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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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/138

of 29 January 2019

amending Regulations (EC) No 1356/2004, (EC) No 1464/2004, (EC) No 786/2007, (EC) No 971/2008, (EU) No 1118/2010, (EU) No 169/2011 and Implementing Regulations (EU) No 888/2011 and (EU) No 667/2013 as regards the name of the holder of the authorisation for feed additives

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾ and in particular Article 13(3) thereof,

Whereas:

- (1) In accordance with Council Directive 70/524/EEC ⁽²⁾ monensin sodium and narasin, were authorised as feed additives by, respectively, Commission Regulations (EC) No 1356/2004 ⁽³⁾ and (EC) No 1464/2004 ⁽⁴⁾.
- (2) In accordance with Regulation (EC) No 1831/2003, endo-1,4-beta-mannanase and diclazuril were authorised as feed additives by, respectively, Commission Regulations (EC) No 786/2007 ⁽⁵⁾, (EC) No 971/2008 ⁽⁶⁾, (EU) No 1118/2010 ⁽⁷⁾, (EU) No 169/2011 ⁽⁸⁾ and Commission Implementing Regulations (EU) No 888/2011 ⁽⁹⁾ and (EU) No 667/2013 ⁽¹⁰⁾.
- (3) The holder of authorisation, Eli Lilly and Company Ltd, has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation for the feed additives concerned.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 1356/2004 of 26 July 2004 concerning the authorisation for 10 years of the additive 'Elancoban' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 251, 27.7.2004, p. 6).

⁽⁴⁾ Commission Regulation (EC) No 1464/2004 of 17 August 2004 concerning the authorisation for 10 years of the additive 'Monteban' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 270, 18.8.2004, p. 8).

⁽⁵⁾ Commission Regulation (EC) No 786/2007 of 4 July 2007 concerning the authorisation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell) as a feed additive (OJ L 175, 5.7.2007, p. 8).

⁽⁶⁾ Commission Regulation (EC) No 971/2008 of 3 October 2008 concerning a new use of a coccidiostat as additive in feedingstuffs (OJ L 265, 4.10.2008, p. 3).

⁽⁷⁾ Commission Regulation (EU) No 1118/2010 of 2 December 2010 concerning the authorisation of diclazuril as a feed additive for chickens for fattening (holder of authorisation Janssen Pharmaceutica NV) and amending Regulation (EC) No 2430/1999 (OJ L 317, 3.12.2010, p. 5).

⁽⁸⁾ Commission Regulation (EU) No 169/2011 of 23 February 2011 concerning the authorisation of diclazuril as a feed additive for guinea fowls (holder of authorisation Janssen Pharmaceutica N.V.) (OJ L 49, 24.2.2011, p. 6).

⁽⁹⁾ Commission Implementing Regulation (EU) No 888/2011 of 5 September 2011 concerning the authorisation of diclazuril as a feed additive for turkeys for fattening (holder of authorisation Janssen Pharmaceutica N.V.) and amending Regulation (EC) No 2430/1999 (OJ L 229, 6.9.2011, p. 9).

⁽¹⁰⁾ Commission Implementing Regulation (EU) No 667/2013 of 12 July 2013 concerning the authorisation of diclazuril as a feed additive for chickens reared for laying (holder of authorisation Eli Lilly and Company Ltd) and repealing Regulation (EC) No 162/2003 (OJ L 192, 13.7.2013, p. 35).

- (4) The holder of authorisation claims that, with effect from 30 March 2018, Elanco GmbH, a division of Eli Lilly and Company Ltd owns the marketing rights for the additives concerned. The holder of authorisation has submitted relevant data supporting its request.
- (5) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additives concerned. The European Food Safety Authority was informed of the application.
- (6) To allow Elanco GmbH to exploit its marketing rights it is necessary to change the terms of the authorisations concerned.
- (7) Regulations (EC) No 1356/2004, (EC) No 1464/2004, (EC) No 786/2007, (EC) No 971/2008, (EU) No 1118/2010, (EU) No 169/2011 and Implementing Regulations (EU) No 888/2011 and (EU) No 667/2013, should, therefore, be amended accordingly.
- (8) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to allow a transitional period during which existing stocks may be used up.
- (9) 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

Amendment to Regulation (EC) No 1356/2004

In the second column of the Annex to Regulation (EC) No 1356/2004, the words 'Eli Lilly and Company Limited' are replaced by the words 'Elanco GmbH'.

