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Contents

[1] Text with EEA relevance

(Continued overleaf)

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.

EN

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1817/2006

of 11 December 2006

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables [1], and in particular Article 4(1) thereof,

Whereas:

(1) Regulation (EC) No 3223/94 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 the Annex thereto.

(2) In compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 12 December 2006.

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

Done at Brussels, 11 December 2006.

For the Commission

Jean-Luc DEMARTY

Director-General for Agriculture and Rural Development

[1] OJ L 337, 24.12.1994, p. 66. Regulation as last amended by Regulation (EC) No 386/2005 (OJ L 62, 9.3.2005, p. 3).

ANNEX

to Commission Regulation of 11 December 2006 establishing the 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	052	96,0
	204	48,6
	999	72,3
0707 00 05	052	147,2
	204	67,3
	628	167,7
	999	127,4
0709 90 70	052	153,2
	204	58,4
	999	105,8
0805 10 20	052	58,8
	388	46,7
	508	15,3
	528	26,3
	999	36,8
0805 20 10	052	63,5
	204	58,9
	999	61,2
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	052	66,6
	999	66,6
0805 50 10	052	51,6
	528	35,6
	999	43,6
0808 10 80	400	88,1
	720	80,3
	999	84,2
0808 20 50	052	134,0
	400	113,0
	528	106,5
	720	78,4
	999	108,0

(1) Country nomenclature as fixed by Commission Regulation (EC) No 750/2005 (OJ L 126, 19.5.2005, p. 12). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 1818/2006

of 11 December 2006

on the implementation of the management system of the quantitative ceiling of potassium chloride in relation to the anti-dumping measures applicable on imports of potassium chloride originating in Belarus

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community [1] (the basic Regulation),

Having regard to Council Regulation (EC) No 1050/2006 imposing a definitive anti-dumping duty on imports of potassium chloride originating in Belarus and Russia [2], and in particular Article 2(1) thereof,

After consulting the Advisory Committee,

Whereas:

(1) By Regulation (EC) No 1050/2006, the Council imposed anti-dumping measures on imports of potassium chloride originating, *inter alia*, in Belarus. In view of the special market conditions prevailing on the potassium chloride market, it was considered appropriate to impose measures in the form of a minimum import price (MIP) for product types falling under CN codes 3104 20 50 and 3104 20 90 (TARIC codes 3104 20 50 10, 3104 20 50 90 and 3104 20 90 00), up to a quantitative ceiling, beyond which an *ad valorem* duty of 27,5 % should apply (product concerned).

(2) The Council, in Regulation (EC) No 1050/2006 of 11 July 2006, acknowledged that the introduction of a quantitative ceiling requires a management system which could not be put in place prior to the entry into force of that Regulation. Therefore, the Council in Article 2(1) of Regulation (EC) No 1050/2006 empowered the Commission to set out by a Regulation the modalities for implementing the management system of the quantitative ceiling as soon as it was technically possible.

(3) The effective management of the quantitative ceiling calls for the introduction of a requirement for a Community import authorisation for the release for free circulation in the Community of the product concerned until the quantitative ceiling is exhausted. In order to minimise interference in the market and to provide fair access to the quantitative ceiling to all economic operators it is considered appropriate to issue the import authorisation in a chronological order in which the notifications of Member States are received.

(4) In order to ensure that the quantitative ceiling is not exceeded, it is necessary to establish a procedure whereby the competent authorities of Member States do not issue import authorisations before obtaining confirmation from the Commission that appropriate amounts remain available within the quantitative ceiling.

(5) In order to combat speculative or artificial practices in relation to issue of import authorisation, it is considered appropriate to limit individual applications to the amount stated in the relevant contract entered into between the importer and exporter; as well as to limit the validity of the import authorisations to three months. In this context, the Commission also recalls that Article 5(3) of Council Regulation (EEC) No 2913/92 [3] provides that save in exceptional circumstances, the customs representative designated by the importer must be established within the Community. Moreover, for the same purpose (i.e. to combat speculative and artificial practices) it is considered appropriate to define the exporter, as an economic operator having its registered office, central headquarters or a permanent business establishment in Belarus.

(6) The use of computerised procedures is gradually replacing the manual input of data in different areas of administrative activity. It should therefore also be possible to use computerised and electronic procedures when applying for import authorisation as well as for the issue of such import authorisations.

(7) In the interest of good administration the Commission considers it appropriate to provide sufficient time for the Member States for the implementation of the management system for the quantitative ceiling established by this Regulation, as well as for the economic operators to become accustomed to the new system of import authorisations. Therefore it is considered appropriate that the regulation enters into force on 1 January 2007,

[1] OJ L 56, 6.3.1996, p. 1. Regulation as last amended by Regulation (EC) No 2117/2005 (OJ L 340, 23.12.2005, p. 17).
[2] OJ L 191, 12.7.2006, p. 1.
[3] OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 648/2005 of the European Parliament and of the Council (OJ L 117, 4.5.2005, p. 13).

HAS ADOPTED THIS REGULATION:

General provisions

Article 1

1. This Regulation lays down detailed rules for the management system of the quantitative ceiling of potassium chloride originating in Belarus, as provided for in Article 2(1) of Regulation (EC) No 1050/2006.

2. All products released for free circulation under the quantitative ceiling referred to in paragraph (1) shall be subject to the presentation of an import authorisation issued in accordance with the Articles below.

Article 2

For the purpose of this Regulation:

1. 'contract' means the contract agreed and signed between the exporter and importer;

2. 'exporter' means an economic operator having its registered office, central headquarters or a permanent business establishment in Belarus;

3. 'import authorisation' means the import authorisation which is issued by the national authorities for the release for free circulation of the product concerned in the Community in accordance with this Regulation;

4. 'importer' means any economic operator, which carries out itself, or through a representative acting on its behalf, the formalities for the release for free circulation of the product concerned;

5. 'national authorities' means the national authorities of the Member States competent to issue the import authorisation in accordance with this Regulation, as listed in Annex I;

6. 'product concerned' means potassium chloride originating in Belarus, falling under CN codes 3104 20 50 and 3104 20 90 (TARIC codes 3104 20 50 10, 3104 20 50 90 and 3104 20 90 00).

Modalities applicable to the management of the quantitative ceiling

Article 3

1. Only importers may lodge a request or declaration for import authorisations. Such request or declaration may be lodged with the national authorities, as listed in Annex I, in each of the Member States. The quantities requested in individual applications cannot exceed the quantities agreed for in the corresponding contract.

2. The declaration or request made by the importer in order to obtain the import authorisation shall contain at least the information listed in Annex II.

3. The importer shall present the original of the contract at the time when the request or declaration for the import authorisation is submitted to the national authorities.

4. The national authorities shall refuse declarations or requests for import authorisations that are not lodged in accordance with this Regulation.

Article 4

1. In order to ensure that quantities for which import authorisations are issued do not exceed at any moment the total quantitative ceiling for the product concerned, the national authorities shall issue import authorisations only upon confirmation by the Commission that there are still quantities available within the quantitative ceiling for the product concerned.

2. The authorised imports shall be counted against the quantitative ceiling laid down for the year in which the request for import authorisation was submitted to the national authorities.

3. For the purpose of applying paragraph 1, before issuing import authorisations, the national authorities shall notify the Commission of the amounts of the requests for import authorisations, supported by the contract, which they have received. By return, the Commission shall notify whether the requested amount(s) of quantities are available for release for free circulation in the chronological order in which notifications of the national authorities are received (first come first served).

4. The requests included in the notifications to the Commission shall be valid if they establish clearly in each case the exporting country, the applicable TARIC code, the quantities to be imported, the number of the contract, the CIF or DAF (as applicable and as defined in Incoterms 2000) value of the product concerned at Community frontier by TARIC code and the applicable year of the quantitative ceiling.

5. The notifications referred to in paragraphs 3 to 4 shall be communicated electronically within the integrated network set up for this purpose, unless for imperative technical reasons it is necessary to use other means of communication temporarily.

Article 5

1. To the extent that the Commission, pursuant to Article 4, has confirmed that the amount requested is available within the quantitative ceiling, the national authorities shall issue an import authorisation within a maximum of ten working days from the presentation by the importer of the original corresponding contract. Import authorisations shall be issued by the national authorities of any Member State irrespective of the Member State indicated as destination in the contract to the extent that the Commission has confirmed the availability of the amount within the quantitative ceiling.

2. Import authorisations shall be drawn up in accordance with the model set out in Annex III.

3. The validity of import authorisations issued by the national authorities shall be valid for three months. If a request or declaration for import authorisation is submitted after 1 October of a given year, the validity of the import authorisation issued on the basis of such declaration or request shall not exceed 31 December of the same year.

4. The quantities for which the import authorisation is issued shall not exceed the quantity indicated in the contract on the basis of which the import authorisation is issued.

5. Importers shall not be obliged to import the total quantity covered by an import authorisation in one single consignment.

6. Obligations and rights deriving from import authorisations or extracts shall not be transferable.

7. The import authorisations may be issued by electronic means as long as the customs offices involved have access to the import authorisation via a computer network.

8. Importers shall return the expired import authorisations to the issuing national authorities within 10 working days after the date of their expiry. Importers shall not apply for a new import authorisation as long as 85 % of the quantity of the valid import authorisation has not been imported.

Article 6

Import authorisations shall be issued by national authorities in accordance with Article 4 without discrimination to any importer in the Community wherever the place of his establishment may be in the Community.

Article 7

1. The national authorities shall notify the Commission immediately after being informed of any quantity that is not used during the duration of validity of the import authorisation. Such quantities shall automatically be transferred into the unused quantities of the quantitative ceiling as soon as possible.

2. National authorities shall notify the Commission of any cancellation of import authorisation or any equivalent documents already issued, in case where the corresponding contract has been terminated by either the exporter or the importer. However, if the Commission or the national authorities have been informed by the importer of the termination of the contract after some quantities of the product concerned agreed in the contract have been imported into the Community, the quantities in question shall be counted against the quantitative ceiling for the year in which the declaration or request for the import authorisation was submitted to the national authorities.

Article 8

If the Commission finds that the total quantities of the product concerned covered by the contracts in any year reaches the quantitative ceiling, the national authorities shall be informed immediately in order to suspend the further issue of import authorisations.

