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Price: EUR 3

(Continued overleaf)

⁽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.

★ Commission Implementing Regulation (EU) No 357/2013 of 18 April 2013 amending Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 as regards the minimum content of a preparation of <i>Clostridium butyricum</i> (FERM BP-2789) as a feed additive for chickens for fattening and minor avian species (excluding laying birds) (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.) ⁽¹⁾	22
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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 353/2013

of 18 April 2013

amending Implementing Regulation (EU) No 543/2011 as regards the trigger levels for additional duties on cucumbers, cherries, other than sour, apricots, tomatoes, plums, peaches, including nectarines, and table grapes

THE EUROPEAN COMMISSION,

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

latest data available for 2010, 2011 and 2012, the trigger levels for additional duties on cucumbers and cherries, other than sour, should be amended with effect from 1 May 2013, whilst those on apricots, tomatoes, plums, peaches, including nectarines, and table grapes should be amended with effect from 1 June 2013.

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 143(b), in conjunction with Article 4 thereof,

(3) Implementing Regulation (EU) No 543/2011 should therefore be amended accordingly.

(4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication.

Whereas:

(1) Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾ provides for the surveillance of the imports of the products listed in Annex XVIII thereto. That surveillance is to be carried out in accordance with the rules laid down in Article 308d of Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code ⁽³⁾.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVIII to Regulation (EU) No 543/2011 is replaced by the text set out in the Annex to this Regulation.

(2) For the purposes of Article 5(4) of the Agreement on Agriculture ⁽⁴⁾ concluded during the Uruguay Round of multilateral trade negotiations and in the light of the

Article 2

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

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

⁽³⁾ OJ L 253, 11.10.1993, p. 1.

⁽⁴⁾ OJ L 336, 23.12.1994, p. 22.

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

Done at Brussels, 18 April 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

'ANNEX XVIII

ADDITIONAL IMPORT DUTIES: TITLE IV, CHAPTER I, SECTION 2

Without prejudice to the rules governing the interpretation of the Combined Nomenclature, the description of the products is deemed to be indicative only. The scope of the additional duties for the purposes of this Annex is determined by the scope of the CN codes as they stand at the time of the adoption of this Regulation.

Order number	CN code	Description of products	Period of application	Trigger level (tonnes)
78.0015	0702 00 00	Tomatoes	From 1 October to 31 May	462 389
78.0020			From 1 June to 30 September	30 766
78.0065	0707 00 05	Cucumbers	From 1 May to 31 October	13 080
78.0075			From 1 November to 30 April	15 100
78.0085	0709 91 00	Artichokes	From 1 November to 30 June	37 475
78.0100	0709 93 10	Courgettes	From 1 January to 31 December	85 538
78.0110	0805 10 20	Oranges	From 1 December to 31 May	468 160
78.0120	0805 20 10	Clementines	From 1 November to end of February	86 205
78.0130	0805 20 30 0805 20 50 0805 20 70 0805 20 90	Mandarins (including tangerines and satsumas); wilkings and similar citrus hybrids	From 1 November to end of February	93 949
78.0155	0805 50 10	Lemons	From 1 June to 31 December	311 193
78.0160			From 1 January to 31 May	101 513
78.0170	0806 10 10	Table grapes	From 21 July to 20 November	124 303
78.0175	0808 10 80	Apples	From 1 January to 31 August	703 063
78.0180			From 1 September to 31 December	73 884
78.0220	0808 30 90	Pears	From 1 January to 30 April	225 388
78.0235			From 1 July to 31 December	33 797
78.0250	0809 10 00	Apricots	From 1 June to 31 July	4 930
78.0265	0809 21 00 0809 29 00	Cherries, other than sour cherries	From 21 May to 10 August	33 967
78.0270	0809 30	Peaches, including nectarines	From 11 June to 30 September	2 712
78.0280	0809 40 05	Plums	From 11 June to 30 September	10 441'

COMMISSION IMPLEMENTING REGULATION (EU) No 354/2013**of 18 April 2013****on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(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 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 51 thereof,

Whereas:

- (1) In order to ensure a harmonised approach, it is appropriate to adopt provisions for changes of biocidal products in respect of any of the information submitted in relation to the initial application for the authorisation or registration of biocidal products and biocidal product families authorised or registered in accordance with Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽²⁾ and Regulation (EU) No 528/2012.
- (2) Proposed changes of biocidal products should be classified in different categories, taking into account the extent to which they require a reassessment of the risk for human or animal health or the environment and of the efficacy of the biocidal product or biocidal product family. It is appropriate to establish the criteria to be used for classifying a change of a product in one of the categories referred to in Article 50(3) of Regulation (EU) No 528/2012.
- (3) In order to bring further predictability, the European Chemicals Agency (hereinafter 'the Agency') should issue opinions on the classification of changes of products. The Agency should also issue guidelines on the details of the various categories of changes. Those guidelines should be regularly updated in the light of scientific and technical progress.
- (4) It is necessary to clarify the procedure which will lead to a decision by the Commission in accordance with the first subparagraph of Article 50(2) of Regulation (EU) No 528/2012 and, where relevant, Article 44(5) thereof.
- (5) In order to reduce the overall number of possible applications and to enable Member States, the Agency and the Commission to focus on those changes that have a genuine impact on the properties of biocidal products, an annual reporting system should be introduced for certain changes of an administrative nature. Such changes should not require any prior agreement and

should be notified within 12 months following implementation. However, other types of changes of an administrative nature, whose immediate reporting and prior examination is necessary for the continuous supervision of the biocidal product concerned should not be subject to the annual reporting system.

