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Contents



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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.

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**Notice to readers — Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union*** (see page 3 of the cover)

**Note to readers — way of referring to acts** (see page 3 of the cover)

EN

[1] Text with EEA relevance

II

*(Non-legislative acts)*

# REGULATIONS

## COMMISSION REGULATION (EU) No 820/2013

## of 27 August 2013

## establishing a prohibition of fishing for anglerfish in areas VIIIc, IX and X; EU waters of CECAF 34.1.1 by vessels flying the flag of France

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 39/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available to EU vessels for certain fish stocks and groups of fish stocks which are not subject to international negotiations or agreements [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the 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, 27 August 2013.

*For the Commission,*
*On behalf of the President,*
Lowri EVANS
*Director-General for Maritime Affairs and Fisheries*

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 23, 25.1.2013, p. 1.

*ANNEX*

| | |
|---|---|
| No | 20/TQ39 |
| Member State | France |
| Stock | ANF/83411 |
| Species | Anglerfish (Lophiidae) |
| Zone | VIIIc, IX and X; EU waters of CECAF 34.1.1 |
| Date | 4.2.2013 |

# COMMISSION REGULATION (EU) No 821/2013

## of 27 August 2013

## establishing a prohibition of fishing for redfish in NAFO Area 3M by vessels flying the flag of a Member State of the European Union

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 40/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available in EU waters and, to EU vessels, in certain non-EU waters for certain fish stocks and groups of fish stocks which are subject to international negotiations or agreements [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the 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, 27 August 2013.

*For the Commission,*
*On behalf of the President,*
Lowri EVANS
*Director-General for Maritime Affairs and Fisheries*

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 23, 25.1.2013, p. 54.

*ANNEX*

| | |
|---|---|
| Member State | European Union (All Member States) |
| Stock | RED/N3M |
| Species | Redfish (*Sebastes* spp) |
| Zone | NAFO 3M |
| Closing date | 30.7.2013 |

# COMMISSION REGULATION (EU) No 822/2013

## of 27 August 2013

## establishing a prohibition of fishing for sprat in Union waters of Subdivisions 22-32 by vessels flying the flag of Poland

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 1088/2012 of 20 November 2012 fixing for 2013 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the 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, 27 August 2013.

*For the Commission,*
*On behalf of the President,*
Lowri EVANS
*Director-General for Maritime Affairs and Fisheries*

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 323, 22.11.2012, p. 2.

*ANNEX*

| | |
|---|---|
| No | 19/BAL |
| Member State | Poland |
| Stock | SPR/3BCD-C |
| Species | Sprat *(Sprattus sprattus)* |
| Zone | Union waters of Subdivisions 22-32 |
| Date | 12.7.2013 |

# COMMISSION REGULATION (EU) No 823/2013

## of 27 August 2013

## establishing a prohibition of fishing for saithe in VI; EU and international waters of Vb, XII and XIV flying the flag of Spain

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 40/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available in EU waters and, to EU vessels, in certain non-EU waters for certain fish stocks and groups of fish stocks which are subject to international negotiations or agreements [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the 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, 27 August 2013.

*For the Commission,*
*On behalf of the President,*
Lowri EVANS
*Director-General for Maritime Affairs and Fisheries*

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 23, 25.1.2013, p. 54.

*ANNEX*

| | |
|---|---|
| No | 18/TQ40 |
| Member State | Spain |
| Stock | POK/56-14 |
| Species | Saithe (*Pollachius virens*) |
| Zone | VI; EU and international waters of Vb, XII and XIV |
| Date | 12.7.2013 |

# COMMISSION REGULATION (EU) No 824/2013

## of 28 August 2013

## establishing a prohibition of fishing for cod in Norwegian waters of I and II by vessels flying the flag of Portugal

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 40/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available in EU waters and, to EU vessels, in certain non-EU waters for certain fish stocks and groups of fish stocks which are subject to international negotiations or agreements [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the 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, 28 August 2013.

*For the Commission,*
*On behalf of the President,*
Lowri EVANS
*Director-General for Maritime Affairs and Fisheries*

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 23, 25.1.2013, p. 54.