Community import authorisation — common form

Article 9

1. The forms to be used by the national authorities for issuing the import authorisations referred to in Articles 4 to 7 shall conform to the model of the import authorisation set out in Annex III.

2. Import authorisation forms and extracts thereof shall be drawn up in duplicate, one copy, marked 'Holder's copy' and bearing the number 1 to be issued to the applicant, and the other, marked 'Copy for the issuing authority' and bearing the No 2, to be kept by the authority issuing the import authorisations. For administrative purposes the national authorities may add additional copies to form 2.

3. Forms shall be printed on white paper free of mechanical pulp, dressed for writing and weighing between 55 and 65 g/m^2. Their size shall be 210 × 297 mm; the type space between the lines shall be 4,24 mm (one sixth of an inch); the layout of the forms shall be followed precisely. Both sides of copy No 1, which is the import authorisation itself, shall in addition have a red printed guilloche-pattern background making any falsification by mechanical or chemical means apparent to the eye.

4. Member States shall be responsible for having the forms printed. The forms may also be printed by printers appointed by the Member State in which they are established. In the latter case, reference to the appointment by the Member State must appear on each form. Each form shall bear the printer's name and address or a mark enabling the printer to be identified.

5. At the time of their issue the import authorisations or extracts shall be given an issue number determined by the national authority. The import authorisation number shall be notified to the Commission electronically within the integrated network set up under Article 4.

6. Import authorisations and extracts shall be completed in the official language, or one of the official languages, of the Member State of issue.

7. The marks of the issuing national authorities and the customs offices or competent administrative authorities shall be applied by means of a stamp. However, an embossing press combined with letters or figures obtained by means of perforation, or printing on the import authorisation may be substituted for the issuing national authority's stamp. The issuing national authorities shall use any tamper-proof method to record the quantity allocated in such a way as to make it impossible to insert figures or references.

8. The reverse of copy No 1 and copy No 2 shall bear a box in which quantities may be entered, either by the customs authorities when import formalities are completed, or by the competent administrative authorities when an extract is issued. If the space set aside for debits on an import authorisation or extract thereof is insufficient, the competent authorities of Member States may attach one or more extension pages bearing boxes matching those on the reverse of copy No 1 and copy No 2 of the import authorisation or extract. The competent authorities of Member States shall place their stamp so that one half is on the import authorisation or extract thereof and the other half is on the extension page. If there is more than one extension page, a further stamp shall be placed in like manner across each page and the preceding page.

9. The competent authorities of the Member States concerned may, where indispensable, require the contents of import authorisations or extracts to be translated into the official language or one of the official languages of that Member State.

10. Import authorisations or extract thereof issued, entries and endorsements made by the authorities of a Member State shall have the same legal effects in each of the other Member States as import authorisations or extracts issued, entries and endorsements made by the competent authorities of these Member States. Import authorisations or extracts issued in accordance with this Regulation shall be valid throughout the customs territory of the European Community.

Article 10

This Regulation shall enter into force on the 1 January 2007.

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

Done at Brussels, 11 December 2006.

For the Commission
Peter MANDELSON
Member of the Commission

ANNEX I

LIST OF NATIONAL AUTHORITIES OF THE MEMBER STATES

BELGIQUE/BELGIË

Service public fédéral économie, PME, classes moyennes et énergie
Administration du potentiel économique
Service licences — Licences
Rue de Louvain 44
B-1000 Bruxelles
Fax (32-2) 548 65 56
e-mail:
website:

Federale Overheidsdienst Economie, kmo, Middenstand en Energie
Bestuur Economisch Potentieel
Dienst Vergunningen
Leuvenseweg 44
B-1000 Brussel
Fax: (32-2) 548 65 56
e-mail:
website:

ČESKÁ REPUBLIKA

Ministerstvo průmyslu a obchodu
Licenční správa
Na Františku 32
CZ-110 15 Praha 1
Fax: (420) 224 21 21 33
e-mail:
website:

EESTI

Majandus- ja Kommunikatsiooniministeerium
Harju 11
EE-15072 Tallinn
Fax: + 372 6313 660
e-mail:
website:

ΕΛΛΑΔΑ

Υπουργείο Οικονομίας & Οικονομικών
Διεύθυνση Καθεστώτων Εισαγωγών-Εξαγωγών, Εμπορικής Άμυνας
Κορνάρου 1
GR-105 63 Αθήνα
Φαξ: (30) 210-328 60 94
Διεύθυνση ηλ. ταχ.:
Δικτυακός τόπος:

ESPAÑA

Ministerio de Industria, Turismo y Comercio
Secretaría General de Comercio Exterior
Subdirección General de Comercio Exterior de Productos Industriales
Paseo de la Castellana 162
E-28046 Madrid
Fax (34) 913 49 38 31
Correo electrónico:
Sitio web:

DANMARK

Økonomi- og Erhvervsministeriet
Erhvervs- og Byggestyrelsen
Lange Linie Allé 17
DK-2100 København Ø
Fax: + 45-35 46 60 00
e-mail:
website: www.ebst.dk

DEUTSCHLAND

Bundesamt für Wirtschaft und Ausfuhrkontrolle (BAFA)
Frankfurter Straße 29—35
D-65760 Eschborn 1
Fax: (49-61) 969 42 26
e-mail:
website:

ITALIA

Ministero del Commercio internazionale
Direzione generale per la Politica commerciale
Viale America 341
I-00144 Roma
Fax (39-06) 59 93 26 36
E-mail: polcom3@mincomes.it
Website: www.mincomes.it

FRANCE

Ministère de l'économie, des finances et de l'industrie
Direction générale des entreprises
Sous-direction des biens de consommation
Bureau Textile-Importations
Le Bervil
12, rue Villiot
F-75572 Paris Cedex 12
Fax (33) 153 44 91 81
e-mail:
website:

IRELAND

Department of Enterprise, Trade and Employment
Import/Export Licensing, Block C
Earlsfort Centre
Hatch Street
Dublin 2
Ireland
Fax (353-1) 631 25 62
E-mail:
Website: www.entemp.ie

ÖSTERREICH

Bundesministerium für Wirtschaft und Arbeit
Außenwirtschaftsadministration
Abteilung C2/2
Stubenring 1
A-1011 Wien
Fax: (43-1) 711 00-83 86
e-mail:
website:

ΚΥΠΡΟΣ

Υπουργείο Εμπορίου, Βιομηχανίας και Τουρισμού
Υπηρεσία Εμπορίου
Μονάδα Έκδοσης Αδειών Εισαγωγής/Εξαγωγής
Οδός Ανδρέα Αραούζου αρ. 6
CY-1421 Λευκωσία
Φαξ: (357) 22-37 51 20
Διεύθυνση ηλ. ταχ.:
Δικτυακός τόπος:

LATVIJA

Latvijas Republikas Ekonomikas ministrija
Brīvības iela 55
LV-1519 Rīga
Fax: + 371-728 08 82
E-mail: licencesana@em.gov.lv
Website: www.em.gov.lv

LIETUVA

Lietuvos Respublikos ūkio ministerija
Prekybos departamentas
Gedimino pr. 38/2
LT-01104 Vilnius
Faksas (370-5) 26 23 974
E. paštas: j.vaigauskiene@ukmin.lt,
j.gutkauskiene@ukmin.lt
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POLSKA

Ministerstwo Gospodarki
Plac Trzech Krzyży 3/5
PL-00-507 Warszawa
Fax: + 48-22-693 40 21
e-mail:
website:

PORTUGAL

Ministério das Finanças
Direcção-Geral das Alfândegas e dos Impostos Especiais sobre o Consumo
Rua Terreiro do Trigo, Edifício da Alfândega de Lisboa
PT-1140-060 Lisboa
Fax: (351) 21 881 42 61
E-mail:
Sítio *web*:

SLOVENIJA

Ministrstvo za finance
Carinska uprava Republike Slovenije
Carinski urad Jesenice
Center za TARIC in kvote
Spodnji Plavž 6c
SI-4270 Jesenice
Faks: (386-4) 297 44 72
E-pošta: taric.cuje@gov.si
Spletišče: http://www.carina.gov.si

LUXEMBOURG

Ministère des affaires étrangères
Office des licences
BP 113
L-2011 Luxembourg
Fax (352) 46 61 38
e-mail: office.licences@mae.etat.lu
website: www.eco.public.lu/attributions/office_licences/index.html

MAGYARORSZÁG

Magyar Kereskedelmi Engedélyezési Hivatal
Margit krt. 85.
H-1024 Budapest
Fax: (36-1) 336 73 02
E-mail:
Website:

MALTA

Diviżjoni għall -Kummerċ
Servizzi Kummerċjali
Lascaris
MT-Valletta CMR02
Fax: + 356-25-69 02 99
e-mail:
website:

SLOVENSKÁ REPUBLIKA

Ministerstvo hospodárstva SR
Odbor licencií
Mierová 19
827 15 Bratislava 212
Slovenská republika
Fax: + 421-2-43 42 39 19
e-mail:
internetová stránka:

SUOMI

Tullihallitus
PL 512
FI-00101 Helsinki
Fax: (358-20) 492 28 52
e-mail:
website:

SVERIGE

Statens jordbruksverk
SE-551 82 Jönköping
Fax (46-36) 19 05 46
e-post: jordbruksverket@sjv.se
webbsida: http://www.sjv.se

NEDERLAND

Belastingdienst/Douane centrale dienst voor in- en uitvoer
Postbus 30003, Engelse Kamp 2
NL-9700 RD Groningen
Fax: (31-50) 523 23 41
e-mail:
website:

ROMÂNIA

Ministerul Economiei şi Comerţului
Direcţia Generală Politici Comerciale
Str. Ion Câmpineanu nr. 16
Bucureşti, sector 1
Cod poştal: 010036
Fax: +40 21 315 04 54
e-mail: clc@dce.gov.ro
website: www.dce.gov.ro

UNITED KINGDOM

Department of Trade and Industry
Import Licensing Branch
Queensway House — West Precinct
Billingham
TS23 2NF
United Kingdom
Fax (44-1642) 36 42 69
E-mail:
Website:

БЪЛГАРИЯ

Дирекция 'Регистриране, лицензиране и контрол'
Министерство на икономиката и енергетиката
ул. 'Славянска' 8
1052 София
Fax: +359 2 981 50 41;
+359 2 980 4710;
+359 2 988 3654
website: www.mee.government.bg

ANNEX II

The declaration or request made by the importer in order to obtain an import authorisation shall contain:

1. Exporter (name and full address, telephone/fax number, e-mail address);

2. Importer (name and full address, telephone/fax number, e-mail address and VAT number);

3. The exact description of the goods and the TARIC code(s);

4. Country of origin of the goods;

5. Country of consignment;

6. Quantity requested in tonnes;

7. The CIF or DAF (as applicable and as defined in Incoterms 2000) value of the product concerned at Community frontier by TARIC heading;

8. Date and number of the contract;

9. Place and date and signature of the applicant;

10. The following signed declaration: 'I, the undersigned, declare that all information presented in this request is true, correct and in conformity with the requirements of Commission Regulation (EC) No 1818/2006.'