- (6) Each change should require a separate submission. Grouping of changes should nevertheless be allowed in certain cases, in order to facilitate the review of the changes and reduce the administrative burden.
- (7) Provisions should be introduced regarding the role of the coordination group established under Regulation (EU) No 528/2012 to increase cooperation between Member States and allow for the settlement of disagreements in the evaluation of certain changes.
- (8) This Regulation should clarify when the authorisation holder is allowed to implement a given change, as such clarification is essential for economic operators.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS*Article 1***Subject matter**

This Regulation lays down provisions concerning changes of biocidal products sought in accordance with Article 50(2) of Regulation (EU) No 528/2012 with regard to any of the information submitted in relation to the initial application for the authorisation of biocidal products or biocidal product families in accordance with Directive 98/8/EC and Regulation (EU) No 528/2012 (hereinafter 'changes of products').

*Article 2***Classification of changes of products**

1. Changes of products are classified in accordance with the criteria laid down in the Annex to this Regulation. Certain categories of changes are listed in the tables of the Annex.
2. The holder of an authorisation may request the Agency to provide an opinion on the classification in accordance with the criteria laid down in the Annex to this Regulation of a change not listed in one of the tables of that Annex.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ OJ L 123, 24.4.1998, p. 1.

The opinion shall be delivered within 45 days following receipt of the request and payment of the fee referred to in Article 80(1)(a) of Regulation (EU) No 528/2012.

The Agency shall publish the opinion after deletion of all information of commercial confidential nature.

Article 3

Guidelines on classification

1. The Agency shall, after consulting the Member States, the Commission and interested parties, draw up guidelines on the details of the various categories of changes of products.
2. Those guidelines shall be regularly updated, taking into account the opinions taken in accordance with Article 2(2), contributions from Member States as well as scientific and technical progress.

Article 4

Grouping of changes

1. Where several changes of products are sought, a separate notification or application shall be submitted in respect of each change sought.
2. By way of derogation from paragraph 1, the following rules shall apply:
 - (a) a single notification may cover a series of proposed administrative changes affecting different products in the same manner;
 - (b) a single notification may cover a series of proposed administrative changes affecting the same product;
 - (c) a single application may cover more than one proposed change of the same product in the following cases:
 - (1) one of the proposed changes in the group is a major change of the product; all other proposed changes in the group are a direct consequence of that change;
 - (2) one of the proposed changes in the group is a minor change; all other proposed changes in the group are a direct consequence of that change;
 - (3) all changes in the group are a direct consequence of a new classification of the active substance(s) or non-active substance(s) contained in the product or of the product itself;
 - (4) all changes in the group are a direct consequence of a specific condition of the authorisation;
 - (d) a single application may cover more than one proposed change if the Member State evaluating the application in accordance with Article 7(4) or 8(4), or, in the case of a change of a Union authorisation, the Agency, confirms that it is practically feasible to handle those changes in the same procedure.

The single applications referred to in points (c) and (d) of the first subparagraph shall be made in accordance with Article 7 or 12 where at least one of the proposed changes is a minor change of the product and none of the proposed changes is a major change of the product, and with Article 8 or 13 where at least one of the proposed changes is a major change of the product.

Article 5

Information requirements

An application submitted in accordance with Article 50(2) of Regulation (EU) No 528/2012 shall contain the following:

- (1) the relevant filled application form as available from the Register for Biocidal Products, which shall contain:
 - (a) a list of all the authorisations affected by the proposed change(s);
 - (b) a list indicating all the Member States in which the product is authorised and the changes are sought (hereinafter the 'Member States concerned');
 - (c) for products authorised by national authorisation, the Member State which evaluated the initial application for authorisation of the biocidal product or, if the changes are not sought in that Member State, the Member State having been chosen by the applicant together with written confirmation that that Member State agrees to be reference Member State (hereinafter referred to as the 'reference Member State');
 - (d) for major changes of products authorised by Union authorisation, the Member State who evaluated the initial application for authorisation of the biocidal product or, if the changes are not sought in that Member State, the Member State having been chosen by the applicant together with written confirmation that that Member State agrees to evaluate the application of the change;
 - (e) where relevant, a draft revised summary of the biocidal product characteristics in, as appropriate,
 - (1) for products authorised by national authorisation, the official language(s) of all the Member States concerned;
 - (2) for products authorised by Union authorisation, one of the official languages of the Union, which in case of major changes must be a language accepted by the Member State referred to in point (c) at the time of application;
- (2) a description of all the changes sought;
- (3) where a change leads to or is the consequence of other changes of the terms of the same authorisation, a description of the relation between these changes;

(4) all relevant supporting documents to demonstrate that the proposed change would not adversely affect the conclusions previously reached concerning the compliance with the conditions set out in Article 19 or 25 of Regulation (EU) No 528/2012;

(5) where relevant, the opinion issued by the Agency in accordance with Article 3 of this Regulation.

CHAPTER II

CHANGES OF PRODUCTS AUTHORISED BY MEMBER STATES

Article 6

Notification procedure for administrative changes of products

1. The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned a notification complying with Article 5 and, in each of those Member States, pay the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012.

2. Without prejudice to the second subparagraph, the notification shall be submitted within 12 months following the implementation of the change.

In case of a change referred to in Section 1 of Title 1 of the Annex to this Regulation, the notification shall be submitted before the implementation of the change.