Article 2

Amendment to Regulation (EC) No 1464/2004

In the second column of the Annex to Regulation (EC) No 1464/2004, the words 'Eli Lilly and Company Limited' are replaced by the words 'Elanco GmbH'.

Article 3

Amendment to Regulation (EC) No 786/2007

In the second column of the Annex to Regulation (EC) No 786/2007, the words 'Eli Lilly and Company Ltd' are replaced by the words 'Elanco GmbH'.

Article 4

Amendment to Regulation (EC) No 971/2008

In the second column of the Annex to Regulation (EC) No 971/2008, the words 'Eli Lilly and Company Ltd' are replaced by the words 'Elanco GmbH'.

Article 5

Amendment to Regulation (EU) No 1118/2010

In the second column of the Annex to Regulation (EU) No 1118/2010, the words 'Eli Lilly and Company Ltd' are replaced by the words 'Elanco GmbH'.

Article 6

Amendment to Regulation (EU) No 169/2011

In the second column of the Annex to Regulation (EU) No 169/2011, the words 'Eli Lilly and Company Ltd' are replaced by the words 'Elanco GmbH'.

*Article 7***Amendment to Regulation (EU) No 888/2011**

In the second column of the Annex to Regulation (EU) No 888/2011 the words 'Eli Lilly and Company Ltd' are replaced by the words 'Elanco GmbH'.

*Article 8***Amendment to Regulation (EU) No 667/2013**

Regulation (EU) No 667/2013 is amended as follows:

- (1) In the title, the words 'Eli Lilly and Company Ltd' are replaced by the words 'Elanco GmbH';
- (2) In the second column of the Annex, the words 'Eli Lilly and Company Ltd' are replaced by the words 'Elanco GmbH'.

*Article 9***Transitional measure**

Monensin sodium, narasin, endo-1,4-beta-mannanase, and diclazuril produced and labelled before the date of entry into force of this Regulation in accordance with the rules applicable before that date may continue to be placed on the market and used until stocks are exhausted.

*Article 10***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, 29 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2019/139**of 29 January 2019****approving the active substance *Beauveria bassiana* strain IMI389521, 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 the Annex to 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 13(2) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 the Netherlands received on 28 October 2014 an application from Exosect Limited for the approval of the active substance *Beauveria bassiana* strain IMI389521.
- (2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, the Netherlands, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 2 June 2015 of the admissibility of the application.
- (3) On 22 February 2016 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 2 February 2017.
- (5) On 26 April 2017 the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance *Beauveria bassiana* strain IMI389521 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (6) On 24 October 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the draft review report for *Beauveria bassiana* strain IMI389521 and a draft Regulation providing that *Beauveria bassiana* strain IMI389521 is approved.
- (7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (8) It is therefore appropriate to approve *Beauveria bassiana* strain IMI389521.
- (9) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions. In particular, it is appropriate to include risk mitigation measures where appropriate.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance *Beauveria bassiana* IMI389521. *EFSA Journal* 2017;15(5):4831, 21 pp. doi:10.2903/j.efsa.2017.4831.

- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance *Beauveria bassiana* strain IMI389521, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

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, 29 January 2019.