ANNEX III

European Community import authorisation

1	1. Consignee (name, full address, country, VAT number)	2. Issue number
Holder's copy		3. Year
		4. Authority responsible for issue (name, address and telephone No)
	5. Declarant/representative as applicable (name and full address)	6. Country of origin (and geonomenclature code)
		7. Country of consignment (and geonomenclature code)
		8. Last day of validity
1		

9. Description of goods	10. TARIC code
	11. Quantity expressed in tonnes
	12. Security/guarantee (as applicable)

13. Further particulars

14. Competent authority's endorsement Date: ..... (Signature) (Stamp)

15. ATTRIBUTIONS Indicate the quantity available in part 1 of column 17 and the quantity attributed in part 2 thereof			
16. Net quantity (net mass or other unit of measure stating the unit)		19. Customs document (form and number) or extract No and date of attribution	20. Name, Member State, stamp and signature of the attributing authority
17. In figures	18. In words for the quantity attributed		
1.			
2.			
1.			
2.			
1.			
2.			
1.			
2.			
1.			
2.			
1.			
2.			
1.			
2.			
Extension pages to be attached hereto.			

European Community import authorisation

2

Copy for the issuing authority

1. Consignee (name, full address, country, VAT number)	2. Issue number
	3. Year
	4. Authority responsible for issue (name, address and telephone No)
5. Declarant/representative as applicable (name and full address)	6. Country of origin (and geonomenclature code)
	7. Country of consignment (and geonomenclature code)
	8. Last day of validity

2

9. Description of goods	10. TARIC code
	11. Quantity expressed in tonnes
	12. Security/guarantee (as applicable)
13. Further particulars	
14. Competent authority's endorsement Date: ..... (Signature) (Stamp)	

15. ATTRIBUTIONS Indicate the quantity available in part 1 of column 17 and the quantity attributed in part 2 thereof			
16. Net quantity (net mass or other unit of measure stating the unit)		19. Customs document (form and number) or extract No and date of attribution	20. Name, Member State, stamp and signature of the attributing authority
17. In figures	18. In words for the quantity attributed		
1.			
2.			
1.			
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2.			
Extension pages to be attached hereto.			

COMMISSION DIRECTIVE 2006/130/EC

of 11 December 2006

implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [1], and in particular point (aa) of the first paragraph of Article 67 thereof,

Whereas:

(1) Pursuant to Article 67 of Directive 2001/82/EC, in the cases covered by the first and third paragraphs thereof, veterinary medicinal products may be dispensed to the public only against prescription. However, as certain substances, contained in veterinary medicinal products for food-producing animals, do not present a risk to human or animal health or to the environment, exemptions from that general requirement may be granted in accordance with point (aa) of the first paragraph of Article 67. Such exemptions are without prejudice to the application of any other provision of the first and third paragraphs of that Article.

(2) Consequently it is appropriate to establish criteria on the basis of which Member States may grant exemptions from the general rule, provided for in point (aa) of the first paragraph of Article 67 of Directive 2001/82/EC, requiring a prescription for dispensing to the public veterinary medicinal products for food producing animals.

(3) Where the veterinary medicinal products concerned are easy to administer and, even if administered incorrectly, do not present a risk either to the animal being treated or to the person administering the product, it should be possible for those products to be made available without the need for a veterinary prescription. On the other hand, it should not be possible to grant an exemption for products that feature an unfavourable pharmacovigilance profile or harm the environment.

(4) Inappropriate storage conditions may seriously affect the quality, safety and efficacy of veterinary medicinal products. Therefore, products whose quality, safety and efficacy can be guaranteed only when stored under special conditions should not be granted an exemption.

(5) Exempted veterinary medicinal products should furthermore contain only active substances that do not cause a risk for consumer safety as regards residues in food obtained from treated animals and they should have no potential for causing a risk to human or animal health by developing resistance to antimicrobials or anthelmintics, if used incorrectly.

(6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive establishes the criteria on the basis of which Member States, in accordance with point (aa) of the first paragraph of Article 67 of Directive 2001/82/EC, may grant exemptions from the requirement to dispense veterinary medicinal products intended for food-producing animals to the public only against prescription.

Article 2

Veterinary medicinal products for food-producing animals may be exempted from the requirement to be dispensed only against veterinary prescription, if all of the following criteria are satisfied:

(a) the administration of veterinary medicinal products is restricted to formulations requiring no particular knowledge or skill in using the products;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

[1] OJ L 311, 28.11.2001, p. 1. Directive as amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;

(e) the summary of product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;

(h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

Article 3

1. Where Member States decide to provide for the granting of exemptions pursuant to this Directive, they shall notify the Commission thereof.

2. If a notification in accordance with paragraph 1 has not been made by 31 March 2007 at the latest, the national exemptions referred to in point (aa) of the first paragraph of Article 67 of Directive 2001/82/EC shall cease to apply.

Article 4

1. Within six months of the notification referred to in Article 3, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 5

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission
Günter VERHEUGEN
Vice-President

COMMISSION DIRECTIVE 2006/131/EC

of 11 December 2006

amending Council Directive 91/414/EEC to include methamidophos as an active substance

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([1]), and in particular Article 6(1) thereof,

Whereas:

(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 ([2]), establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes methamidophos.

(2) For methamidophos the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 ([3]), Italy was designated as Rapporteur Member State. Italy submitted on 30 July 1999 the relevant assessment report and recommendations to the Commission in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) The review of methamidophos revealed a number of open questions which were addressed by the Scientific Panel on Plant health, Plant protection products and their Residues (PPR) of the European Food Safety Authority (EFSA). The Scientific Panel was asked to define a value for the degree of dermal adsorption scientifically based on the different results of the studies submitted by the notifier to be used in the assessment of human risk arising from the dermal route of exposure. Moreover, the Scientific Panel was asked to review the estimates of avoidance, time spent foraging in treated areas and proportion of contaminated diet obtained in treated areas, and advise on their implications for estimates of acute, short and long term exposure of birds and mammals to the insecticide methamidophos. In its opinion on the first question the PPR Panel concluded ([4]) that, on the basis of the available data the best estimated dermal adsorption of the diluted preparation is considered to be about 5 %. On the second question, the PPR Panel concentrated its assessment on two species considered by the notifier and Rapporteur Member State, yellow wagtail and wood mouse, as they make substantial use of the crops supported for methamidophos. The PPR Panel disagreed ([5]) with the values proposed by the notifier and the Rapporteur Member State as regards the proportion of contaminated diet set for yellow wagtails and the estimates used in dietary composition for yellow wagtails and wood mouse. The PPR Panel noted that these values would underestimate acute exposure of individual animals. The PPR Panel developed an alternative approach for assessing the potential role of avoidance. The mechanisms involved are complex but it appears possible that both yellow wagtail and wood mouse might feed quickly enough for mortality to occur in field conditions. The PPR Panel identified several options for laboratory or field studies, which could be considered to assess these risks with more certainty.

(5) Articles 5(4) and 6(1) of Directive 91/414/EEC provide that inclusion of a substance in Annex I may be subject to restrictions and conditions. In this case, restrictions on the inclusion period and on the authorised crops are deemed necessary. The original measures presented to the Standing Committee on the Food Chain and Animal

([1]) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/85/EC (OJ L 293, 24.10.2006, p. 3).
([2]) OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).
([3]) OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).
([4]) Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request from the Commission related to the evaluation of methamidophos in toxicology in the context of Council Directive 91/414/EEC (*The EFSA Journal* (2004), 95, 1 to 15). Adopted on 14 September 2004.
([5]) Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request from the Commission related to the evaluation of methamidophos in ecotoxicology in the context of Council Directive 91/414/EEC (*The EFSA Journal* (2004), 144, 1 to 50). Adopted on 14 December 2004.

Health, proposed the restriction of the inclusion period to seven years, so that Member States would give priority to reviewing plant protection products already on the market containing methamidophos. In order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC was intended to be limited to the uses of methamidophos that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC. This implies that other uses, which were not or only partially covered by this assessment, had first to be subject to a complete assessment, before their inclusion in Annex I of Directive 91/414/EEC could be considered. Finally, due to the hazardous nature of methamidophos, it was considered necessary to provide for a minimum harmonisation at Community level of certain risk mitigation measures that were to be applied by Member States when granting authorisations.

(6) Under the procedures laid down by Directive 91/414/EEC, the approval of active substances, including the definition of risk management measures, is decided by the Commission. Member States bear the responsibility for the implementation, application and control of the measures intended to mitigate the risks generated by plant protection products. Concerns expressed by several Member States reflect their judgment that additional restrictions are necessary to reduce the risk to a level that can be considered acceptable and consistent with the high level of protection that is sought within the Community. At present, it is a question of risk management to set the adequate level of safety and protection for the continued production, commercialisation and use of methamidophos.

(7) As a consequence of the above, the Commission re-examined its position. In order to correctly reflect the high level of protection of human and animal health and a sustainable environment sought in the Community, it considered appropriate, in addition to the principles set out in Recital 5, to further reduce the period of inclusion to 18 months instead of seven years. This further reduces any risk by ensuring a priority re-assessment of this substance.

(8) It may be expected that plant protection products containing methamidophos satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report and providing that the necessary risk mitigation measures are applied.