3. Within 30 days following receipt of the notification, where one of the Member States concerned disagrees with the change or the relevant fee has not been paid, that Member State shall inform the authorisation holder, or its representative, and the other Member States concerned that the change is rejected and the grounds for the rejection.

If, within 30 days following receipt of the notification, a Member State concerned has not expressed its disagreement, that Member State shall be deemed to have agreed with the change.

4. Each of the Member States concerned which has not rejected the change in accordance with paragraph 3 shall, where relevant, amend the authorisation of the biocidal product in conformity with the agreed change.

Article 7

Procedure for minor changes of products

1. The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned an application complying with Article 5.

2. Each Member State concerned shall inform the applicant of the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012. If the applicant fails to pay the fee within 30 days, the Member State concerned shall reject the application and inform the applicant and the other Member States concerned accordingly. Upon receipt of the fee, the Member State concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

3. The reference Member State shall validate the application within 30 days of its acceptance, if it complies with the requirements laid down in Article 5 and inform the applicant and the Member States concerned accordingly.

In the context of the validation referred to in the first subparagraph, the reference Member State shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

Where the reference Member State considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the application to be completed and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 45 days.

The reference Member State shall, within 30 days of receipt of the additional information, validate the application if the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

4. Within 90 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report and shall send its assessment report and, where relevant, the revised summary of the biocidal product characteristics to the Member States concerned and to the applicant.

5. Where it appears that additional information is necessary to carry out the evaluation, the reference Member State shall ask the applicant to submit such information within a specified time limit. The period referred to in paragraph 4, shall be suspended from the date of the request until the date the information is received. The time limit given to the applicant shall not exceed 45 days in total unless justified by the nature of the data requested or by exceptional circumstances.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

6. If, within 45 days of receipt of the assessment report and, where relevant, of the revised summary of the biocidal product characteristics, the Member States concerned express no disagreement in accordance with Article 10, those Member States shall be deemed to have agreed with the conclusions of the assessment report and, where relevant, the revised summary of the biocidal product characteristics.

7. Within 30 days of reaching agreement, the reference Member State shall inform the applicant of the agreement and make it available in the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No 528/2012. The reference Member State and each of the Member States concerned shall, where relevant, amend the authorisations of the biocidal product in conformity with the agreed change.

*Article 8***Procedure for major changes of products**

1. The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned an application complying with Article 5.

2. Each Member State concerned shall inform the applicant of the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012. If the applicant fails to pay the fee within 30 days, the Member State concerned shall reject the application and inform the applicant and the other Member States concerned accordingly. Upon receipt of the fee, the Member State concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

3. The reference Member State shall validate the application within 30 days of its acceptance if it complies with the requirements laid down in Article 5 and inform the applicant and the Member States concerned accordingly.

In the context of the validation referred to in the first subparagraph, the reference Member State shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

Where the reference Member State considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The reference Member State shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

4. Within 180 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report and shall send its assessment report and, where relevant, the revised summary of the biocidal product characteristics to the Member States concerned and to the applicant.

5. Where it appears that additional information is necessary to carry out the evaluation, the reference Member State shall ask the applicant to submit such information within a specified time limit. The period referred to in paragraph 4 shall be suspended from the date of the request until the date on which the information is received. The time limit given to the applicant shall not exceed 90 days in total unless justified by the nature of the data requested or by exceptional circumstances.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

6. If, within 90 days of receipt of the assessment report and, where relevant, of the revised summary of the biocidal product

characteristics, the Member States concerned express no disagreement in accordance with Article 10, those Member States shall be deemed to agree with the conclusions of the assessment report and, where appropriate, the revised summary of the biocidal product characteristics.

7. Within 30 days of reaching agreement, the reference Member State shall inform the applicant of the agreement, and the reference Member State and each of the Member States concerned shall, where relevant, amend the authorisations of the biocidal product in conformity with the agreed change.

*Article 9***Biocidal products authorised in accordance with Article 26 of Regulation (EU) No 528/2012**

1. Where the authorisation has been granted in accordance with Article 26 of Regulation (EU) No 528/2012, the authorisation holder or its representative shall notify each Member State, on the territory of which the biocidal product is made available, of notifications or applications made to the reference Member State in accordance with Article 6, 7 or 8 of this Regulation.

2. Where a reference Member State has agreed with a revised summary of the biocidal product characteristics, the authorisation holder or its representative shall submit the revised summary to each Member State on the territory of which the biocidal product is made available in the official language(s) of that Member State.

*Article 9a***Procedure for changes already agreed by other Member States**

1. Where an administrative change has already been agreed in one or more Member States and the authorisation holder seeks the same administrative change in an additional Member State concerned, the authorisation holder or its representative shall submit a notification in accordance with Article 6(1) to the additional Member State concerned.

2. Where a minor or a major change has already been agreed in one or more Member States and the authorisation holder seeks the same minor or major change in an additional Member State concerned, the authorisation holder, or its representative, shall submit an application complying with Article 5 to the additional Member State concerned.

3. The Member State concerned shall inform the applicant of the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012. If the applicant fails to pay the fee within 30 days, the Member State concerned shall reject the application and inform the applicant and the other Member States concerned accordingly. Upon receipt of the fee, the Member State concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

4. If within 45 days in the case of a minor change, or 90 days in the case of a major change, of the date of acceptance, the Member State concerned express no disagreement in accordance with Article 10, it shall be deemed to agree with the conclusions of the assessment report and, where appropriate, the revised summary of the biocidal product characteristics.