*ANNEX*

| | |
|---|---|
| No | 23/TQ40 |
| Member State | Portugal |
| Stock | COD/1N2AB. |
| Species | Cod (*Gadus Morhua*) |
| Zone | Norwegian waters of I and II |
| Date | 30.7.2013 |

# COMMISSION REGULATION (EU) No 825/2013

## of 28 August 2013

## establishing a prohibition of fishing for cod in areas I and IIb by vessels flying the flag of Portugal

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 40/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available in EU waters and, to EU vessels, in certain non-EU waters for certain fish stocks and groups of fish stocks which are subject to international negotiations or agreements [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the 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, 28 August 2013.

*For the Commission,*
*On behalf of the President,*
Lowri EVANS
*Director-General for Maritime Affairs and Fisheries*

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 23, 25.1.2013, p. 54.

*ANNEX*

| | |
|---|---|
| No | 22/TQ40 |
| Member State | Portugal |
| Stock | COD/1/2B. |
| Species | Cod (*Gadus Morhua*) |
| Zone | I and IIb |
| Date | 30.7.2013 |

# COMMISSION IMPLEMENTING REGULATION (EU) No 826/2013

## of 29 August 2013

## approving the active substance sedaxane, 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 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 sedaxane the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2011/123/EU ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC France received on 14 June 2010 an application from Syngenta Crop Protection AG for the inclusion of the active substance sedaxane in Annex I to Directive 91/414/EEC. Decision 2011/123/EU 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 10 May 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 sedaxane ([4]) on 6 July 2012.

(5) In November 2012, the Commission requested further toxicological assessment from the Authority. The rapporteur Member State submitted an addendum to its draft assessment report. The Authority updated its conclusion and undertook a final consultation with the Member States.

(6) The Authority presented to the Commission its updated conclusion on the review of the pesticide risk assessment of the active substance sedaxane ([5]) on 18 December 2012. The draft assessment report and the updated 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 16 July 2013 in the format of the Commission review report for sedaxane.

(7) It has appeared from the various examinations made that plant protection products containing sedaxane 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 sedaxane.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) OJ L 230, 19.8.1991, p. 1.
([3]) OJ L 49, 24.2.2011, p. 40.
([4]) EFSA Journal (2012); 10(7):2823. Available online: www.efsa.europa.eu
([5]) EFSA Journal (2012); 11(1):3057. Available online: www.efsa.europa.eu

(8) 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.

(9) 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.

(10) 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 sedaxane. 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.

(11) 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 [1] 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. 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.

(12) 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 [2] should be amended accordingly.

(13) 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 sedaxane, 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 sedaxane as an active substance by 31 July 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 sedaxane 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 31 January 2014 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 sedaxane as the only active substance, where necessary, amend or withdraw the authorisation by 31 July 2015 at the latest; or

(b) in the case of a product containing sedaxane as one of several active substances, where necessary, amend or withdraw the authorisation by 31 July 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.

[1] OJ L 366, 15.12.1992, p. 10.
[2] OJ L 153, 11.6.2011, p. 1.

*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 February 2014.

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

Done at Brussels, 29 August 2013.

*For the Commission*
*The President*
José Manuel BARROSO

*ANNEX I*

| Common Name, Identification Numbers | IUPAC Name | Purity [1] | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|
| Sedaxane<br><br>CAS No 874967-67-6<br><br>(trans isomer: 599197-38-3/cis isomer: 599194-51-1)<br><br>CIPAC No 833 | mixture of 2 cis-isomers 2′-[(1RS,2RS)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 trans-isomers 2′-[(1RS,2SR)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide | ≥ 960 g/kg Sedaxane<br><br>(range 820-890 g/kg for the 2 trans-isomers 50:50 mixture of enantiomers and range 100-150 g/kg for the 2 cis-isomers 50:50 mixture of enantiomers) | 1 February 2014 | 31 January 2024 | PART A<br><br>Only uses for seed treatment may be authorised.<br><br>PART B<br><br>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 sedaxane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to:<br><br>(a) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;<br><br>(b) the long-term risk to birds and mammals.<br><br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br><br>The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite CSCD465008 in vulnerable zones, where appropriate.<br><br>The Member States concerned shall request the submission of confirmatory information as regards the relevance of the metabolite CSCD465008, and the corresponding groundwater risk assessment, if sedaxane is classified under Regulation (EC) No 1272/2008 as ‘suspected of causing cancer’.<br><br>The notifier shall submit to the Commission, the Member States and the Authority the relevant information within six months from the application date of the Regulation classifying sedaxane. |

