematic exchange, by electronic means, of information relating to refusals to grant authorisations to acquire or possess certain firearms****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on the control of the acquisition and possession of weapons ⁽¹⁾, and in particular Article 18(5), the second subparagraph, thereof,

Whereas:

- (1) Articles 9 and 10 of Directive (EU) 2021/555 provide for the grant of authorisations to acquire or possess firearms classified in category A or category B, including grants made by confirming, renewing or prolonging an existing authorisation. Chapter 2 of that Directive also provides for the periodic review and withdrawal of such authorisations.
- (2) Article 18(4) of Directive (EU) 2021/555 requires the competent authorities of the Member States to exchange information with regard to refusals to grant authorisations as provided for in Articles 9 and 10 of that Directive on grounds of security or relating to the reliability of the person concerned. Since Directive (EU) 2021/555 does not define the concepts of grounds of security or relating to the reliability of the person concerned, Member States should take into account the objectives of Directive (EU) 2021/555 and in particular of Article 6(1)(b) thereof, when interpreting those concepts.
- (3) The obligation under Article 18(4) of Directive (EU) 2021/555 with regard to refusals to grant authorisations is understood to cover any administrative or judicial decision made by a public authority of a Member State, the object or effect of which is to preclude a person from acquiring or possessing a firearm falling within the scope of Article 9 or 10 of that Directive, whether or not following a request for authorisation, whether or not relating to specific firearms and whether or not made pursuant to powers arising under that Directive specifically. For example, the obligation covers a blanket ban on the acquisition or possession of firearms by a particular person, regardless of whether that person had previously applied for an authorisation. It also covers any administrative or judicial decision withdrawing an existing authorisation or refusing to confirm, renew or prolong an existing authorisation. Article 18(4) of Directive (EU) 2021/555 requires competent authorities to exchange information on all these various types of decision, provided the decision was made either on grounds of security or relating to the person's reliability.
- (4) Article 18(5) of Directive (EU) 2021/555 requires the Commission to provide for a system for the exchange of any information mentioned in that Article. This would therefore include a system for exchange of the information mentioned in paragraph 4 of that Article relating to refusals to grant authorisations.

⁽¹⁾ OJ L 115, 6.4.2021, p. 1.

- (5) The administrative cooperation provisions in Article 18 of Directive (EU) 2021/555 relating to the transfer of firearms from one Member State to another are the subject of a pilot project under Article 4 of Regulation (EU) No 1024/2012 of the European Parliament and of the Council ⁽²⁾. The Internal Market Information System established by that Regulation could also be an effective tool in implementing the administrative cooperation provision set out in Article 18(4) of Directive (EU) 2021/555 relating to refusals to grant authorisations. Accordingly, Commission Implementing Decision (EU) 2021/1427 ⁽³⁾ makes that provision subject to a pilot project under Article 4 of Regulation (EU) No 1024/2012. In order to protect the personal data of individuals and their rights to privacy, that Implementing Decision specifies that the Internal Market Information System will only allow national authorities to check whether information relating to specific individuals is included in the Internal Market Information System, not to search by reference to more general criteria. Regulation (EU) No 1024/2012 also contains specific safeguards governing access to and the processing of personal data in the Internal Market Information System, for example the rules under Article 9(4) allowing access on a need-to-know basis only. It is therefore appropriate to identify the Internal Market Information System as the system to be used by the competent authorities of the Member States for the purposes of the exchange of information relating to refusals to grant authorisations, and to lay down the detailed arrangements for such exchanges.
- (6) In order to avoid a disproportionate administrative burden on Member States, the detailed arrangements laid down by this Regulation for the exchange of information via the Internal Market Information System should only apply to refusal decisions made by national administrative or judicial authorities on or after the date of application of this Regulation.
- (7) In order to respect the data protection rights of the individuals concerned, the information to be entered into the Internal Market Information System by a competent authority should be confined to the minimum necessary to enable the competent authorities of other Member States to verify whether a given person is or has been the subject of a refusal decision made on grounds of security or relating to their reliability. The information should therefore only include personal data such as a person's name, their place and country of birth and their nationality.
- (8) Similarly, in order to protect the personal data of individuals and their rights to privacy, information on the specific reasons why a refusal decision was made should not be recorded in the Internal Market Information System. In particular, information on a person's criminal record or their medical or psychological status should not be recorded in the Internal Market Information System. Where a competent authority in a Member State needs further information about the reasons for a refusal decision made in another Member State, that competent authority would be able to contact the relevant authority in the other Member State outside of the Internal Market Information System using an appropriate means of communication and in compliance with relevant data protection legislation. To that end, when recording a refusal decision in the Internal Market Information System, Member States should indicate the name and contact details of the administrative or judicial authority that made the refusal decision and, where different, the name and contact details of the authority that can be contacted by the competent authorities of other Member States when they are seeking further information about the refusal decision.
- (9) Refusals should be recorded in the Internal Market Information System even if they may be subject to administrative or judicial appeal. If a refusal decision is annulled or otherwise held to be invalid after information relating to it has been entered in the Internal Market Information System, the relevant authority should be required to remove the entry relating to that refusal no later than 30 calendar days after the refusal decision was annulled or found to be invalid.