5. Within 30 days of the agreement referred to in paragraph 4, the Member State concerned shall inform the applicant of the agreement, and, where relevant, amend the authorisation of the biocidal product in conformity with the agreed change.

Article 10

Coordination group, arbitration and derogation from mutual recognition

1. A Member State concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation in accordance with Article 37 of Regulation (EU) No 528/2012.

2. Where, regarding matters other than those referred to in paragraph 1, the Member States concerned do not reach an agreement on the conclusions of the assessment report or, where relevant, on the revised summary of the biocidal product characteristics in accordance with Article 7(6) or 8(6), or a Member State concerned has disagreed in accordance with Article 6(3), the reference Member State shall refer the matter to the coordination group referred to in Article 35 of Regulation (EU) No 528/2012.

Where a Member State concerned is in disagreement with the reference Member State, the former shall give a detailed statement of the reasons for its position to all Member States concerned and to the applicant.

3. Articles 35 and 36 of Regulation (EU) No 528/2012 shall apply to matters of disagreement referred to in paragraph 2.

CHAPTER III

CHANGES OF PRODUCTS AUTHORISED BY THE COMMISSION

Article 11

Notification procedure for administrative changes of products

1. The authorisation holder, or its representative, shall submit to the Agency a notification complying with Article 5 and pay the fee referred to in Article 80(1)(a) of Regulation (EU) No 528/2012.

2. Without prejudice to the second subparagraph, that notification shall be submitted within 12 months following implementation of the change.

In case of a change referred to in Section 1 of Title 1 of the Annex to this Regulation, the notification shall be submitted before the implementation of the change.

3. Within 30 days following receipt of the notification and subject to the payment of the relevant fee, the Agency shall prepare and submit to the Commission an opinion on the proposed change.

4. If, within 30 days following receipt of the notification, the relevant fee has not been paid, the Agency shall reject the application and inform the applicant accordingly.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against Agency decisions under this paragraph.

5. The Agency shall inform the applicant of its opinion and shall, where relevant, request the applicant to submit in all the

official languages of the Union, a draft revised summary of the biocidal product characteristics.

6. Within 30 days of the submission of its opinion to the Commission, the Agency shall, where relevant, transmit to the Commission, in all the official languages of the Union, the revised summary of the biocidal product characteristics, as referred to in Article 22(2) of Regulation (EU) No 528/2012.

Article 12

Procedure for minor changes of products

1. The authorisation holder, or its representative, shall submit to the Agency an application complying with the Article 5.

2. The Agency shall inform the applicant of the fee payable under Article 80(1)(a) of Regulation (EU) No 528/2012, and shall reject the application if the applicant fails to pay the fee within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fee, the Agency shall accept the application and inform the applicant accordingly.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against Agency decisions under this paragraph.

3. The Agency shall validate the application within 30 days of the date of acceptance if it complies with the requirements laid down in Article 5.

In the context of the validation referred to in the first subparagraph, the Agency shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

Where the Agency considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the completeness of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 45 days.

The Agency shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and inform the applicant accordingly. In such cases, part of the fee paid in accordance with paragraph 2 shall be reimbursed.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against Agency decisions under this paragraph.

4. Within 90 days of accepting an application as valid, the Agency shall prepare and submit to the Commission an opinion on the proposed change. In case of a favourable opinion, the Agency shall indicate whether the proposed change would require an amendment of the authorisation.

The Agency shall inform the applicant of its opinion and make it available in the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No 528/2012, and shall, where relevant, request the applicant to submit in all the official languages of the Union, a draft revised summary of the biocidal product characteristics.

5. Where it appears that additional information is necessary to carry out the evaluation, the Agency shall ask the applicant to submit such information within a specified time limit. The period referred to in paragraph 4 shall be suspended from the date of the request until the date the information is received. The time limit given to the applicant shall not exceed 45 days in total unless justified by the nature of the data requested or by exceptional circumstances.

6. Within 30 days of the submission of its opinion to the Commission, the Agency shall, where relevant, transmit to the Commission, in all the official languages of the Union, the revised summary of the biocidal product characteristics, as referred to in Article 22(2) of Regulation (EU) No 528/2012.

Article 13

Procedure for major changes of products

1. The authorisation holder, or its representative, shall submit to the Agency an application complying with Article 5.

2. The Agency shall inform the applicant of the fee payable under Article 80(1)(a) of Regulation (EU) No 528/2012, and shall reject the application if the applicant fails to pay the fee within 30 days. It shall inform the applicant and the competent authority of the Member State referred to in Article 5(1)(d) (hereinafter referred to as the 'evaluating competent authority') accordingly.

Upon receipt of the fee, the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against decisions of the Agency under this paragraph.

3. Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if it complies with the requirements laid down in Article 5.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

The evaluating competent authority shall, within 15 days from the Agency's acceptance of an application, inform the applicant of the fee payable under Article 80(2) of Regulation (EU) No 528/2012 and shall reject the application if the applicant fails to pay the fee within 30 days.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the completeness of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application

if it determines that the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Agency accordingly. In such cases, part of the fee paid in accordance with paragraph 2 shall be reimbursed.

5. The evaluating competent authority shall, within 180 days of the validation of an application, evaluate it and send an assessment report and the conclusions of its evaluation, including, where relevant, a draft revised summary of the product characteristics, to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

6. Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The period referred to in paragraph 5 shall be suspended from the date of the request until the date the information is received. The time limit given to the applicant shall not exceed 90 days in total unless justified by the nature of the data requested or by exceptional circumstances.