For the Commission
The President
Jean-Claude JUNKER

⁽³⁾ 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).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<i>Beauveria bassiana</i> strain IMI389521 Accession number in the CABI Genetic Resource Collection: IMI389521	Not applicable	Max. level of beauvericin: 0,09 mg/kg	19 February 2019	19 February 2029	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain IMI389521, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the storage stability of the formulation(s) containing <i>B. bassiana</i> strain IMI389521 including the level of the metabolite beauvericin content after storage, — the content of the metabolite beauvericin produced under the application conditions, — the risk posed by beauvericin in infected insects present in the stored grain. Measures are required to ensure that such products do not enter the food and feed chain, taking into account the natural background level of beauvericin on cereal grains, — the protection of operators and workers, taking into account that <i>B. bassiana</i> strain IMI389521 is to be considered, as any micro-organism, as a potential sensitiser. The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾ Conditions of use shall include risk mitigation measures where appropriate.

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

'130	<i>Beauveria bassiana</i> strain IMI389521 Accession number in the CABI Genetic Resource Collection: IMI389521	Not applicable	Max. level of beauvericin: 0,09 mg/kg	19 February 2019	19 February 2029	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain IMI389521, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the storage stability of the formulation(s) containing <i>B. bassiana</i> strain IMI389521 including the level of the metabolite beauvericin content after storage; — the content of the metabolite beauvericin produced under the application conditions; — the risk posed by beauvericin in infected insects present in the stored grain. Measures are required to ensure that such products do not enter the food and feed chain, taking into account the natural background level of beauvericin on cereal grains; — the protection of operators and workers, taking into account that <i>B. bassiana</i> strain IMI389521 is to be considered, as any micro-organism, as a potential sensitiser. The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (*). Conditions of use shall include risk mitigation measures where appropriate.
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(*) https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf

DECISIONS

COUNCIL DECISION (EU, Euratom) 2019/140

of 28 January 2019

appointing a member, proposed by the Kingdom of the Netherlands, of the European Economic and Social Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

Having regard to the proposal of the Government of the Netherlands,

Having regard to the opinion of the European Commission,

Whereas:

- (1) On 18 September 2015 and 1 October 2015, the Council adopted Decisions (EU, Euratom) 2015/1600 ⁽¹⁾ and (EU, Euratom) 2015/1790 ⁽²⁾ appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020.
- (2) A member's seat on the European Economic and Social Committee has become vacant following the end of the term of office of Ms Annie VAN WEZEL,

HAS ADOPTED THIS DECISION:

Article 1

Mr A. (Fredy) PELTZER, *policy advisor at FNV (Federatie Nederlandse Vakbeweging / The Netherlands Trade Union Confederation)*, is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2020.

Article 2

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

Done at Brussels, 28 January 2019.

For the Council

The President

P. DAEA

⁽¹⁾ Council Decision (EU, Euratom) 2015/1600 of 18 September 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 248, 24.9.2015, p. 53).

⁽²⁾ Council Decision (EU, Euratom) 2015/1790 of 1 October 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 260, 7.10.2015, p. 23).

COUNCIL DECISION (EU) 2019/141**of 28 January 2019****appointing an alternate member, proposed by the Federal Republic of Germany, of the Committee of the Regions**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the German Government,

Whereas:

- (1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ⁽¹⁾, (EU) 2015/190 ⁽²⁾ and (EU) 2015/994 ⁽³⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020.
- (2) An alternate member's seat on the Committee of the Regions has become vacant following the passing away of Mr Ralf GEISTHARDT,

HAS ADOPTED THIS DECISION:

Article 1

The following is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

Mr Markus KURZE, *Mitglied des Landtages von Sachsen-Anhalt*.

Article 2

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

Done at Brussels, 28 January 2019.

For the Council

The President

P. DAEA

⁽¹⁾ Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).

⁽²⁾ Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).