⁽²⁾ Regulation (EU) No 1024/2012 of the European Parliament and of the Council of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC (OJ L 316, 14.11.2012, p. 1).

⁽³⁾ Commission Implementing Decision (EU) 2021/1427 of 21 May 2021 on a pilot project to implement the administrative cooperation provisions relating to refusals to grant authorisations set out in Directive (EU) 2021/555 by means of the Internal Market Information System (See page 20 of this Official Journal).

- (10) In order to ensure that the information contained in the Internal Market Information System remains accurate and complete, Member States should be required to update their entries whenever a relevant change occurs. For example, if a 5-year ban were subsequently reduced to 3 years, the Member State would need to update the entry to record the new end date of the ban. In the case of bans of more than 10 years, including indefinite bans, Member States should also be required to review the entry at least once every 10 years and confirm that it remains valid (or update it accordingly).
- (11) It is necessary to determine the period of time that information on a given refusal is to remain accessible by Member States in the Internal Market Information System. That period has to strike a balance between the need to make the information exchange system as effective and useful as possible for Member States and the need to protect the personal data of individuals and their rights to privacy. A refusal could be a simple, one-off decision rejecting a request for authorisation and leaving the applicant free to re-apply for authorisation at any time in the future, or it could be a decision with on-going effect, such as a rejection decision that has the effect, directly or indirectly, of barring the applicant from re-applying for authorisation for a period of time or a decision banning a person from possessing firearms for a fixed or indefinite period. Taking into account current practices in Member States for the various types of refusal that could occur, it is appropriate to provide in this Regulation for information on a refusal decision to remain accessible in the Internal Market Information System for a period of 10 years after the refusal decision was made, in the case of simple, one-off decisions, or for a period of 10 years after the refusal decision ceased to have effect, in the case of decisions with on-going effect.
- (12) The Commission should review this Regulation within two years of its date of application in order to take into account possible implementation issues that could be raised by Member States.
- (13) Application of this Regulation should be deferred in order to allow Member States sufficient time to put in place the necessary procedures,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation applies to the exchange, via the system referred to in Article 18(5) of Directive (EU) 2021/555, of information concerning refusals to grant authorisations as provided for in Articles 9 and 10 of that Directive on grounds of security or relating to the reliability of the person concerned.

A refusal falls within the scope of this Regulation only if the administrative or judicial decision by which the person concerned is precluded from acquiring or possessing the relevant firearms (referred to in this Regulation as 'the refusal decision') was made on or after the date of application of this Regulation.

Article 2

The electronic exchange system

For the purposes of exchanging information to which this Regulation applies, the system referred to in Article 18(5) of Directive (EU) 2021/555 shall be the Internal Market Information System as provided for in Implementing Decision (EU) 2021/1427.