(9) Without prejudice to the conclusion that plant protection products containing methamidophos may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that methamidophos should be subjected to further testing for confirmation of the risk assessment for birds and mammals and that such studies should be presented by the notifiers. In addition, Member States should require authorisation holders to provide information on the use of methamidophos including any information on incidences on operator health.

(10) As with all substances included in Annex I to Directive 91/414/EEC, the status of methamidophos could be reviewed under Article 5(5) of that Directive in the light of any new data becoming available. Equally, the fact that the inclusion of this substance in Annex I expires on a particular date does not prevent the inclusion being renewed according to the procedures laid down in the Directive.

(11) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.

(12) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(13) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing methamidophos to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations. in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC. Given the hazardous properties of methamidophos, the period for Member States to verify whether the plant protection products, which contain methamidophos as the only active substance or in combination with other authorised active substances, comply with the provisions of Annex VI should not exceed 18 months.

(14) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(15) The measures provided for in this Directive are not in accordance with the opinion delivered by the Standing Committee on the Food Chain and Animal Health. The Commission therefore submitted to the Council a proposal relating to these measures. On the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures and it is accordingly for the Commission to adopt these measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2007 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing methamidophos as an active substance by 30 June 2007.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to methamidophos are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By derogation from paragraph 1, for each authorised plant protection product containing methamidophos, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning methamidophos. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall for products containing methamidophos, where necessary amend or withdraw the authorisation by 30 June 2008.

Article 4

This Directive shall enter into force on 1 January 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'145	Methamidophos CAS No 10265-92-6 CIPAC No 355	O,S-dimethyl phosphoramidothioate	≥ 680 g/kg	1 January 2007	30 June 2008	PART A Only use as insecticide on potato may be authorised. The following conditions of use must be respected: — At rates not exceeding 0,5 kg active substance per hectare per application, — Maximum 3 applications per season. The following uses must not be authorised: — air application, — knapsack and all hand-held applications, neither by amateur nor by professional users, — home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of: — birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species, — aquatic organisms and non-target arthropods. An appropriate distance must be kept between treated areas and surface water bodies as well as margins of the crop. This distance may depend on the application or not of drift reducing techniques, — operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and respiratory protective devices during mixing-loading and gloves, coveralls, rubber boots and face protection or safety glasses during application and cleaning of equipment. The above measures must be applied, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on methamidophos, and in particular Appendices I and II thereof, shall be taken into account. Member States must ensure that the authorisation holders report at the latest on 31 December of each year on any reported effect on operator health. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of methamidophos can be obtained. Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals. They shall ensure that the notifiers at whose request methamidophos has been included in this Annex provide such studies to the Commission within 1 year from the entry into force of this Directive.'

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

COMMISSION DIRECTIVE 2006/132/EC

of 11 December 2006

amending Council Directive 91/414/EEC to include procymidone as active substance

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(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 [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes procymidone.

(2) For procymidone the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 [3], France was designated as Rapporteur Member State. France submitted the relevant assessment report and recommendations to the Commission on 15 January 2001 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) It has appeared from the various examinations made that plant protection products containing procymidone may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report, provided that adequate risk mitigation measures are applied. As procymidone is a hazardous substance, its use should not be unrestricted. In particular there are concerns about its intrinsic toxic effects, including potential endocrine disrupting properties. There is at present no scientific consensus on the exact extent of the risk. Applying the precautionary principle, and taking into account the current state of scientific knowledge, risk mitigation measures should be imposed in order to achieve the high level of protection of human and animal health and the environment chosen in the Community.

(5) Articles 5(4) and 6(1) of Directive 91/414/EEC provide that inclusion of a substance in Annex I may be subject to restrictions and conditions. In this case, restrictions on the inclusion period and on the authorised crops are deemed necessary. The original measures presented to the Standing Committee on the Food Chain and Animal Health, proposed the restriction of the inclusion period to seven years, so that Member States would give priority to reviewing plant protection products already on the market containing procymidone. In order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC was intended to be limited to the uses of procymidone that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC. This implies that other uses, which were not or only partially covered by this assessment, had first to be subject to a complete assessment, before their inclusion in Annex I of Directive 91/414/EEC could be considered. Finally, due to the hazardous nature of procymidone, it was considered necessary to provide for a minimum harmonisation at Community level of certain risk mitigation measures that were to be applied by Member States when granting authorisations.

(6) Under the procedures laid down by Directive 91/414/EEC, the approval of active substances, including the definition of risk management measures, is decided by the Commission. Member States bear the responsibility for the implementation, application and control of the measures intended to mitigate the risks generated by plant protection products. Concerns expressed by several Member States reflect their judgment that additional restrictions are necessary to reduce the risk to a level that can be considered acceptable and consistent with the high level of

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/85/EC (OJ L 293, 24.10.2006, p. 3).
[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).
[3] OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

protection that is sought within the Community. At present, it is a question of risk management to set the adequate level of safety and protection for the continued production, commercialisation and use of procymidone.

(7) As a consequence of the above, the Commission re-examined its position. In order to correctly reflect the high level of protection of human and animal health and a sustainable environment sought in the Community, it considered appropriate, in addition to the principles set out in recital 5, to further reduce the period of inclusion to 18 months instead of seven years. This further reduces any risk by ensuring a priority re-assessment of this substance.

(8) It may be expected that plant protection products containing procymidone satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report and providing that the necessary risk mitigation measures are applied.

(9) Without prejudice to the conclusion that plant protection products containing procymidone may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. The potential endocrine-disrupting properties of procymidone have been assessed in test which follow the best currently available practice. The Commission is aware that the Organisation for Economic Cooperation and Development (OECD) is developing test guidelines in order to further refine the assessment of potential endocrine disrupting properties. Therefore it is appropriate to require that procymidone should be subjected to such further testing as soon as agreed OECD test guidelines exist and that such studies should be presented by the notifier. In addition, Member States should require authorisation holders to provide information on the use of procymidone including any information on incidences on operator health.

(10) As with all substances included in Annex I to Directive 91/414/EEC, the status of procymidone could be reviewed pursuant to Article 5(5) of that Directive in the light of any new data becoming available. Equally, the fact that the inclusion of this substance in Annex I expires on a particular date does not prevent the inclusion being renewed according to the procedures laid down in the Directive.

(11) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.

(12) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(13) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing procymidone to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations. in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC. Given the hazardous properties of procymidone, the period for Member States to verify whether plant protection products containing procymidone, alone or in combination with other authorised active substances, comply with the provisions of Annex VI should not exceed 18 months.

(14) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(15) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion within the time limit laid down by its Chairman and the Commission therefore submitted to the Council a proposal relating to these measures. On the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures and it is accordingly for the Commission to adopt these measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2007 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing procymidone as an active substance by 30 June 2007. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to procymidone are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By derogation from paragraph 1, for each authorised plant protection product containing procymidone, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning procymidone. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall for products containing procymidone, where necessary, amend or withdraw the authorisation by 30 June 2008.

Article 4

This Directive shall enter into force on 1 January 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'146	Procymidone CAS No 32809-16-8 CIPAC No 383	N-(3,5-dichlorophenyl)-1,2-dimethylcyclopropane-1,2-dicarboximide	985 g/kg	1 January 2007	30 June 2008	PART A Only uses as fungicide on the following crops may be authorised: — cucumbers in greenhouses (closed hydroponic systems), — plums (for processing). at rates not exceeding — 0,75 g active substance per hectare per application. The following uses must not be authorised: — air application, — knapsack and hand-held applications neither by amateur nor by professional users, — home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of: — aquatic organisms. Where relevant, an appropriate distance must be kept between treated areas and surface water bodies. This distance may depend on the application or not of drift reducing techniques or devices, — birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species, — consumers, the acute dietary exposure of which must be controlled, — groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, — operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment,

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						— workers, who must wear suitable protective clothing, in particular gloves, if they must enter a treated area before the specific re-entry period has expired. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on procymidone, and in particular Appendices I and II thereof, shall be taken into account. Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of procymidone can be obtained. Member States shall request the submission of further confirmatory data and information to prove the acceptability of the active substance when applied in situations where there is a likelihood of long term exposure of wild mammals, and on the sewage treatment applied in the case of greenhouse applications. Member States shall request the submission of further studies to address the potential endocrine disrupting properties of procymidone within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD). They shall ensure that the notifier at whose request procymidone has been included in this Annex provide such studies to the Commission within two years of the adoption of the above test guidelines.'

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

COMMISSION DIRECTIVE 2006/133/EC

of 11 December 2006

amending Council Directive 91/414/EEC to include flusilazole as active substance

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(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 [2], establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes flusilazole.

(2) For flusilazole the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 [3], Ireland was designated as Rapporteur Member State. Ireland submitted the relevant assessment report and recommendations to the Commission on 30 April 1996 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) As regards flusilazole two questions were submitted to the Scientific Committee on Plants (the Scientific Committee). The first concerned the adequacy of the proposed NOEC (No Observed Effect Concentration) for ensuring a sufficient protection from adverse effects on reproduction and, more generally, the comparative sensitivity of the early life stage test compared to the full fish life cycle study. The second question related to the potential impact on organic matter decomposition. In both cases, the recommendations of the Scientific Committee [4] have been taken into consideration in formulating this Directive and the relevant review report.

(5) It has appeared from the various examinations made that plant protection products containing flusilazole may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report, provided that adequate risk mitigation measures are applied. As flusilazole is a hazardous substance, its use should not be unrestricted. In particular there are concerns about its intrinsic toxic effects, including potential endocrine disrupting properties. There is at present no scientific consensus on the exact extent of the risk. Applying the precautionary principle, and taking into account the current state of scientific knowledge, risk mitigation measures should be imposed in order to achieve the high level of protection of human and animal health and the environment chosen in the Community.

(6) Articles 5(4) and 6(1) of Directive 91/414/EEC provide that inclusion of a substance in Annex I may be subject to restrictions and conditions. In this case, restrictions on the inclusion period and on the authorised crops are deemed necessary. The original measures presented to the Standing Committee on the Food Chain and Animal Health, proposed the restriction of the inclusion period to seven years, so that Member States would give priority to reviewing plant protection products already on the market containing flusilazole. In order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC was intended to be limited to the uses of flusilazole that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC. This implies that other uses,

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/85/EC (OJ L 293, 24.10.2006, p. 3).