7. Within 90 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the proposed change. In case of a favourable opinion, the Agency shall indicate whether the proposed change would require an amendment of the authorisation.

The Agency shall inform the applicant of its opinion and shall, where relevant, request the applicant to submit, in all the official languages of the Union, a draft revised summary of the biocidal product characteristics.

8. Within 30 days of the submission of its opinion to the Commission, the Agency shall, where relevant, transmit to the Commission, in all the official languages of the Union, the draft revised summary of the biocidal product characteristics, as referred to in Article 22(2) of Regulation (EU) No 528/2012.

CHAPTER IV

IMPLEMENTATION OF CHANGES

Article 14

Administrative changes of products

1. Administrative changes referred to in Section 2 of Title 1 of the Annex may be implemented any time before completion of the procedures laid down in Articles 6 and 11.

Administrative changes referred to in Section 1 of Title 1 of the Annex may be implemented at the earliest on the date when the Member State or, in the case of changes of a product authorised by Union authorisation, the Commission explicitly agrees with the change, or 45 days following receipt of the notification submitted in accordance with Articles 6 and 11, whichever is earliest.

2. Where one of the changes referred to in paragraph 1 is rejected, the authorisation holder shall cease to apply the concerned change within 30 days following notification of the decision of the relevant Member States or, in the case of changes of a product authorised by Union authorisation, the Commission.

Article 15

Minor changes

1. Subject to a favourable opinion from the Agency, minor changes of a product authorised by Union authorisation may be implemented any time after the Agency's opinion has been made available in the Register for Biocidal Products in accordance with Article 12(4).

2. Where the proposed minor change of the product is rejected by the Commission in accordance with Article 50(2) of Regulation (EU) No 528/2012, the authorisation holder shall cease to apply the proposed change within 30 days following notification of the decision of the Commission.

3. Minor changes of a product authorised by Member States may be implemented any time after the reference Member State has made the agreement available in the Register for Biocidal Products in accordance with Article 7(7).

Article 16

Major changes

Major changes may only be implemented after the concerned Member States have or, in the case of changes of a product authorised by Union authorisation, the Commission has agreed with the change and, where relevant, amended the decision granting the authorisation by the decision referred to in Article 50(2) of Regulation (EU) No 528/2012.

CHAPTER V

FINAL PROVISIONS

Article 17

Continuous monitoring of implementation of changes

Where requested by a Member State, the Agency or the Commission and for the purpose of monitoring biocidal products placed on the market, authorisation holders shall without delay supply the requesting authority with any information related to the implementation of a given change.

Article 18

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*.

It shall apply from 1 September 2013.

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

Done at Brussels, 18 April 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

CLASSIFICATION OF CHANGES OF PRODUCTS

TITLE 1

Administrative changes of products

An administrative change of a product is a change following which any change of the existing authorisation can be expected to be only administrative within the meaning of Article 3(1)(aa) of Regulation (EU) No 528/2012.

SECTION 1

Administrative changes of products requiring prior notification before implementation

An administrative change of a product requiring prior notification before implementation is an administrative change, the knowledge of which is important for purposes of control and enforcement. Such changes include those listed in the following table, provided that the conditions therein are met:

Name of the biocidal product	
1.	Changes of the name of the biocidal product where there is no risk of confusion with the names of other biocidal products.
2.	Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.
Authorisation holder	
3.	Transfer of the authorisation to a new holder established in the European Economic Area (EEA).
4.	Change in the name or address of the authorisation holder, which remains in the EEA.
Manufacturer(s) of the active substance(s)	
5.	Addition of a manufacturer of the active substance or change in the manufacturer's identity or in manufacturing location or process, where the technical equivalence between the substances from the two manufacturers, manufacturing locations and processes has been established by the Agency in accordance with Article 54 of Regulation (EU) No 528/2012, and the manufacturer or importer is listed in accordance with Article 95(2) of Regulation (EU) No 528/2012.
Biocidal product family	
6.	Authorisation as a biocidal product family of a number of authorised products falling within the specifications of a frame-formulation established in accordance with Directive 98/8/EC in accordance with the same terms and conditions.

SECTION 2

Administrative changes of products which can be notified after implementation

An administrative change of a product which can be notified after implementation is an administrative change, the knowledge of which is not important for purposes of control and enforcement. Such changes include those listed in the following table, provided that the conditions therein are met:

Authorisation holder	
1.	Change in other administrative details of the authorisation holder than the name and address.
Formulator(s) of the biocidal product	
2.	Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged.

3.	Deletion of a formulating location or a formulator of the biocidal product
4.	Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.

Manufacturer(s) of the active substance(s)

5.	Change in the name or the administrative details of a manufacturer of the active substance, where the manufacturing location and process remain unchanged and the manufacturer remains listed in accordance with Article 95(2) of Regulation (EU) No 528/2012
6.	Deletion of a manufacturer or a manufacturing location of the active substance

Conditions of use

7.	More precise instructions for use, where only wording but not content of instructions are changed.
8.	Removal of a particular claim, such as a specific target organism or a specific use.
9.	Removal of a category of users.
10.	Addition, replacement or modification of a measuring or administration device not relevant for the risk assessment and not regarded as a risk mitigation measure.