*Article 3***Information to be exchanged**

1. The information to be exchanged pursuant to Article 18(4) of Directive (EU) 2021/555 with regard to a refusal to grant an authorisation as provided for in Article 9 or 10 of that Directive on grounds of security or relating to the reliability of the person concerned shall comprise the following:

- (a) the name of the person concerned;
- (b) the date of birth of that person;
- (c) the place and country of birth of that person;
- (d) the nationality of that person;
- (e) the date on which the refusal decision was made;
- (f) the national reference number or other unique identifier of the refusal decision, if such a number or identifier has been allocated to the refusal decision in the Member State where it was made;
- (g) the name and contact details of the administrative or judicial authority that made the refusal decision and, if different, the name and contact details of the authority to be contacted in order to seek further information about the refusal;
- (h) to which one of the following three categories the refusal decision belongs:
 - (i) refusal decisions that operate to preclude a person from acquiring or possessing a firearm indefinitely, without a fixed end date;
 - (ii) refusal decisions that operate to preclude a person from acquiring or possessing a firearm for a defined period, with a fixed end date (including decisions rejecting a request for authorisation that have the effect of barring the person from re-applying for authorisation within a defined period, with a fixed end date);
 - (iii) refusal decisions that do not fall within either point (i) or point (ii);
- (i) if the refusal decision falls within point (h)(ii), the fixed end date in question;
- (j) to which one of the following three categories the refusal decision belongs:
 - (i) refusal decisions made in response to a request for authorisation as provided for in Article 9 or 10 of Directive (EU) 2021/555, or in response to a request to confirm, renew or prolong such an authorisation;
 - (ii) refusal decisions withdrawing an authorisation granted, confirmed, renewed or prolonged under Article 9 or 10 of Directive (EU) 2021/555;
 - (iii) refusal decisions that do not fall within either point (i) or point (ii).

2. In addition to information mentioned in paragraph 1, points (a) to (d), Member States may choose to provide further identification details of the person concerned, such as a tax code, passport number or identity card number, where necessary to correctly identify that person.

3. The information listed in paragraph 1 and, where applicable, the further details referred to in paragraph 2 shall be entered in the Internal Market Information System within 30 calendar days of the date on which the refusal decision was made and shall be immediately accessible by the competent authorities of all Member States.

*Article 4***Obligations to remove, update and review information**

1. Where a refusal decision is annulled or otherwise held to be invalid after information relating to it has been entered in the Internal Market Information System, the competent authority shall remove the entry from the Internal Market Information System within 30 calendar days of the annulment or finding of invalidity.

2. Where, in circumstances other than those referred to in paragraph 1, information entered in the Internal Market Information System relating to a refusal decision ceases to be accurate and complete for whatever reason, including as a result of the subsequent revocation or amendment of the refusal decision, the competent authority shall update the information in the Internal Market Information System relating to that refusal within 30 calendar days from the date on which the information ceased to be accurate or complete. In a case involving revocation of the refusal decision, the date from which the revocation takes effect ('the revocation date') shall be added to the entry in the Internal Market Information System.

3. In the case of an entry in the Internal Market Information System for a refusal decision falling within Article 3(1)(h)(i), the competent authority shall review the entry at least once every 10 years from the date on which the refusal decision was made and shall update the entry, immediately following each such review, to confirm that the refusal decision remains in force or, if the decision has been revoked, to record the revocation date in accordance with paragraph 2.

4. In the case of an entry for a refusal decision falling within Article 3(1)(h)(ii) with a fixed end date that is more than 10 years after the date on which the refusal decision was made, the competent authority shall review the entry at least once every 10 years from the date on which the refusal decision was made, up until the date recorded in the Internal Market Information System as the fixed end date, and shall update the entry, immediately following each such review, to confirm that the refusal decision remains in force or, if the decision has been revoked, to add the revocation date in accordance with paragraph 2.

5. If a refusal decision is revoked, the obligation in paragraph 3 or, as applicable, paragraph 4 shall cease to apply to the entry once it has been updated to add the revocation date in accordance with paragraph 2.

Article 5

Period for which information remains accessible in the Internal Market Information System

1. Information exchanged via the Internal Market Information System in accordance with this Regulation shall remain accessible in the Internal Market Information System for 10 years from whichever of the following dates is the latest one, insofar as they are applicable to the refusal decision in question and taking account of any updates made pursuant to Article 4:

- (a) the date recorded in the Internal Market Information System as the date on which the refusal decision was made;
- (b) the date recorded in the Internal Market Information System as the date on which the entry was last updated to confirm that the refusal decision remains in force;
- (c) the date recorded in the Internal Market Information System as the fixed end date of the refusal decision.

However, in the case of an entry in the Internal Market Information System subject to the obligation under Article 4(4), if the competent authority fails to comply with that obligation, the entry shall cease to be accessible in the Internal Market Information System on expiry of the deadline set by that Article for compliance with that obligation.