[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 |
|---|---|---|---|---|---|---|
| '48 | Sedaxane<br><br>CAS No 874967-67-6<br><br>(trans isomer: 599197-38-3/cis isomer: 599194-51-1)<br><br>CIPAC No 833 | mixture of 2 cis-isomers 2′-[(1RS,2RS)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 trans-isomers 2′-[(1RS,2SR)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide | ≥ 960 g/kg Sedaxane<br><br>(range 820-890 g/kg for the 2 trans-isomers 50:50 mixture of enantiomers and range 100-150 g/kg for the 2 cis-isomers 50:50 mixture of enantiomers) | 1 February 2014 | 31 January 2024 | PART A<br><br>Only uses for seed treatment may be authorised.<br><br>PART B<br><br>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 sedaxane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to:<br><br>(a) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;<br><br>(b) the long-term risk to birds and mammals.<br><br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br><br>The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite CSCD465008 in vulnerable zones, where appropriate.<br><br>The Member States concerned shall request the submission of confirmatory information as regards the relevance of the metabolite CSCD465008, and the corresponding groundwater risk assessment, if sedaxane is classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer'.<br><br>The notifier shall submit to the Commission, the Member States and the Authority the relevant information within six months from the application date of the Regulation classifying sedaxane.' |

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

# COMMISSION IMPLEMENTING REGULATION (EU) No 827/2013

## of 29 August 2013

## approving the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2008/953/EC ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC Austria received on 17 April 2008 an application from bio-ferm Biotechnologische Entwicklung und Produktion GmbH for the inclusion of the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) in Annex I to Directive 91/414/EEC. Decision 2008/953/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 17 December 2009. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ([4]) additional information was requested from the applicant on 26 July 2011. The evaluation of the additional data by Austria was submitted in the format of an updated draft assessment report in January 2012.

(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 ([5]) on the review of the pesticide risk assessment of the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) on 2 April 2013. 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 finalised on 16 July 2013 in the format of the Commission review report for *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941).

(5) It has appeared from the various examinations made that plant protection products containing *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941).

(6) 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.

(7) 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

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

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

([3]) Commission Decision 2008/953/EC of 8 December 2008 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of *Aureobasidium pullulans* and disodium phosphonate in Annex I to Council Directive 91/414/EEC (OJ L 338, 17.12.2008, p. 62)

([4]) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

([5]) *EFSA Journal* (2013) 11(4):3183. Available online: www.efsa.europa.eu

period of six months after approval to review authorisations of plant protection products containing *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941). 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 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.

(8) 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 [1] 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. 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.

(9) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [2] should be amended accordingly.

(10) 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) as an active substance by 31 July 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) 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 31 January 2014 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) as the only active substance, where necessary, amend or withdraw the authorisation by 31 July 2015 at the latest; or

(b) in the case of a product containing *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) as one of several active substances, where necessary, amend or withdraw the authorisation by 31 July 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 February 2014.

[1] 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 (OJ L 366, 15.12.1992, p. 10).

[2] 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).

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

Done at Brussels, 29 August 2013.

*For the Commission*
*The President*
José Manuel BARROSO

*ANNEX I*

| Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|
| *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941)<br><br>Collection number: German Collection of Microorganisms and cell Cultures (DSMZ) with the accession numbers DSM 14940 and DSM 14941 | Not applicable | Minimum $5,0 \times 10^9$ CFU/g for each strain;<br><br>Maximum $5,0 \times 10^{10}$ CFU/g for each strain | 1 February 2014 | 31 January 2024 | 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) is to be considered as a potential sensitizer.<br><br>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 |
|---|---|---|---|---|---|---|
| '52 | *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941)<br><br>Collection number: German Collection of Microorganisms and cell Cultures (DSMZ) with the accession numbers DSM 14940 and DSM 14941 | Not applicable | Minimum $5{,}0 \times 10^{9}$ CFU/g for each strain;<br><br>Maximum $5{,}0 \times 10^{10}$ CFU/g for each strain | 1 February 2014 | 31 January 2024 | 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 *Aureobasidium* pullulans (strains DSM 14940 and DSM 14941), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) is to be considered as a potential sensitizer.<br><br>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 828/2013

## of 29 August 2013

## approving the active substance emamectin, 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 emamectin the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2007/669/EC [3].