Classification and labelling

11.	Change to the classification and labelling, where the change is limited to what is necessary to comply with newly applicable requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁾ .
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⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

TITLE 2**Minor changes of products**

A minor change of a product is a change, following which any change of the existing authorisation can be expected to be minor within the meaning of Article 3(1)(ab) of Regulation (EU) No 528/2012, since the change of the product is not expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation. Such changes include the changes listed in the following table, provided that the conditions therein are met:

Composition

1.	Increase or reduction, addition, deletion or replacement of a non-active substance intentionally incorporated in the product, where: — The added or increased non active-substance is not a substance of concern. — The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern. — The physical-chemical properties and the shelf-life of the product are expected to remain the same. — The risk and efficacy profile are expected to remain the same. — A new quantitative risk assessment is not expected to be necessary
2.	Increase, reduction, addition or deletion, or replacement of a non-active substance intentionally incorporated in a biocidal product family outside the authorised range, where: — The added or increased non-active substance is not a substance of concern. — The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern. — The physical-chemical properties and the shelf-life of the products of the biocidal product family remain the same. — The risk and efficacy profile are expected to remain the same. — A new quantitative risk assessment is not expected to be necessary.

Conditions of use

3.	Changed instructions for use, where the changes do not adversely affect the exposure
4.	Addition, replacement or modification of a measuring or administration device relevant for the risk assessment and regarded as a risk mitigation measure, where: — The new device accurately delivers the required dose for the biocidal product concerned in line with the approved conditions of use. — The new device is compatible with the biocidal product. — The change is not expected to adversely affect the exposure.

Shelf-life and conditions of storage

5.	Change in the shelf-life.
6.	Change in the conditions of storage

Pack size

7.	Change in the pack size range, where: — New range is consistent with the dose rate and instructions for use as approved in the summary of the biocidal product characteristics. — No change of user category. — The same risk-mitigation measures apply.
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TITLE 3

Major changes of products

A major change of a product is a change, following which any change of the existing authorisation can be expected to be major within the meaning of Article 3(1)(ac) of Regulation (EU) No 528/2012, since the change of the product can be expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation.

COMMISSION IMPLEMENTING REGULATION (EU) No 355/2013

of 18 April 2013

approving the active substance maltodextrin, 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) and Article 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For maltodextrin the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2008/20/EC ⁽³⁾.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC the United Kingdom received on 8 October 2008 an application from Biological Crop Protection Ltd for the inclusion of the active substance maltodextrin in Annex I to Directive 91/414/EEC. Decision 2008/20/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant (now Certis Europe B.V.). The designated rapporteur Member State submitted a draft assessment report on 29 November 2011.
- (4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the review of the pesticide risk assessment of the active substance maltodextrin ⁽⁴⁾ on 3 December 2012. The draft assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the

Standing Committee on the Food Chain and Animal Health and the draft assessment report was finalised on 15 March 2013 in the format of the Commission review report for maltodextrin.

- (5) It has appeared from the various examinations made that plant protection products containing maltodextrin may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve maltodextrin.
- (6) 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 and restrictions.
- (7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.
- (8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing maltodextrin. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽⁵⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 1, 4.1.2008, p. 5.

⁽⁴⁾ EFSA Journal 2013; 11(1):3007. Available online: www.efsa.europa.eu

⁽⁵⁾ OJ L 366, 15.12.1992, p. 10.

However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to 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⁽¹⁾ should be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance maltodextrin, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing maltodextrin as an active substance by 31 March 2014.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

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

Done at Brussels, 18 April 2013.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing maltodextrin as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 September 2013 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing maltodextrin as the only active substance, where necessary, amend or withdraw the authorisation by 31 March 2015 at the latest; or
- (b) in the case of a product containing maltodextrin as one of several active substances, where necessary, amend or withdraw the authorisation by 31 March 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or substances, whichever is the latest.

Article 3

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 4

Entry into force and date of application

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 1 October 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ 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
Maltodextrin CAS No 9050-36-6 CIPAC No 801	None allocated	≥ 910 g/kg	1 October 2013	30 September 2023	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 maltodextrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the potential increased growth of fungi and possible presence of mycotoxins on the surface of treated fruits; (b) the potential risk to honeybees and non-target arthropods. 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.

ANNEX II

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'44	Maltodextrin CAS No 9050-36-6 CIPAC No 801	None allocated	≥ 910 g/kg	1 October 2013	30 September 2023	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 maltodextrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the potential increased growth of fungi and possible presence of mycotoxins on the surface of treated fruits; (b) the potential risk to honeybees and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate.'

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

COMMISSION IMPLEMENTING REGULATION (EU) No 356/2013

of 18 April 2013

approving the active substance halosulfuron-methyl, 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 Articles 13(2) and 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For halosulfuron-methyl the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2006/586/EC ⁽³⁾.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC, Italy received on 19 May 2005 an application from Nissan Chemical Europe S.A.R.L. for the inclusion of the active substance halosulfuron-methyl in Annex I to Directive 91/414/EEC. Decision 2006/586/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 30 March 2007.
- (4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the review of the pesticide risk assessment of the active substance halosulfuron-methyl ⁽⁴⁾ on 26 November 2012. The draft assessment

report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and the draft assessment report was finalised on 15 March 2013 in the format of the Commission review report for halosulfuron-methyl.

- (5) It has appeared from the various examinations made that plant protection products containing halosulfuron-methyl may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the use which was examined and detailed in the Commission review report. It is therefore appropriate to approve halosulfuron-methyl.
- (6) 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 and restrictions. It is, in particular, appropriate to require further confirmatory information.
- (7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.
- (8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing halosulfuron-methyl. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽⁵⁾ has shown

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 236, 31.8.2006, p. 31.