⁽³⁾ Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

COMMISSION IMPLEMENTING DECISION (EU) 2019/142**of 29 January 2019****on recognition of the ‘U.S. Soybean Sustainability Assurance Protocol’ for demonstrating compliance with the sustainability criteria under Directives 98/70/EC and 2009/28/EC of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC ⁽¹⁾, and in particular the second subparagraph of Article 7c(4) thereof,

Having regard to Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC ⁽²⁾, and in particular the second subparagraph of Article 18(4) thereof,

Whereas:

- (1) Articles 7b and 7c of, and Annex IV to, Directive 98/70/EC and Articles 17 and 18 of, and Annex V to, Directive 2009/28/EC lay down similar sustainability criteria for biofuels and bioliquids, and similar procedures for verifying that biofuels and bioliquids comply with those criteria.
- (2) Where biofuels and bioliquids are to be taken into account for the purposes referred to in Article 17(1)(a), (b) and (c) of Directive 2009/28/EC, Member States must require economic operators to show that biofuels and bioliquids fulfil the sustainability criteria set out in Article 17(2) to (5) of that Directive.
- (3) The request for recognition that the ‘U.S. Soybean Sustainability Assurance Protocol’ demonstrates that consignments of biofuel comply with the sustainability criteria set out in Directives 98/70/EC and 2009/28/EC was submitted to the Commission on 15 November 2018. The scheme is based in 16305 Swingley Ridge Road, Suite 200 Chesterfield, MO 63017, United States. It covers soybeans produced in the United States and the chain of custody from the farms producing the soybeans to the place where they are exported.
- (4) In assessing the ‘U.S. Soybean Sustainability Assurance Protocol’ the Commission found that the scheme covers adequately the sustainability criteria set out in Directives 98/70/EC and 2009/28/EC, and uses a mass balance system in accordance with Article 7c(1) of Directive 98/70/EC and Article 18(1) of Directive 2009/28/EC.
- (5) The assessment of the ‘U.S. Soybean Sustainability Assurance Protocol’ found that it meets adequate standards of reliability, transparency and independent auditing and complies with the methodological requirements set out in Annex IV to Directive 98/70/EC and in Annex V to Directive 2009/28/EC.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Committee on the Sustainability of Biofuels and Bioliquids,

HAS ADOPTED THIS DECISION:

Article 1

The ‘U.S. Soybean Sustainability Assurance Protocol’ (‘the scheme’), submitted for recognition to the Commission on 15 November 2018, demonstrates that consignments of biofuels and bioliquids produced in accordance with the standards for the production of biofuels and bioliquids set in the scheme comply with the sustainability criteria laid down in Article 7b(3), (4) and (5) of Directive 98/70/EC and Article 17(3), (4) and (5) of Directive 2009/28/EC.

The scheme contains accurate data for the purposes of Article 17(2) of Directive 2009/28/EC and Article 7b(2) of Directive 98/70/EC in as far as it concerns annualised emissions from carbon stock changes caused by land-use change (e) referred to in point 1 of part C of Annex IV to Directive 98/70/EC and point 1 of part C of Annex V to Directive 2009/28/EC, which it demonstrates to be equal to zero.

⁽¹⁾ OJ L 350, 28.12.1998, p. 58.

⁽²⁾ OJ L 140, 5.6.2009, p. 16.

Article 2

The Commission shall be notified without delay of any change in the contents of the scheme, as submitted for recognition to the Commission on 15 November 2018, that might affect the basis of this Decision.

The Commission shall assess the notified changes with a view to establishing whether the scheme still adequately covers the sustainability criteria for which it is recognised.

Article 3

The Commission may repeal this Decision, inter alia, in any of the following circumstances:

- (a) where it is clearly demonstrated that the scheme does not implement elements considered to be important for this Decision or if serious and structural breach of those elements has taken place;
- (b) where the scheme fails to submit annual reports to the Commission pursuant to Article 7c(6) of Directive 98/70/EC and Article 18(6) of Directive 2009/28/EC;
- (c) where the scheme fails to implement the standards of independent auditing specified by means of implementing acts pursuant to the third subparagraph of Article 7c(5) of Directive 98/70/EC and the third subparagraph of Article 18(5) of Directive 2009/28/EC or carry out improvements to other elements of the scheme considered to be important for a continued recognition.

Article 4

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

It shall apply until 30 June 2021.

Done at Brussels, 29 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