[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).

[3] OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

[4] Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of flusilazole in the context of Council Directive 91/414/EEC (Opinion adopted by the Scientific Committee on Plants on 18 July 2002).

which were not or only partially covered by this assessment, had first to be subject to a complete assessment, before their inclusion in Annex I of Directive 91/414/EEC could be considered. Finally, due to the hazardous nature of flusilazole, it was considered necessary to provide for a minimum harmonisation at Community level of certain risk mitigation measures that were to be applied by Member States when granting authorisations.

(7) Under the procedures laid down by Directive 91/414/EEC, the approval of active substances, including the definition of risk management measures, is decided by the Commission. Member States bear the responsibility for the implementation, application and control of the measures intended to mitigate the risks generated by plant protection products. Concerns expressed by several Member States reflect their judgment that additional restrictions are necessary to reduce the risk to a level that can be considered acceptable and consistent with the high level of protection that is sought within the Community. At present, it is a question of risk management to set the adequate level of safety and protection for the continued production, commercialisation and use of flusilazole.

(8) As a consequence of the above, the Commission re-examined its position. In order to correctly reflect the high level of protection of human and animal health and a sustainable environment sought in the Community, it considered appropriate, in addition to the principles set out in recital 6, to further reduce the period of inclusion to 18 months instead of seven years. This further reduces any risk by ensuring a priority re-assessment of this substance.

(9) It may be expected that plant protection products containing flusilazole satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report and providing that the necessary risk mitigation measures are applied.

(10) Without prejudice to the conclusion that plant protection products containing flusilazole may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. The potential endocrine disrupting properties of flusilazole have been assessed in tests which follow the best currently available practice. The Commission is aware that the Organisation for Economic Cooperation and Development (OECD) is developing test guidelines in order to further refine the assessment of potential endocrine disrupting properties. Therefore it is appropriate to require that flusilazole should be subjected to such further testing as soon as agreed OECD Test Guidelines exist and that such studies should be presented by the notifier. In addition, Member States should require authorisation holders to provide information on the use of flusilazole including any information on incidences on operator health.

(11) As with all substances included in Annex I to Directive 91/414/EEC, the status of flusilazole could be reviewed under Article 5(5) of that Directive in the light of any new data becoming available. Equally, the fact that the inclusion of this substance in Annex I expires on a particular date does not prevent the inclusion being renewed according to the procedures laid down in the Directive.

(12) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.

(13) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(14) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing flusilazole to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC. Given the hazardous properties of flusilazole, the period for Member States to verify whether plant protection products containing flusilazole, alone or in combination with other authorised active substances, comply with the provisions of Annex VI should not exceed 18 months.

(15) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(16) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion within the time limit laid down by its Chairman and the Commission therefore submitted to the Council a proposal relating to these measures. On the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures and it is accordingly for the Commission to adopt these measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2007 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing flusilazole as an active substance by 30 June 2007. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to flusilazole are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By derogation from paragraph 1, for each authorised plant protection product containing flusilazole, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning flusilazole. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall for products containing flusilazole, where necessary, amend or withdraw the authorisation by 30 June 2008.

Article 4

This Directive shall enter into force on 1 January 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'147	Flusilazole CAS No 85509-19-9 CIPAC No 435	Bis(4-fluorophenyl)(methyl)(1H-1,2.4-triazol-1-ylmethyl)silane	925 g/kg	1 January 2007	30 June 2008	PART A Only uses as fungicide on the following crops may be authorised: — cereals other than rice, — maize, — rape seed, — sugar beet, at rates not exceeding 200 g active substance per hectare per application. The following uses must not be authorised: — air application, — knapsack and hand-held applications, neither by amateur nor by professional users, — home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of: — aquatic organisms. An appropriate distance must be kept between treated areas and surface water bodies. This distance may depend on the application or not of drift reducing techniques or devices, — birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species, — operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flusilazole, and in particular Appendices I and II thereof, shall be taken into account. Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of flusilazole can be obtained. Member States shall request the submission of further studies to address the potential endocrine disrupting properties of flusilazole within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD). They shall ensure that the notifier at whose request flusilazole has been included in this Annex provide such studies to the Commission within two years of the adoption of the above test guidelines.'

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

COMMISSION DIRECTIVE 2006/134/EC

of 11 December 2006

amending Council Directive 91/414/EEC to include fenarimol as active substance

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(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 [2], establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes fenarimol.

(2) For fenarimol the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 [3], the United Kingdom was designated as Rapporteur Member State. The United Kingdom submitted the relevant assessment report and recommendations to the Commission on 30 April 1996 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) As regards fenarimol two questions were submitted to the Scientific Committee on Plants (the Scientific Committee). The Scientific Committee was asked to comment on the interpretation of the multi-generation studies and to consider the aromatase inhibition effects of fenarimol. In addition its opinion was sought on the establishment of a reliable acceptable daily intake (ADI) and acceptable operator exposure level (AOEL) [4]. The Scientific Committee concluded that the effects of fenarimol on male fertility seen in rats had to be considered relevant for human risk assessment although man is less sensitive than rats to the effects of aromatase inhibition. It also concluded that the effects of fenarimol on parturition in rats could be considered as not relevant for human risk assessment. It was further concluded that, apart from male-mediated reduced fertility and effects associated with delayed parturition, there was no convincing evidence for other adverse reproductive effects associated with aromatase inhibition by fenarimol. Finally, the Scientific Committee agreed that the toxicological studies submitted permitted the establishment of a reliable ADI and AOEL. A second opinion [5] addressed the question whether the approach taken to calculate the Predicted Environmental Concentrations (PEC) in soil was adequate. The Committee proposed a combination of field dissipation and laboratory degradation data to calculate an accumulated soil PEC. This opinion has been examined by the rapporteur Member State who considered nevertheless that this procedure was no more scientifically justified than relying on field dissipation measurements alone. Therefore it was decided to await the outcome of the field dissipation studies that were ongoing. The interim results from these studies are consistent with the results of the model calculation and consequently the issue was considered to be adequately addressed. It is therefore concluded that in all cases, the recommendations from the Scientific Committee have been taken into consideration in formulating this Directive and the relevant review report.

(5) It has appeared from the various examinations made that plant protection products containing fenarimol may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report, provided that adequate risk

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/85/EC (OJ L 293, 24.10.2006, p. 3).

[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).

[3] OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

[4] Opinion of the Scientific Committee on Plants regarding the possible inclusion of fenarimol in Annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/FENARI/005 — Final) (Opinion adopted by the Scientific Committee on Plants on 18 May 1999).

[5] Opinion of the Scientific Committee on Plants on a specific question from the Commission concerning the evaluation of Fenarimol in the context of Council Directive 91/414/EEC (Opinion adopted by the Scientific Committee on Plants on 8 November 2001).

mitigation measures are applied. As fenarimol is a hazardous substance, its use should not be unrestricted. In particular there are concerns about its intrinsic toxic effects, including potential endocrine disrupting properties. There is at present no scientific consensus on the exact extent of the risk. Applying the precautionary principle, and taking into account the current state of scientific knowledge, risk mitigation measures should be imposed in order to achieve the high level of protection of human and animal health and the environment chosen in the Community.

(6) Articles 5(4) and 6(1) of Directive 91/414/EEC provide that inclusion of a substance in Annex I may be subject to restrictions and conditions. In this case, restrictions on the inclusion period and on the authorised crops are deemed necessary. The original measures presented to the Standing Committee on the Food Chain and Animal Health, proposed the restriction of the inclusion period to seven years, so that Member States would give priority to reviewing plant protection products already on the market containing fenarimol. In order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC was intended to be limited to the uses of fenarimol that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC. This implies that other uses, which were not or only partially covered by this assessment, had first to be subject to a complete assessment, before their inclusion in Annex I of Directive 91/414/EEC could be considered. Finally, due to the hazardous nature of fenarimol, it was considered necessary to provide for a minimum harmonisation at Community level of certain risk mitigation measures that were to be applied by Member States when granting authorisations.

(7) Under the procedures laid down by Directive 91/414/EEC, the approval of active substances, including the definition of risk management measures, is decided by the Commission. Member States bear the responsibility for the implementation, application and control of the measures intended to mitigate the risks generated by plant protection products. Concerns expressed by several Member States reflect their judgment that additional restrictions are necessary to reduce the risk to a level that can be considered acceptable and consistent with the high level of protection that is sought within the Community. At present, it is a question of risk management to set the adequate level of safety and protection for the continued production, commercialisation and use of fenarimol.

(8) As a consequence of the above, the Commission re-examined its position. In order to correctly reflect the high level of protection of human and animal health and a sustainable environment sought in the Community, it considered appropriate, in addition to the principles set out in recital 6, to further reduce the period of inclusion to 18 months instead of seven years. This further reduces any risk by ensuring a priority re-assessment of this substance.

(9) It may be expected that plant protection products containing fenarimol satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report and providing that the necessary risk mitigation measures are applied.

(10) Without prejudice to the conclusion that plant protection products containing fenarimol may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. The potential endocrine disrupting properties of fenarimol have been assessed in tests which follow the best currently available practice. The Commission is aware that the Organisation for Economic Cooperation and Development (OECD) is developing test guidelines in order to further refine the assessment of potential endocrine disrupting properties. Therefore it is appropriate to require that fenarimol should be subjected to such further testing as soon as agreed OECD Test Guidelines exist and that such studies should be presented by the notifier. In addition, Member States should require authorisation holders to provide information on the use of fenarimol including any information on incidences on operator health.

(11) As with all substances included in Annex I to Directive 91/414/EEC, the status of fenarimol could be reviewed under Article 5(5) of that Directive in the light of any new data becoming available. Equally, the fact that the inclusion of this substance in Annex I expires on a particular date does not prevent the inclusion being renewed according to the procedures laid down in the Directive.

(12) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.

(13) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(14) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing fenarimol to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC. Given the hazardous properties of fenarimol, the period for Member States to verify whether plant protection products containing fenarimol, alone or in combination with other authorised active substances, comply with the provisions of Annex VI should not exceed 18 months.