(2) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands received on 23 June 2006 an application from Syngenta Crop Protection AG for the inclusion of the active substance emamectin in Annex I to Directive 91/414/EEC. Decision 2007/669/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 6 March 2008.

(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 [4] on the pesticide risk assessment of the active substance emamectin on 13 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 finalised on 16 July 2013 in the format of the Commission review report for emamectin.

(5) It has appeared from the various examinations made that plant protection products containing emamectin 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 emamectin.

(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 emamectin. 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 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

[1] OJ L 309, 24.11.2009, p. 1.
[2] OJ L 230, 19.8.1991, p. 1.
[3] OJ L 274, 18.10.2007, p. 15.
[4] *EFSA Journal 2012*; 10(11):2955. Available online: www.efsa.europa.eu
[5] OJ L 366, 15.12.1992, p. 10.

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 emamectin, 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 emamectin as an active substance by 31 October 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 emamectin 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 April 2014 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 emamectin as the only active substance, where necessary, amend or withdraw the authorisation by 31 October 2015 at the latest; or

(b) in the case of a product containing emamectin as one of several active substances, where necessary, amend or withdraw the authorisation by 31 October 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 May 2014.

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

Done at Brussels, 29 August 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 |
|---|---|---|---|---|---|
| Emamectin<br><br>CAS No<br>emamectin: 119791-41-2<br><br>(formerly 137335-79-6) and 123997-28-4<br><br>emamectin benzoate: 155569-91-8<br><br>(formerly 137512-74-4 and 179607-18-2)<br><br>emamectin B1a benzoate: 138511-97-4<br><br>emamectin B1b benzoate: 138511-98-5<br><br>CIPAC No<br>emamectin: 791<br><br>emamectin benzoate: 791.412 | Emamectin B1a:<br><br>(10.,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6′-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1$^{4,8}$.0$^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-*O*-methyl-4-*O*-(2,4,6-trideoxy-3-*O*-methyl-4-methylamino-α-L-*lyxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside<br><br>Emamectin B1b:<br><br>(10*E*,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,24-dihydroxy-6′-isopropyl-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1$^{4,8}$.0$^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-*O*-methyl-4-*O*-(2,4,6-trideoxy-3-*O*-methyl-4-methylamino-α-L-l*yxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside<br><br>Emamectin B1a benzoate:<br><br>(10*E*,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6′-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1$^{4,8}$.0$^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-*O*-methyl-4-*O*-(2,4,6-trideoxy-3-*O*-methyl-4-methylamino-α-L-*lyxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside benzoate | ≥ 950 g/kg<br><br>as emamectin benzoate anhydrous<br><br>(a mixture of min. 920 g/kg emamectin B1a benzoate and max. 50 g/kg emamectin B1b benzoate) | 1 May 2014 | 30 April 2024 | 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 emamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to:<br><br>— the risk to non-target invertebrates;<br><br>— the protection of workers and operators.<br><br>Conditions of use shall include risk mitigation measures, where appropriate.<br><br>The applicant shall submit confirmatory information as regards the risk of enantio-selective metabolisation or degradation.<br><br>The applicant shall submit to the Commission, Member States and the Authority the relevant information two years after adoption of the pertinent guidance document on evaluation of isomer mixtures. |

| Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|
| | Emamectin B1b benzoate:<br>(10*E*,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,24-dihydroxy-6′-isopropyl-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.$1^{4,8}$.$0^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-*O*-methyl-4-*O*-(2,4,6-trideoxy-3-*O*-methyl-4-methylamino-α-L-l*yxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside benzoate | | | | |