⁽⁴⁾ EFSA Journal (2012) 10(11):2987. Available online: www.efsa.europa.eu

⁽⁵⁾ OJ L 366, 15.12.1992, p. 10.

that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to 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⁽¹⁾ should be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance halosulfuron-methyl, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing halosulfuron-methyl as an active substance by 31 March 2014.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive

91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing halosulfuron-methyl as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 September 2013 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing halosulfuron-methyl as the only active substance, where necessary, amend or withdraw the authorisation by 31 March 2015 at the latest; or
- (b) in the case of a product containing halosulfuron-methyl as one of several active substances, where necessary, amend or withdraw the authorisation by 31 March 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

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 4

Entry into force and date of application

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 1 October 2013.

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

Done at Brussels, 18 April 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ 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
Halosulfuron-methyl CAS No 100785-20-1 CIPAC No 785.201	methyl 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylate	≥ 980 g/kg	1 October 2013	30 September 2023	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 halosulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk of leakage to groundwater of the metabolite 'halosulfuron rearrangement' (HSR) ⁽²⁾ under vulnerable conditions. This metabolite is considered toxicologically relevant based on the available information for halosulfuron, — the risk to non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) information as regards the equivalence between the technical specifications of the material, as commercially manufactured, and those of the material used in the toxicological and ecotoxicological studies; (b) information on the toxicological relevance of the impurities present in the technical specification of the material as commercially manufactured; (c) data to clarify the potential genotoxic properties of chlorosulfonamide acid ⁽³⁾. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.

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

⁽²⁾ 3-chloro-5-[(4,6-dimethoxy-2-pyrimidinyl)amino]-1-methyl-1H-pyrazole-4-carboxylic acid.

⁽³⁾ 3-chloro-1-methyl-5-sulfamoyl-1H-pyrazole-4-carboxylic acid.

ANNEX II

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

'35	Halosulfuron-methyl CAS No 100785-20-1 CIPAC No 785.201	methyl 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylate	≥ 980 g/kg	1 October 2013	30 September 2023	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 halosulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk of leakage to groundwater of the metabolite 'halosulfuron rearrangement' (HSR) ⁽¹⁾ under vulnerable conditions. This metabolite is considered toxicologically relevant based on the available information for halosulfuron, — the risk to non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) information as regards the equivalence between the specifications of the technical material, as commercially manufactured, and the test material used in the toxicological and ecotoxicological studies; (b) information on the toxicological relevance of the impurities present in the technical specification as commercially manufactured; (c) data to clarify the potential genotoxic properties of chlorosulfonamide acid ⁽²⁾. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.
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⁽¹⁾ 3-chloro-5-[(4,6-dimethoxy-2-pyrimidinyl)amino]-1-methyl-1*H*-pyrazole-4-carboxylic acid.

⁽²⁾ 3-chloro-1-methyl-5-sulfamoyl-1*H*-pyrazole-4-carboxylic acid.'

COMMISSION IMPLEMENTING REGULATION (EU) No 357/2013

of 18 April 2013

amending Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 as regards the minimum content of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for chickens for fattening and minor avian species (excluding laying birds) (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.)

(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) The use of a preparation of *Clostridium butyricum* (FERM BP-2789), belonging to the additive category of 'zoo-technical additives', was authorised for 10 years as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 903/2009⁽²⁾ and for minor avian species (excluding laying birds) and for weaned piglets and minor porcine species (weaned) by Commission Implementing Regulation (EU) No 373/2011⁽³⁾.
- (2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of the preparation concerned by reducing its minimum content from 5×10^8 CFU/kg to $2,5 \times 10^8$ CFU/kg complete feedingstuff as regards the use on chickens for fattening and minor avian species (excluding laying birds). The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').
- (3) The Authority concluded in its opinion of 11 December 2012⁽⁴⁾ that, under the new proposed conditions of use, the preparation concerned shows some potential to improve performance at the requested minimum dose of $2,5 \times 10^8$ CFU/kg on chickens for fattening and

minor avian species (excluding laying birds). 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.

- (4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (5) Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In the Annex to Regulation (EC) No 903/2009, in the column 'Minimum content', the words ' 5×10^8 CFU' are replaced by the words ' $2,5 \times 10^8$ '.

Article 2

In the Annex to Implementing Regulation (EU) No 373/2011, in the column 'Minimum content', for minor avian species (excluding laying birds) the words ' 5×10^8 CFU' are replaced by the words ' $2,5 \times 10^8$ ' and for piglets (weaned) and minor porcine species (weaned) the words ' $2,5 \times 10^8$ CFU' are replaced by the words ' $2,5 \times 10^8$ '.

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, 18 April 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 256, 29.9.2009, p. 26.

⁽³⁾ OJ L 102, 16.4.2011, p. 10.

⁽⁴⁾ EFSA Journal 2013; 11(1):3040.

COMMISSION IMPLEMENTING REGULATION (EU) No 358/2013**of 18 April 2013****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 18 April 2013.