(15) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(16) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion within the time limit laid down by its Chairman and the Commission therefore submitted to the Council a proposal relating to these measures. On the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures and it is accordingly for the Commission to adopt these measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2007 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing fenarimol as an active substance by 30 June 2007. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to fenarimol are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By derogation from paragraph 1, for each authorised plant protection product containing fenarimol, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning fenarimol. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall for products containing fenarimol, where necessary, amend or withdraw the authorisation by 30 June 2008.

Article 4

This Directive shall enter into force on 1 January 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'148	Fenarimol CAS No 60168-88-9 (unstated stereochemistry) CIPAC No 380	(±)-2,4′-dichloro-α-(pyrimidin-5-yl) benzhydryl alcohol	980 g/kg	1 January 2007	30 June 2008	PART A Only uses as fungicide on the following crops may be authorised: — Tomatoes, — peppers in greenhouses, — aubergines, — cucumbers in greenhouses, — melons, — ornamentals, nursery trees and perennial plants, at rates not exceeding — 0,058 kg active substance per hectare per application for tomatoes in field and 0,072 kg active substance per hectare per application for tomatoes in greenhouses, — 0,072 kg active substance per hectare per application for peppers, — 0,038 kg active substance per hectare per application for aubergines, — 0,048 kg active substance per hectare per application for cucumbers, — 0,024 kg active substance per hectare per application for melons in field and 0,048 kg active substance per hectare per application for melons in greenhouse, — 0,054 kg active substance per hectare per application for ornamentals, nursery trees and perennial plants in field and 0,042 kg active substance per hectare per application for ornamentals in greenhouses. The following uses must not be authorised: — air application, — knapsack and hand-held applications by amateur users, — home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of: — aquatic organisms. Where relevant, an appropriate distance must be kept between treated areas and surface water bodies. This distance may depend on the application or not of drift reducing techniques or devices,

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						— earthworms. Conditions of authorisation shall include risk mitigation measures, such as the selection of the most appropriate combination of numbers and timing of applications, rates of application, and, if necessary, the degree of concentration of the active substance, — birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species, — operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment, — workers, who must wear suitable protective clothing, in particular gloves, if they must enter a treated area before the specific re-entry period has expired. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenarimol, and in particular Appendices I and II thereof, shall be taken into account. Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of fenarimol can be obtained. Member States shall request the submission of further studies to address the potential endocrine disrupting properties of fenarimol within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD). They shall ensure that the notifier at whose request fenarimol has been included in this Annex provide such studies to the Commission within two years of the adoption of the above test guidelines.’

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

COMMISSION DIRECTIVE 2006/135/EC

of 11 December 2006

amending Council Directive 91/414/EEC to include carbendazim as active substance

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(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 [2], establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes carbendazim.

(2) For carbendazim the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 [3], Germany was designated as Rapporteur Member State. Germany submitted the relevant assessment report and recommendations to the Commission on 10 February 1998 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) The review of carbendazim revealed a number of open questions which were addressed by the Scientific Committee on Plants. The Scientific Committee was asked to comment on the advisability of establishing an Acceptable Daily Intake (ADI) and Acceptable Operator Exposure Level (AOEL) having regard particularly to the results of mutagenicity, carcinogenicity and reproductive studies for benomyl, carbendazim and thiophanate-methyl. The Committee [4] noted that carbendazim is the biologically active substance common to these three substances. Benomyl in particular, but also thiophanate-methyl, is metabolised to carbendazim and all three substances produce numerical chromosomal aberrations (aneuploidy) in mammalian cells, exposed in vivo. There is no evidence that any other form of damage to genetic material is induced by any of these substances. Carcinogenicity is not a concern. The known effects of these fungicides upon reproduction are explicable by interaction with the microtubules of the spindle apparatus. The mechanism of aneuploidy induction is well understood and consists of inhibition of polymerisation of tubulin, the protein that is essential for the segregation of chromosomes during cell division: it does not involve any interaction with DNA. Since multiple copies of tubulin molecules are present in proliferating cells, in the presence of low concentration of the fungicides a limited number of tubulin molecules will be affected and consequently no toxicologically adverse effects will ensue. Consequently, a clear no adverse effect level is recognisable and both an ADI and an AOEL can be established.

(5) Articles 5(4) and 6(1) of Directive 91/414/EEC provide that inclusion of a substance in Annex I may be subject to restrictions and conditions. In this case, restrictions on the inclusion period and on the authorised crops are deemed necessary. The original measures presented to the Standing Committee on the Food Chain and Animal Health, proposed the restriction of the inclusion period to seven years, so that Member States would give priority to reviewing plant protection products already on the market containing carbendazim. In order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC was intended to be limited to the uses of carbendazim that have been actually assessed within the

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/85/EC (OJ L 293, 24.10.2006, p. 3).
[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).
[3] OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).
[4] Opinion of the Scientific Committee on Plants (SCP/BENOMY/002 — final, SCP/CARBEN/002 — final, SCP/THIOPHAN/002 — final 002) dated 23 March 2001 regarding the evaluation of benomyl, carbendazim and thiophanate-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion adopted by the Scientific Committee on Plants on 7 March 2001).

Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC. This implies that other uses, which were not or only partially covered by this assessment, had first to be subject to a complete assessment, before their inclusion in Annex I of Directive 91/414/EEC could be considered. Finally, due to the hazardous nature of carbendazim, it was considered necessary to provide for a minimum harmonisation at Community level of certain risk mitigation measures that were to be applied by Member States when granting authorisations.

(6) Under the procedures laid down by Directive 91/414/EEC, the approval of active substances, including the definition of risk management measures, is decided by the Commission. Member States bear the responsibility for the implementation, application and control of the measures intended to mitigate the risks generated by plant protection products. Concerns expressed by several Member States reflect their judgment that additional restrictions are necessary to reduce the risk to a level that can be considered acceptable and consistent with the high level of protection that is sought within the Community. At present, it is a question of risk management to set the adequate level of safety and protection for the continued production, commercialisation and use of carbendazim.

(7) As a consequence of the above, the Commission re-examined its position. In order to correctly reflect the high level of protection of human and animal health and a sustainable environment sought in the Community, it considered appropriate, in addition to the principles set out in Recital 5, to further reduce the period of inclusion to three instead of seven years. This further reduces any risk by ensuring a priority re-assessment of this substance.

(8) It may be expected that plant protection products containing carbendazim satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report and providing that the necessary risk mitigation measures are applied.

(9) Without prejudice to the conclusion that plant protection products containing carbendazim may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. Member States should require authorisation holders to provide information on the use of carbendazim including any information on incidences on operator health.

(10) As with all substances included in Annex I to Directive 91/414/EEC, the status of carbendazim could be reviewed under Article 5(5) of that Directive in the light of any new data becoming available. Equally, the fact that the inclusion of this substance in Annex I expires on a particular date does not prevent the inclusion being renewed according to the procedures laid down in the Directive.

(11) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.

(12) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(13) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing carbendazim to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations. in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC. Given the hazardous properties of carbendazim, the period for Member States to verify whether the plant protection products, which contain carbendazim as the only active substances or in combination with other authorised active substances, comply with the provisions of Annex VI should not exceed three years.

(14) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(15) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion within the time limit laid down by its Chairman and the Commission therefore submitted to the Council a proposal relating to these measures. On the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures and it is accordingly for the Commission to adopt these measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2007 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing carbendazim as an active substance by 30 June 2007. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to carbendazim are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By derogation from paragraph 1, for each authorised plant protection product containing carbendazim, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning carbendazim. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall for products containing carbendazim, where necessary, amend or withdraw the authorisation by 31 December 2009.

Article 4

This Directive shall enter into force on 1 January 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'149	Carbendazim (unstated stereochemistry) CAS No 10605-21-7 CIPAC No 263	Methyl benzimidazol-2-ylcarbamate	980 g/kg	1 January 2007	31 December 2009	PART A Only uses as fungicide on the following crops may be authorised: — cereals — rapeseed — sugar beet — maize at rates not exceeding — 0,25 kg active substance per hectare per application for cereals and rapeseed, — 0,075 kg active substance per hectare per application for sugar beet, — 0,1 kg active substance per hectare per application for maize. The following uses must not be authorised: — air application, — knapsack and hand-held applications neither by amateur nor by professional users, — home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of: — aquatic organisms. An appropriate distance must be kept between treated areas and surface water bodies. This distance may depend on the application or not of drift reducing techniques or devices, — earthworms and other soil macro-organisms. Conditions of authorisation shall include risk mitigation measures, such as the selection of the most appropriate combination of numbers and timing of application, rates of application, and, if necessary, the degree of concentration of the active substance, — birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species,

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						— operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on carbendazim, and in particular Appendices I and II thereof, shall be taken into account. Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of carbendazim can be obtained.'

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

COMMISSION DIRECTIVE 2006/136/EC

of 11 December 2006

amending Council Directive 91/414/EEC to include dinocap as active substance

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(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 [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes dinocap.

(2) For dinocap, the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 [3], as amended by Regulation (EC) No 491/95 of 3 March 1995 [4], Austria was designated as Rapporteur Member State. Austria submitted the relevant assessment report and recommendations to the Commission on 18 May 2000 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) As regards dinocap, two questions were submitted to the Scientific Panel on Plant Health, Plant Protection Products and their Residues of the European Food Safety Authority (the Scientific Panel). The first question concerned the relevance to humans of eye effects that have been observed in dogs and the second related to the appropriate value for dermal absorption that could be derived from the different studies that have been made available by the notifier. On the first question the Scientific Panel considered that there is not sufficient information to conclude that the eye effects in dogs would only be specific to that species and that more research on the mechanisms involved may be necessary. Consequently, it is concluded that these effects in dogs cannot be regarded to be irrelevant to humans. On the second question, the Scientific Panel [5] considered a value of 10 % dermal absorption to be appropriate for the purpose of the assessment. In both cases, the recommendations of the Scientific Panel have been taken into consideration in formulating this Directive and the relevant review report.