(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 [1] | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|---|
| '49 | Emamectin<br><br>CAS No<br>emamectin: 119791-41-2<br><br>(formerly 137335-79-6) and 123997-28-4<br><br>emamectin benzoate: 155569-91-8<br><br>(formerly 137512-74-4 and 179607-18-2)<br><br>emamectin B1a benzoate: 138511-97-4<br><br>emamectin B1b benzoate: 138511-98-5<br><br>CIPAC No<br>emamectin: 791<br><br>emamectin benzoate: 791.412 | Emamectin B1a:<br><br>(10*E*,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6′-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1$^{4,8}$.0$^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-*O*-methyl-4-*O*-(2,4,6-trideoxy-3-*O*-methyl-4-methylamino-α-L-*lyxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside<br><br>Emamectin B1b:<br><br>(10*E*,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,24-dihydroxy-6′-isopropyl-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1$^{4,8}$.0$^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-*O*-methyl-4-*O*-(2,4,6-trideoxy-3-*O*-methyl-4-methylamino-α-L-*lyxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside<br><br>Emamectin B1a benzoate:<br><br>(10*E*,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6′-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1$^{4,8}$.0$^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-*O*-methyl-4-*O*-(2,4,6-trideoxy-3-*O*-methyl-4-methylamino-α-L-*lyxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside benzoate | ≥ 950 g/kg<br><br>as emamectin benzoate anhydrous<br><br>(a mixture of min. 920 g/kg emamectin B1a benzoate and max. 50 g/kg emamectin B1b benzoate) | 1 May 2014 | 30 April 2024 | 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 emamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to:<br><br>— the risk to non-target invertebrates;<br><br>— the protection of workers and operators.<br><br>Conditions of use shall include risk mitigation measures, where appropriate.<br><br>The applicant shall submit confirmatory information as regards the risk of enantio-selective metabolisation or degradation.<br><br>The applicant shall submit to the Commission, Member States and the Authority the relevant information two years after adoption of the pertinent guidance document on evaluation of isomer mixtures.' |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|---|
| | | Emamectin B1b benzoate:<br><br>(10*E*,14*E*,16*E*)-(1*R*,4*S*,5′*S*,6*S*,6′*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,24-dihydroxy-6′-isopropyl-5′,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1$^{4,8}$.0$^{20,24}$]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′*H*-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-*lyxo*-hexapyranosyl)-α-L-*arabino*-hexapyranoside benzoate | | | | |

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

# COMMISSION IMPLEMENTING REGULATION (EU) No 829/2013

## of 29 August 2013

## approving the active substance *Pseudomonas* sp. strain DSMZ 13134, 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 *Pseudomonas* sp. strain DSMZ 13134 the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2008/599/EC ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands received on 28 August 2007 an application from Sourcon-Padena GmbH & Co. KG for the inclusion of the active substance *Pseudomonas* sp. strain DSMZ 13134 in Annex I to Directive 91/414/EEC. Decision 2008/599/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 3 November 2009.

(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 ([4]) on the pesticide risk assessment of the active substance *Pseudomonas* sp. strain DSMZ 13134 on 12 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 finalised on 16 July 2013 in the format of the Commission review report for *Pseudomonas* sp. strain DSMZ 13134.

(5) It has appeared from the various examinations made that plant protection products containing *Pseudomonas* sp. strain DSMZ 13134 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 *Pseudomonas* sp. strain DSMZ 13134.

(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 *Pseudomonas* sp. strain DSMZ 13134. 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 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

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) OJ L 230, 19.8.1991, p. 1.
([3]) OJ L 193, 22.7.2008, p. 14.
([4]) EFSA Journal 2012; 10(12):2954. Available online: www.efsa.europa.eu

of plant protection products on the market ([1]) 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. 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 ([2]) 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 *Pseudomonas* sp. strain DSMZ 13134, 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 *Pseudomonas* sp. strain DSMZ 13134 as an active substance by 31 July 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 *Pseudomonas* sp. strain DSMZ 13134 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 31 January 2014 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 *Pseudomonas* sp. strain DSMZ 13134 as the only active substance, where necessary, amend or withdraw the authorisation by 31 July 2015 at the latest; or

(b) in the case of a product containing *Pseudomonas* sp. strain DSMZ 13134 as one of several active substances, where necessary, amend or withdraw the authorisation by 31 July 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 February 2014.