*For the Commission,
On behalf of the President,*

Jerzy PLEWA
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	MA	57,0
	TN	98,3
	TR	106,5
	ZZ	87,3
0707 00 05	AL	46,1
	MA	99,6
	TR	131,8
	ZZ	92,5
0709 93 10	MA	91,2
	TR	108,8
	ZZ	100,0
0805 10 20	EG	53,2
	IL	68,8
	MA	63,4
	TN	68,7
	TR	68,9
	US	84,5
	ZZ	67,9
0805 50 10	TR	86,0
	ZA	91,7
	ZZ	88,9
0808 10 80	AR	106,9
	BR	88,0
	CL	121,2
	CN	72,7
	MK	28,7
	NZ	141,4
	US	195,4
	ZA	109,9
	ZZ	108,0
0808 30 90	AR	128,0
	CL	139,1
	CN	72,9
	TR	204,5
	ZA	126,3
	ZZ	134,2

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION IMPLEMENTING REGULATION (EU) No 359/2013**of 18 April 2013****amending Regulation (EC) No 1484/95 as regards representative prices in the poultrymeat and egg sectors and for egg albumin**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 143 in conjunction with Article 4 thereof,

Having regard to Council Regulation (EC) No 614/2009 of 7 July 2009 on the common system of trade for ovalbumin and lactalbumin ⁽²⁾, and in particular Article 3(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 ⁽³⁾ lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for

egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.

(3) Regulation (EC) No 1484/95 should be amended accordingly.

(4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 18 April 2013.

*For the Commission,
On behalf of the President,*

*Jerzy PLEWA
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 181, 14.7.2009, p. 8.

⁽³⁾ OJ L 145, 29.6.1995, p. 47.

ANNEX

'ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security pursuant to Article 3(3) (EUR/100 kg)	Origin ⁽¹⁾
0207 12 10	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as "70 % chickens", frozen	148,8	0	AR
0207 12 90	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as "65 % chickens", frozen	164,4	0	AR
		157,2	0	BR
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	254,8	14	AR
		247,1	16	BR
		303,9	0	CL
		258,1	13	TH
0207 27 10	Turkeys, boneless cuts, frozen	315,6	0	BR
		306,2	0	CL
0408 11 80	Egg yolks	375,8	0	AR
0408 91 80	Eggs, not in shell, dried	469,1	0	AR
1602 32 11	Preparations of fowls of the species <i>Gallus domesticus</i> , uncooked	292,4	0	BR
3502 11 90	Egg albumin, dried	750,3	0	AR

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code "ZZ" stands for "of other origin".

COMMISSION IMPLEMENTING REGULATION (EU) No 360/2013**of 18 April 2013****fixing the export refunds on poultrymeat**

THE EUROPEAN COMMISSION,

European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽³⁾.

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 164(2) and Article 170, in conjunction with Article 4, thereof,

Whereas:

(1) Article 162(1) of Regulation (EC) No 1234/2007 provides that the difference between prices on the world market for the products referred to in Part XX of Annex I to that Regulation and prices in the Union for those products may be covered by an export refund.

(2) In view of the current situation on the market in poultrymeat, export refunds should be fixed in accordance with the rules and criteria provided for in Articles 162, 163, 164, 167 and 169 of Regulation (EC) No 1234/2007.

(3) Article 164(1) of Regulation (EC) No 1234/2007 provides that refunds may vary according to destination, especially where the world market situation, the specific requirements of certain markets, or obligations resulting from agreements concluded in accordance with Article 300 of the Treaty make this necessary.

(4) Refunds should be granted only on products which are authorised to move freely in the Union and bear the identification mark provided for in Article 5(1)(b) of 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 ⁽²⁾. Those products should also comply with the requirements of Regulation (EC) No 852/2004 of the

(5) The currently applicable refunds have been fixed by Commission Implementing Regulation (EU) No 33/2013 ⁽⁴⁾. Since new refunds should be fixed, that Regulation should therefore be repealed.

(6) In order to prevent divergence with the current market situation, to prevent market speculation and to ensure efficient management this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*.

(7) The Management Committee for the Common Organisation of Agricultural Markets has not delivered an opinion within the time limit set by its Chair,

HAS ADOPTED THIS REGULATION:

Article 1

1. Export refunds as provided for in Article 164 of Regulation (EC) No 1234/2007 shall be granted on the products and for the amounts set out in the Annex to this Regulation subject to the conditions provided for in paragraph 2 of this Article.

2. The products eligible for a refund under paragraph 1 shall meet the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and, in particular, shall be prepared in an approved establishment and comply with the identification marking conditions laid down in Section I of Annex II to Regulation (EC) No 853/2004.

Article 2

Implementing Regulation (EU) No 33/2013 is hereby repealed.

*Article 3*This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.⁽¹⁾ OJ L 299, 16.11.2007, p. 1.⁽²⁾ OJ L 139, 30.4.2004, p. 55.⁽³⁾ OJ L 139, 30.4.2004, p. 1.⁽⁴⁾ OJ L 14, 18.1.2013, p. 15.

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

Done at Brussels, 18 April 2013.

*For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and
Rural Development*

ANNEX

Export refunds on poultrymeat applicable from 19 April 2013

Product code	Destination	Unit of measurement	Amount of refund
0105 11 11 9000	A02	EUR/100 pcs	0,00
0105 11 19 9000	A02	EUR/100 pcs	0,00
0105 11 91 9000	A02	EUR/100 pcs	0,00
0105 11 99 9000	A02	EUR/100 pcs	0,00
0105 12 00 9000	A02	EUR/100 pcs	0,00
0105 14 00 9000	A02	EUR/100 pcs	0,00
0207 12 10 9900	V03	EUR/100 kg	10,85
0207 12 90 9190	V03	EUR/100 kg	10,85
0207 12 90 9990	V03	EUR/100 kg	10,85

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1).

The other destinations are defined as follows:

V03: A24, Angola, Saudi Arabia, Kuwait, Bahrain, Qatar, Oman, United Arab Emirates, Jordan, Yemen, Lebanon, Iraq and Iran.

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