(5) Articles 5(4) and 6(1) of Directive 91/414/EEC provide that inclusion of a substance in Annex I may be subject to restrictions and conditions. In this case, restrictions on the inclusion period and on the authorised crops are deemed necessary. The original measures presented to the Standing Committee on the Food Chain and Animal Health, proposed the restriction of the inclusion period to seven years, so that Member States would give priority to reviewing plant protection products already on the market containing dinocap. In order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC was intended to be limited to the uses of dinocap that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC. This implies that other uses, which were not or only partially covered by this assessment, had first to be subject to a complete assessment, before their inclusion in Annex I of Directive 91/414/EEC could be considered. Finally, due to the hazardous nature of dinocap, it was considered necessary to provide for a minimum harmonisation at Community level of certain risk mitigation measures that were to be applied by Member States when granting authorisations.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/85/EC (OJ L 293, 24.10.2006, p. 3).
[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).
[3] OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).
[4] OJ L 49, 4.3.1995, p. 50.
[5] Opinion of the Scientific Committee on Plant Health, Plant Protection Products and their Residues on a request from the Commission related to the evaluation of dinocap in the context of Council Directive 91/414/EEC (Question No EFSA-Q-2004-26, Opinion adopted on 30 June 2004).

(6) Under the procedures laid down by Directive 91/414/EEC, the approval of active substances, including the definition of risk management measures, is decided by the Commission. Member States bear the responsibility for the implementation, application and control of the measures intended to mitigate the risks generated by plant protection products. Concerns expressed by several Member States reflect their judgment that additional restrictions are necessary to reduce the risk to a level that can be considered acceptable and consistent with the high level of protection that is sought within the Community. At present, it is a question of risk management to set the adequate level of safety and protection for the continued production, commercialisation and use of dinocap.

(7) As a consequence of the above, the Commission re-examined its position. In order to correctly reflect the high level of protection of human and animal health and a sustainable environment sought in the Community, it considered appropriate, in addition to the principles set out in recital 5, to further reduce the period of inclusion to three instead of seven years. This further reduces any risk by ensuring the need for a priority reassessment of this substance.

(8) It may be expected that plant protection products containing dinocap satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report and providing that the necessary risk mitigation measures are applied.

(9) Without prejudice to the conclusion that plant protection products containing dinocap may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. Member States should require authorisation holders to provide information on the use of dinocap including any information on incidences on operator health.

(10) As with all substances included in Annex I to Directive 91/414/EEC, the status of dinocap could be reviewed pursuant to Article 5(5) of that Directive in the light of any new data becoming available. Equally, the fact that the inclusion of this substance in Annex I expires on a particular date does not prevent the inclusion being renewed according to the procedures laid down in the Directive.

(11) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.

(12) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(13) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing dinocap to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations. in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC. Given the hazardous properties of dinocap, the period for Member States to verify whether the plant protection products, which contain dinocap as the only active substances or in combination with other authorised active substances, comply with the provisions of Annex VI should not exceed three years.

(14) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(15) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion within the time limit laid down by its Chairman and the Commission therefore submitted to the Council a proposal relating to these measures. On the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures and it is accordingly for the Commission to adopt these measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2007 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing dinocap as an active substance by 30 June 2007. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to dinocap are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By derogation from paragraph 1, for each authorised plant protection product containing dinocap, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning dinocap. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall for products containing dinocap, where necessary, amend or withdraw the authorisation by 31 December 2009.

Article 4

This Directive shall enter into force on 1 January 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'150	Dinocap CAS No 39300-45-3 (for isomer mixture) CIPAC No 98	2,6-dinitro-4-octylphenyl crotonates and 2,4-dinitro-6-octylphenyl crotonates in which octyl is a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl groups	920 g/kg	1 January 2007	31 December 2009	PART A Only uses as fungicide on the following crop may be authorised: — wine grapes at rates not exceeding 0,21 kg active substance per hectare per application. The following uses must not be authorised: — air application, — knapsack and hand-held applications by amateur users, — home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of: — aquatic organisms. An appropriate distance must be kept between treated areas and surface water bodies. This distance may depend on the application or not of drift reducing techniques or devices, — birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species, — operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment, — workers, who must wear suitable protective clothing, in particular gloves, if they must enter a treated area before the specific re-entry period has expired. This re-entry period may not be less than 24 hours.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dinocap, and in particular Appendices I and II thereof, shall be taken into account. Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of dinocap can be obtained.'

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

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 13 November 2006

concerning the conclusion of the Agreement between the European Community and Kingdom of Norway on the revision of the amount of the financial contribution from Norway provided for in the Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

(2006/914/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152 in conjunction with the first sentence of the first subparagraph of Article 300(2) and the first subparagraph of Article 300(3) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) Council Regulation (EEC) No 302/93 of 8 February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction [2] provides, in Article 13 thereof, that the Centre is to be open to the participation of non-Community countries which share the Community's interests and those of its Member States in the Centre's objectives and work.

(2) The Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the European Monitoring Centre for Drugs and Drug Addiction [3] was signed on 19 October 2000 and entered into force on 1 January 2001. Article 5 of that Agreement provides for the financial contribution from Norway to the work of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

(3) Norway has requested the revision of its financial contribution to the work of the EMCDDA, following the enlargement of the European Union.

(4) The Commission has negotiated on behalf of the Community an Agreement with Norway on the revision of the amount of the financial contribution from Norway provided for in the Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the European Monitoring Centre for Drugs and Drug Addiction.

(5) The Agreement initialled on 11 November 2005 should be approved,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement between the European Community and the Kingdom of Norway on the revision of the amount of the financial contribution from Norway provided for in the Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is hereby approved on behalf of the Community.

The text of the Agreement is attached to this Decision.

[1] Opinion delivered on 24 October 2006 (not yet published in the Official Journal).
[2] OJ L 36, 12.2.1993, p. 1. Regulation as last amended by Regulation (EC) No 1651/2003 (OJ L 245, 29.9.2003, p. 30).
[3] OJ L 257, 11.10.2000, p. 24.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement in order to bind the Community.

Article 3

The President of the Council is hereby authorised to designate the person(s) empowered to transmit the diplomatic note provided for in Article 3 of the Agreement.

Article 4

This Decision shall be published in the *Official Journal of the European Union*.

Done at Brussels, 13 November 2006.

For the Council
The President
E. TUOMIOJA

AGREEMENT

between the European Community and the Kingdom of Norway on the revision of the amount of the financial contribution from Norway provided for in the Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

THE EUROPEAN COMMUNITY (hereinafter referred to as the Community),

of the one part,

AND THE KINGDOM OF NORWAY (hereinafter referred to as Norway),

of the other part,

RECALLING the Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), which was signed on 19 October 2000 and entered into force on 1 January 2001, and in particular Article 5 thereof which lays down Norway's financial contribution to the work of the EMCDDA;

CONSIDERING THAT Norway has requested the revision of its financial contribution to the work of the EMCDDA in view of the enlargement of the European Union;

HAVE DECIDED TO CONCLUDE THIS AGREEMENT:

Article 1

Article 5 of the Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the EMCDDA shall be replaced by the following:

'*Article 5*

Norway shall contribute financially to the activities of the Centre in accordance with the provisions laid down in the Annex to this Agreement, which shall form an integral part thereof.'.

Article 2

The Annex to this Agreement shall become the Annex to the Agreement between the European Community and the Kingdom of Norway on the participation of Norway in the work of the EMCDDA.

The formula set out in the Annex shall apply to the calculation of Norway's financial contribution to the EMCDDA's budget as from the beginning of the year in which this Agreement enters into force.

Article 3

This Agreement shall enter into force on the first day of the second month following the date of receipt of the latter diplomatic note confirming that legal requirements of the respective Contracting Party concerning the entry into force of the Agreement have been fulfilled.

ANNEX

Norway's financial contribution

1. In order to take account of possible future enlargement of the European Union and to avoid further adjustments, the formula for the calculation of Norway's contribution will be as follows:

   Amount of the Community subsidy excluding Reitox financing/(Number of Member States of the European Union + 1) – 10 %.

2. The financial contribution from Norway must not be less than EUR 271 000 (2004 prices) irrespective of the number of Member States of the Union. This amount corresponds to the cost of enlargement per country as estimated by the EMCDDA in 2001. That amount will be subject to a technical adjustment each year based on price trends and gross national income (GNI) in the European Union.

COMMISSION

COMMISSION DECISION

of 11 December 2006

extending the period of validity of Decision 2002/887/EC in respect of naturally or artificially dwarfed plants of *Chamaecyparis* Spach, *Juniperus* L. and *Pinus* L., originating in Japan

(notified under document number C(2006) 5997)

(2006/915/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community [1], and in particular Article 15(1) thereof,

Having regard to the request made by the United Kingdom,

Whereas:

(1) Commission Decision 2002/887/EC of 8 November 2002 authorising derogations from certain provisions of Council Directive 2000/29/EC in respect of naturally or artificially dwarfed plants of *Chamaecyparis* Spach, *Juniperus* L. and *Pinus* L., originating in Japan [2] authorises Member States to provide for derogations from certain provisions of Directive 2000/29/EC in respect of plants of *Chamaecyparis* Spach, *Juniperus* L. and *Pinus* L., originating in Japan, for limited periods and subject to specific conditions.

(2) Since the circumstances justifying the authorisation still apply and there is no new information giving cause for revision of the specific conditions, the authorisation should be extended.

(3) Decision 2002/887/EC should therefore be extended accordingly.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2002/887/EC is amended as follows:

1. In the first paragraph and in the second paragraph of Article 2, '1 August 2005 and 1 August 2006' is replaced by '1 August 2007 and 1 August 2008'.

2. The table in Article 4 is replaced by the following table:

'Plants	Period
Chamaecyparis:	1.1.2007 to 31.12.2008
Juniperus:	1.11.2006 to 31.3.2007, and 1.11.2007 to 31.3.2008
Pinus:	1.1.2007 to 31.12.2008'

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2006/35/EC (OJ L 88, 25.3.2006, p. 9).
[2] OJ L 309, 12.11.2002, p. 8. Decision as amended by Decision 2004/826/EC (OJ L 358, 3.12.2004, p. 32).

COMMISSION DECISION

of 11 December 2006

providing for a derogation from certain provisions of Council Directive 2000/29/EC in respect of plants of *Vitis* L., other than fruits, originating in Croatia or the former Yugoslav Republic of Macedonia

(notified under document number C(2006) 6365)

(2006/916/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community [1], and in particular Article 15(1) thereof,

Having regard to the request made by Slovenia,

Whereas:

(1) Under Directive 2000/29/EC, plants of *Vitis* L., other than fruits, originating in third countries may not in principle be introduced into the Community.