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

Done at Brussels, 29 August 2013.

*For the Commission*
*The President*
José Manuel BARROSO

([1]) OJ L 366, 15.12.1992, p. 10.
([2]) 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 |
|---|---|---|---|---|---|
| *Pseudomonas* sp. strain DSMZ 13134<br>Collection number: DSMZ 13134 | Not applicable | Minimum concentration: $3 \times 10^{14}$ cfu/kg | 1 February 2014 | 31 January 2024 | 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 *Pseudomonas* sp. strain DSMZ 13134, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Pseudomonas* sp. strain DSMZ 13134 is to be considered as a potential sensitizer.<br>Conditions of use shall include risk mitigation measures, where appropriate.<br>The applicant shall submit information to confirm the absence of an acute intratracheal and intraperitoneal toxicity/infectivity/pathogenicity potential.<br>The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016. |

(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 (1) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|---|
| '50 | *Pseudomonas* sp. strain DSMZ 13134<br>Collection number: DSMZ 13134 | Not applicable | Minimum concentration: $3\times10^{14}$ cfu/kg | 1 February 2014 | 31 January 2024 | 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 *Pseudomonas* sp. strain DSMZ 13134, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Pseudomonas* sp. strain DSMZ 13134 is to be considered as a potential sensitizer.<br>Conditions of use shall include risk mitigation measures, where appropriate.<br>The applicant shall submit information to confirm the absence of an acute intratracheal and intraperitoneal toxicity/infectivity/pathogenicity potential.<br>The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016.' |

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

# COMMISSION IMPLEMENTING REGULATION (EU) No 830/2013

## of 29 August 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 multilateral 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, 29 August 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 |
|---|---|---|
| 0707 00 05 | TR | 95,4 |
| | ZZ | 95,4 |
| 0709 93 10 | TR | 133,0 |
| | ZZ | 133,0 |
| 0805 50 10 | AR | 117,7 |
| | CL | 120,7 |
| | TR | 70,0 |
| | UY | 121,3 |
| | ZA | 113,2 |
| | ZZ | 108,6 |
| 0806 10 10 | EG | 174,1 |
| | TR | 142,0 |
| | ZZ | 158,1 |
| 0808 10 80 | AR | 101,6 |
| | BR | 108,7 |
| | CL | 131,8 |
| | CN | 113,3 |
| | NZ | 131,0 |
| | US | 130,9 |
| | ZA | 119,5 |
| | ZZ | 119,5 |
| 0808 30 90 | AR | 195,1 |
| | CN | 88,3 |
| | TR | 145,6 |
| | ZA | 92,9 |
| | ZZ | 130,5 |
| 0809 30 | BA | 45,1 |
| | TR | 141,3 |
| | ZZ | 93,2 |
| 0809 40 05 | BA | 50,3 |
| | MK | 51,8 |
| | XS | 56,0 |
| | ZZ | 52,7 |

(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'.

# DECISIONS

## COMMISSION IMPLEMENTING DECISION

**of 28 August 2013**

**concerning the Italian draft Decree on the methods for indicating the origin for shelf-stable milk, UHT milk, microfiltered pasteurised milk and high-temperature pasteurised milk**

*(notified under document C(2013) 5517)*

**(Only the Italian text is authentic)**

**(Text with EEA relevance)**

(2013/444/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1], and in particular Article 19 thereof,

Whereas:

(1) In accordance with the procedure provided for in the second paragraph of Article 19 of Directive 2000/13/EC, the Italian authorities notified to the Commission on 9 November 2012 a draft Decree providing, inter alia, for mandatory labelling requirements on shelf-stable milk, UHT milk, microfiltered pasteurised milk and high-temperature pasteurised milk.

(2) Article 2(1) of the notified Decree provides that the labels of sterilised shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk must indicate the country of origin of the dairy farm the treated milk comes from or the indication of either 'EU' or 'third countries', in the event that the provenance of the milk is respectively from one or more European Union Member States or from third countries.

(3) Directive 2000/13/EC harmonises the rules governing the labelling of foodstuffs by making provision for, on the one hand, harmonisation of certain national provisions and, secondly, arrangements for non-harmonised national provisions. The scope of harmonisation is defined in Article 3(1) of that Directive, which lists all the particulars that are compulsory on the labelling of foodstuffs in accordance with Articles 4 to 17 and subject to the exceptions contained therein.