2. Notwithstanding paragraph 1, for any refusal decision for which a date is recorded in the Internal Market Information System as the date from which revocation of the decision takes effect, the entry shall cease to be accessible in the Internal Market Information System on expiry of the period of 10 years from the date so recorded in the Internal Market Information System as the revocation date.

Article 6

The Commission shall review this Regulation within two years of its date of application.

Article 7

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

It shall apply from 31 January 2022.

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

Done at Brussels, 21 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1424**of 31 August 2021****concerning the renewal of the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening, and repealing Regulation (EU) No 998/2010 (holder of authorisation Lactosan GmbH & Co KG)****(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 and renewing such authorisation.
- (2) The preparation of *Enterococcus faecium* DSM 7134 was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EU) No 998/2010 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of the preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening, requesting the additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2021 ⁽³⁾ that the applicant had provided evidence that the additive complies with the existing conditions of authorisation. The Authority further concluded that the preparation of *Enterococcus faecium* DSM 7134 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the preparation is not irritant to skin and eyes, but it should be considered a potential skin sensitiser and a respiratory 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 verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of *Enterococcus faecium* DSM 7134 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed.
- (6) As a consequence of the renewal of the authorisation of the preparation of *Enterococcus faecium* DSM 7134 as a feed additive, Regulation (EU) No 998/2010 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 998/2010 of 5 November 2010 concerning the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening (holder of the authorisation Lactosan GmbH & Co KG) (OJ L 290, 6.11.2010, p. 22).

⁽³⁾ EFSA Journal 2021;19(3):6451.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EU) No 998/2010 is repealed.

Article 3

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, 31 August 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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives									
Functional group: gut flora stabilisers									
4b1841	Lactosan GmbH & Co KG	Enterococcus faecium DSM 7134	Additive composition Preparation of Enterococcus faecium DSM 7134 containing a minimum of: Powder: 1 × 10 ¹⁰ CFU/g of additive Granules (microencapsulated): 1x10 ¹⁰ CFU/g of additive Characterisation of the active substance Viable cells of Enterococcus faecium DSM 7134 Analytical method ⁽¹⁾ For enumeration: Spread plate method using bile esculin azid agar (EN 15788). For identification: Pulsed Field Gel Electrophoresis (PFGE).	Chickens for fattening	-	5 × 10 ⁸	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the following permitted coccidiostats: robenidine hydrochloride, maduramicin ammonium, diclazuril, decoquinate, halofuginone hydrobromide, monensin sodium and lasalocid A sodium. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing and skin protection.	21 September 2031

⁽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) 2021/1425**of 31 August 2021****concerning the authorisation of manganese chelate of lysine and glutamic acid as 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 manganese chelate of lysine and glutamic acid. The 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 preparation of manganese chelate of lysine and glutamic acid as a feed additive for all animal species to be classified in the additive category 'nutritional additives' and the functional group 'compounds of trace elements'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 10 January 2020 ⁽²⁾ and 27 January 2021 ⁽³⁾ that, under the proposed conditions of use, manganese chelate of lysine and glutamic acid does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that the handling of the additive poses a risk to users by inhalation and that it should be considered as an eye irritant, skin and respiratory 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 concluded that the additive is efficacious in chickens for fattening; this conclusion can be extended to all other animal species. 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.
- (5) The assessment of manganese chelate of lysine and glutamic acid shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (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 preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(2):6001.

⁽³⁾ EFSA Journal 2021;19(3):6454.

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, 31 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives									
Functional group: compounds of trace elements									
3b509	-	Manganese chelate of lysine and glutamic acid	<i>Additive composition:</i> Preparation of chelates of manganese with lysine and chelates of manganese with glutamic acid in a ratio of 1:1 as a powder with a manganese content between 15 and 17 %, a lysine content between 20 and 21,5 %, a glutamic acid content between 22 and 24 %, a maximum of 3,5 % moisture and a maximum of 4 ppm nickel.	All animal species	-	-	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing.	21 September 2031
			<i>Characterisation of the active substances:</i> Chemical formulas: Manganese-2,6- diaminohexanoic acid, chloride and hydrogen sulfate salt: C₆H₁₉ClN₂O₈SMn Manganese-2-aminopentanedioic acid, sodium and hydrogen sulfate salt:						