(4) Article 3(1) point 8 of Directive 2000/13/EC provides that information on the place of origin or provenance shall be given 'where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff'.

(5) Article 4(2) of Directive 2000/13/EC provides that other particulars in addition to those listed in Article 3(1) of that Directive may be required, in the case of specified foodstuffs, by Union provisions or, in their absence, by national provisions.

(6) Article 18(2) of Directive 2000/13/EC allows the adoption of non-harmonised national provisions if they are justified on one of the grounds listed therein, including, inter alia, the protection of public health and the prevention of fraud, provided they are not of such a nature as to impede application of the definitions and rules laid down by Directive 2000/13/EC. Therefore, where draft national labelling provisions have been proposed in a Member State, it is necessary to examine their compatibility with the above-mentioned requirements and the provisions of the Treaty on the Functioning of the European Union.

(7) The Italian authorities maintain that the notified measure is necessary to ensure protection of consumer interests and to strengthen enforcement of the prevention and repression of food fraud. It is explained that, contrary to the belief of the Italian consumers, milk marketed in Italy is not solely of national origin and therefore, the indication of the origin on the label has become indispensable in order to avoid consumers being misled. In view of the above considerations, the Italian authorities maintain that the provisions of Article 2(1) are justified in the light of Article 3(1) point 8 of Directive 2000/13/EC.

(8) Article 3(1) point 8 of Directive 2000/13/EC puts in place an appropriate mechanism to counter the risk of consumers being misled in cases where some elements could imply that a given food comes from an origin or provenance different from the true one. It is for food

[1] OJ L 109, 6.5.2000, p. 29.

operators to ensure that information on the place of origin or provenance is present on the label where its omission could create confusion in the mind of the consumer. And it is for national enforcement authorities to ascertain compliance with this obligation.

(9) Provisions of Article 2(1) of the notified Decree would entail that the foods at issue are always presented in such a way that they confuse the Italian consumer as to their true origin or place of provenance. In this regard, the Commission notes that the scope of the notified Decree does not apply to milks with a (very) limited shelf life (raw milk, pasteurised milk). Thus, precisely the latter are likely to suggest the consumer the Italian origin of milks in question.

(10) Apart from the reference to the need of protecting the interests of the consumer, the Italian authorities did not provide sufficient justifications allowing to conclude that, as regards the products listed in Article 1 of the notified Decree, the mandatory indication of the origin, beyond the obligation laid down in Article 3(1) point 8 of Directive 2000/13/EC, is necessary.

(11) Therefore, the Italian authorities did not demonstrate that the indication of origin as provided by the notified Decree is necessary to attain one of the objectives listed in Article 18(2) of Directive 2000/13/EC.

(12) In light of these observations, the Commission has delivered a negative opinion on the above-mentioned provisions of the notified Decree, pursuant to the third paragraph of Article 19 of Directive 2000/13/EC.

(13) The Italian authorities should accordingly be requested not to adopt the provisions of Article 2(1) of the notified Decree.

(14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

The Italian Republic shall not adopt the provisions of Article 2(1) of the notified Decree on the methods for indicating the origin for shelf-stable milk, UHT milk, microfiltered pasteurised milk and high-temperature pasteurised milk.

*Article 2*

This Decision is addressed to the Italian Republic.

Done at Brussels, 28 August 2013.

*For the Commission*

Tonio BORG

*Member of the Commission*

**NOTICE TO READERS**

**Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union***

In accordance with Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* (OJ L 69, 13.3.2013, p. 1), as of 1 July 2013, only the electronic edition of the Official Journal shall be considered authentic and shall have legal effect.

Where it is not possible to publish the electronic edition of the Official Journal due to unforeseen and exceptional circumstances, the printed edition shall be authentic and shall have legal effect in accordance with the terms and conditions set out in Article 3 of Regulation (EU) No 216/2013.

**NOTE TO READERS — WAY OF REFERRING TO ACTS**

As of 1 July 2013 the way of referring to acts has changed.

During a transitional period this new practice will coexist with the previous one.

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