			C ₅ H ₁₀ NNaO ₉ SMn						
			<i>Analytical methods</i> (*): For the quantification of total manganese in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621); For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621). For the quantification of the lysine and glutamic acid content in the feed additive:						

			— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For proving the chelated structure of the feed additive: — mid-infrared (IR) spectrometry together with the determination of the content of the trace element and lysine and glutamic acid in the feed additive							
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(*) 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) 2021/1426**of 31 August 2021****concerning the authorisation of serine protease produced by *Bacillus licheniformis* DSM 19670 as a feed additive for chickens for fattening (holder of the authorisation: DSM Nutritional Products Ltd., represented in the Union by DSM Nutritional Products Sp. z o.o.)****(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 a preparation of serine protease produced by *Bacillus licheniformis* (DSM 19670). The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of serine protease produced by *Bacillus licheniformis* (DSM 19670) as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2021 ⁽²⁾ that, under the proposed conditions of use, serine protease produced by *Bacillus licheniformis* DSM 19670 does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that that additive should be considered a skin irritant, potential skin sensitiser and a respiratory 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 that additive. The Authority concluded that the additive has the potential to be efficacious for chickens for fattening. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of serine protease produced by *Bacillus licheniformis* DSM 19670 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(3):6448.

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, 31 August 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
						Units of activity/kg of complete feed with a moisture content of 12 %			

Category of zootechnical additives**Functional group: digestibility enhancers**

4a13	DSM Nutritional Products Ltd., represented in the Union by DSM Nutritional Products Sp. z o. o.	Serine protease (EC 3.4.21.-)	<i>Additive composition:</i> Solid and liquid preparation of serine protease (EC 3.4.21.-) produced by <i>Bacillus licheniformis</i> DSM 19670 having a minimum activity of 75 000 PROT ⁽¹⁾ /g	Chickens for fattening	-	15 000 PROT		1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	21 September 2031
			<i>Characterisation of the active substance:</i> Serine protease (EC 3.4.21.-) produced by <i>Bacillus licheniformis</i> DSM 19670						
			<i>Analytical method ⁽²⁾</i> For the quantification of the serine protease activity in the feed additive, premixtures, compound feed and feed materials: — colourimetric method based on the enzymatic reaction of serine protease on the Suc-Ala-Ala-Pro-Phe-pNA substrate.						

⁽¹⁾ One PROT is the amount of enzyme that releases 1 µmol of p-nitroaniline from 1mM substrate (Suc-Ala-Ala-Pro-Phe-pNA) per minute at pH 9,0 and temperature 37 °C.

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

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/1427

of 21 May 2021

on a pilot project to implement the administrative cooperation provisions relating to refusals to grant authorisations set out in Directive (EU) 2021/555 of the European Parliament and of the Council by means of the Internal Market Information System

(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 1024/2012 of the European Parliament and of the Council of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC ('the IMI Regulation') ⁽¹⁾, and in particular Article 4(1) thereof,

Whereas:

- (1) The Internal Market Information System ('IMI') established by Regulation (EU) No 1024/2012 is a software application that is accessible via the internet and was developed by the Commission, in cooperation with the Member States, to help Member States comply with information exchange requirements in Union acts by providing a centralised communication mechanism to facilitate the cross-border exchange of information and mutual assistance.
- (2) Article 4(1) of Regulation (EU) No 1024/2012 allows the Commission to carry out pilot projects to assess the effectiveness of IMI in the implementation of administrative cooperation provisions in Union acts not listed in the Annex to that Regulation.
- (3) Directive (EU) 2021/555 of the European Parliament and of the Council ⁽²⁾ provides for administrative cooperation between Member States in relation to controls on the acquisition and possession of firearms. Article 18 of that Directive requires the Commission to lay down detailed arrangements for the systematic exchange, by electronic means, of information mentioned in that Article. The Commission has adopted Delegated Regulation (EU) 2021/1423 ⁽³⁾ laying down detailed arrangements for the systematic exchange of the information mentioned in paragraph 4 of that Article relating to refusals to grant authorisations. IMI could be an effective tool in the implementation of the administrative cooperation provision falling within the scope of that Delegated Regulation. That administrative cooperation provision should therefore be the subject of a pilot project under Article 4 of Regulation (EU) No 1024/2012.
- (4) IMI should provide the technical functionality, including the establishment of a repository, to allow the competent authorities of the Member States to meet their obligations set out in Delegated Regulation (EU) 2021/1423.
- (5) IMI should facilitate administrative cooperation between Member States' authorities by allowing them to search the IMI repository in order to check whether a particular individual has been precluded from acquiring or possessing a firearm. In order to respect the data protection rights of the individuals in relation to whom data is recorded in the repository, national authorities should only be able to consult information relating to a particular individual. They should not be able to search by other criteria, for example all refusals for a given period or for a given Member State.

⁽¹⁾ OJ L 316, 14.11.2012, p. 1.

⁽²⁾ Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).

⁽³⁾ Commission Delegated Regulation (EU) 2021/1423 of 21 May 2021 laying down the detailed arrangements under Directive (EU) 2021/555 of the European Parliament and of the Council for the systematic exchange, by electronic means, of information relating to refusals to grant authorisations to acquire or possess certain firearms (see page 3 of this Official Journal).

- (6) To ensure that personal data exchanged as part of the pilot project is blocked as soon as it is no longer needed in accordance with Article 14 of Regulation (EU) No 1024/2012, the date when such data is to be considered for the purposes of that Article as no longer needed should be made clear. That date should correspond to the date determined in accordance with Article 5 of Delegated Regulation (EU) 2021/1423 as the date when information relating to the refusal decision is to cease to remain accessible in IMI. It is also appropriate to clarify that, once the data is blocked, it is to be automatically deleted in IMI three years later without the need for formal closure.
- (7) Pursuant to Article 4(2) of Regulation (EU) No 1024/2012, the Commission is to submit an evaluation of the outcome of the pilot project to the European Parliament and the Council. It is appropriate to specify the date by which the evaluation should be submitted.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 24 of Regulation (EU) No 1024/2012,

HAS ADOPTED THIS DECISION:

Article 1

The pilot project

Paragraph 4 of Article 18 of Directive (EU) 2021/555, insofar as the exchange of information mentioned in that paragraph falls within the scope of Delegated Regulation (EU) 2021/1423, shall be subject to a pilot project to implement the administrative cooperation provision set out in that paragraph, as further detailed in that Delegated Regulation, by means of the Internal Market Information System ('IMI').

Article 2

Competent authorities

For the purposes of the pilot project, the national authorities referred to in Article 18(3) of Directive (EU) 2021/555 shall be considered as competent authorities.

Article 3

Administrative cooperation between competent authorities

For the purposes of the pilot project, IMI shall provide the following functionality:

- (a) a repository for storing and sharing information on refusals in accordance with Delegated Regulation (EU) 2021/1423;
- (b) a search facility allowing competent authorities to search the repository in order to check whether it contains information on refusals with respect to a specific individual;
- (c) a facility allowing entries to be removed and updated in accordance with Article 4 of Delegated Regulation (EU) 2021/1423;
- (d) a system for sending regular email reminders to the competent authorities to remind them to review certain entries in accordance with Article 4 of Delegated Regulation (EU) 2021/1423.

Article 4

Retention of personal data

For the purposes of blocking personal data pursuant to Article 14 of Regulation (EU) No 1024/2012 that have been stored and shared in the repository as part of the pilot project, the date to be considered as the date, with respect to each refusal decision, when personal data no longer need to be so stored and shared shall be the date when, in accordance with Article 5 of Delegated Regulation (EU) 2021/1423, the information relating to that refusal decision is to cease to remain accessible. The blocked data shall be automatically deleted in IMI three years after the date when the data were blocked.

*Article 5***Monitoring and reporting**

The Commission shall provide Member States with statistics on the number of entries recorded in the repository. Such reporting shall not include information on individual refusal decisions.

*Article 6***Evaluation**

The evaluation of the outcome of the pilot project required by Article 4(2) of Regulation (EU) No 1024/2012 shall be submitted to the European Parliament and the Council by [... O]: *please insert date that is three years after entry into force of this Decision*].

*Article 7***Entry into force**

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

Done at Brussels, 21 May 2021.

For the Commission

The President

Ursula VON DER LEYEN

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