(2) Slovenia has requested a derogation to permit imports of plants of *Vitis* L., other than fruits, from Croatia or the former Yugoslav Republic of Macedonia for a limited period of time in order to enable specialised nurseries to multiply these plants in the Community before re-exporting them to Croatia or the former Yugoslav Republic of Macedonia.

(3) The Commission considers that there is no risk of spreading harmful organisms to plants or plant products provided that plants of *Vitis* L., other than fruits originating in Croatia or the former Yugoslav Republic of Macedonia are subject to the specific conditions laid down in this Decision.

(4) Member States should therefore for a limited period be authorised to permit the introduction into their territory of such plants subject to specific conditions.

(5) That authorisation should be terminated if it is established that the specific conditions laid down in this Decision are not sufficient to prevent the introduction of harmful organisms into the Community or have not been complied with.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from Article 4(1) of Directive 2000/29/EC with regard to point 15 of Part A of Annex III to that Directive, Member States shall be authorised to permit the introduction into their territory of plants of *Vitis* L., other than fruits, intended for grafting in the Community and originating in Croatia or the former Yugoslav Republic of Macedonia (hereinafter referred to as 'the plants').

In order to qualify for that derogation the plants shall be subject, in addition to the requirements laid down in Annexes I and II to Directive 2000/29/EC, to the conditions provided for in the Annex to this Decision, and be introduced into the Community between 1 January 2007 and 31 March 2007.

Article 2

Member States which make use of the derogation provided for in Article 1 shall provide the Commission and the other Member States, by 15 November 2007 at the latest, with:

(a) the information on the quantities of plants imported pursuant to this Decision; and

(b) a detailed technical report on the official inspections referred to in point 6 of the Annex.

Any Member State in which the plants are subsequently grafted after their introduction into its territory, shall also provide the Commission and the other Member States, by 15 November 2007 at the latest, with a detailed technical report of the official inspections and testing referred to in point 8(b) of the Annex.

[1] OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2006/35/EC (OJ L 88, 25.3.2006, p. 9).

Article 3

Member States shall immediately notify the Commission and the other Member States of all consignments introduced into their territory pursuant to this Decision which were subsequently found not to comply with this Decision.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Specific conditions applying to plants of *Vitis* L., other than fruits, originating in Croatia or the former Yugoslav Republic of Macedonia benefiting from the derogation provided for in Article 1

1. The plants shall be propagating material in the form of dormant buds of the varieties Babić, Borgonja, Dišeča belina, Graševina, Grk, Hrvatica, Kraljevina, Malvazija istarska, Maraština, Malvasija, Muškat momjanski, Muškat ruža porečki, Plavac mali, Plavina-Plavka, Pošip, Škrlet, Teran, Trnjak, Plavac veli, Vugava or Žlahtina that shall be:

   (a) intended to be grafted in the Community at the premises referred to in point 7, onto rootstocks produced in the Community;

   (b) harvested in stock nurseries, which are officially registered in Croatia or the former Yugoslav Republic of Macedonia. Member States making use of this derogation shall make the lists of the registered nurseries available to the Commission and to the other Member States, at the latest by 31 December 2006. These lists shall include the name of the variety, the number of rows planted with this variety, the number of plants per row for each of these nurseries, as far as they are deemed suitable for dispatch to the Community in 2007, under the conditions laid down in this Decision;

   (c) properly packed and the packaging made recognisable with a marking, enabling the identification of the registered nursery and the variety.

2. The plants shall be accompanied by a phytosanitary certificate issued in Croatia or the former Yugoslav Republic of Macedonia in accordance with Article 13(1) of Directive 2000/29/EC, on the basis of the examination laid down therein, confirming, in particular, freedom from the following harmful organisms:

   Daktulosphaira vitifoliae (Fitch)

   Xylophilus ampelinus (Panagopoulos) Willems et al.

   Grapevine Flavescence dorée

   Xylella fastidiosa (Well et Raju)

   Trechispora brinkmannii (Bresad.) Rogers

   Tobacco ringspot virus

   Tomato ringspot virus

   Blueberry leaf mottle virus

   Peach rosette mosaic virus.

   The certificate shall state under 'Additional Declaration', the indication 'This consignment meets the conditions laid down in Decision 2006/916/EC'.

3. The official plant protection organisation of Croatia or the former Yugoslav Republic of Macedonia shall ensure the identity and integrity of the plants from the time of harvesting as referred to in point 1(b) until they are exported to the Community.

4. The plants shall be introduced through points of entry designated for the purpose by the Member State in which they are situated.

   Those points of entry and the name and address of the responsible official body referred to in Directive 2000/29/EC in charge of each point of entry shall be notified sufficiently in advance by the Member State making use of the derogation to the Commission and shall be made available on request to other Member States.

   Where the introduction of the plants into the Community takes place in a Member State other than the Member State making use of the authorisation referred to in Article 1, hereinafter referred to as 'the authorisation', the responsible official bodies of the Member State of introduction shall inform and cooperate with the responsible official bodies of the Member States making use of the authorisation to ensure that this Decision is complied with.

5. Prior to introduction into the Community, the importer shall be officially informed of the conditions laid down in points 1 to 4; the said importer shall notify details of each introduction sufficiently in advance to the responsible official bodies in the Member State of introduction and that Member State, without delay, shall convey the details of the notification to the Commission, indicating:

   (a) the type of material;

(b) the variety and the quantity;

(c) the declared date of introduction and confirmation of the point of entry;

(d) the names, addresses and the locations of the premises referred to in point 7 where the buds will be grafted and stored.

The importer shall inform the official bodies concerned of any changes to the above details as soon as they are known.

The Member State concerned shall inform the Commission of the above details, and details of any change to them without delay.

At least two weeks before the date of introduction the importer shall notify the responsible official body of the premises referred to in point 7 where the plants are to be grafted.

6. The inspections, including testing, as appropriate, required pursuant to Article 13 of Directive 2000/29/EC and in accordance with provisions laid down in the present Decision, shall be made by the responsible official bodies of the Member State making use of this authorisation, and where appropriate, in cooperation with the responsible official bodies of the Member State where the plants are to be stored.

During those inspections, Member State(s) shall also inspect, and where appropriate, test for harmful organisms mentioned in point 2. Any finding of such harmful organisms shall immediately be notified to the Commission. Appropriate action shall be taken to destroy the harmful organisms and where appropriate the plants concerned.

7. The plants shall be grafted only at premises officially registered and approved for the purposes of this authorisation.

The person who intends to graft the plants shall notify in advance the responsible official bodies of the Member State in which the premises are situated of the name and address of the owner of those premises.

Where the place of grafting is situated in a Member State other than the Member State making use of the authorisation, the responsible official bodies of the Member State making use of the authorisation shall inform the responsible official bodies of the Member State where the plants are to be grafted of the names and addresses of the premises where the plants are to be grafted. Such information shall be given at the moment of the receipt of the advance notification from the importer as referred to in the fourth paragraph of point 5.

8. At the premises referred to in point 7:

(a) the plants which have been found free from the harmful organisms referred to in point 2 may then be used for grafting onto rootstock of Community origin. The grafted plants shall subsequently be kept under appropriate conditions in a suitable growing medium but shall not be planted or further grown in fields. The grafted plants shall remain at the premises for no more than eighteen months before being exported to a destination outside the Community as referred to in point 9;

(b) in the period following grafting the plants shall be visually inspected by the said responsible official bodies of the Member State in which they are grafted, at appropriate times, for the presence of harmful organisms or for signs or symptoms caused by any harmful organism; as a result of such visual inspection any harmful organism having caused such signs or symptoms shall be identified by an appropriate testing procedure;

(c) any grafted plant which has not been found free, during the said inspections or testing referred to in points (a) and (b), from harmful organisms listed in point 2, or otherwise of quarantine concern, shall be immediately destroyed under the control of the said responsible official bodies.

9. Any plant resulting from a successful grafting using the buds referred to in point 1 shall only be released as grafted plants for export to Croatia or to the former Yugoslav Republic of Macedonia. The responsible official bodies of a Member State making use of this authorisation shall ensure that any plant or part of the plant not so exported shall be officially destroyed. Records shall be kept of the amounts of successfully grafted plants, of officially destroyed plants and of plants subsequently re-exported to Croatia or to the former Yugoslav Republic of Macedonia. This information shall be made available to the Commission.

COMMISSION DECISION

of 11 December 2006

establishing the Community's financial contribution to the expenditure incurred in the context of the emergency measures taken to combat bluetongue in France in 2004 and 2005

(notified under document number C(2006) 6382)

(Only the French text is authentic)

(2006/917/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1], and in particular Article 3(3) thereof,

Whereas:

(1) Outbreaks of bluetongue occurred in France in 2004 and 2005. The emergence of that disease presented a serious risk to the Community's livestock population.

(2) In order to prevent the spread of the disease and to help eradicate it as quickly as possible, the Community should contribute financially towards the eligible expenditure incurred by the Member State under the emergency measures taken to combat the disease, as provided for in Decision 90/424/EEC.

(3) Commission Decision 2005/659/EC of 15 September 2005 concerning a financial contribution by the Community in the context of the vaccination campaigns against bluetongue in France in 2004 and 2005 [2] granted a financial contribution from the Community to France towards the expenditure incurred under the emergency measures to combat bluetongue implemented in 2004 and 2005.

(4) In accordance with that Decision, a first instalment of EUR 150 000 was granted.

(5) Pursuant to that Decision, the balance of the Community financial contribution is to be paid on the basis of the application submitted by France on 6 December 2005 and supporting documents setting out the figures quoted in the application.

(6) In view of those considerations, the total amount of the Community's financial contribution to the eligible expenditure incurred associated with the eradication of bluetongue in France in 2004 and 2005 should now be fixed.

(7) The results of the inspections carried out by the Commission in compliance with the Community veterinary rules and the conditions for granting Community financial contributions mean the entire amount of the expenditure submitted cannot be recognised as eligible.

(8) The Commission's observations, method of calculating the eligible expenditure and final conclusions were communicated to France in a letter dated 20 September 2006.

(9) 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 total Community financial contribution towards the expenditure associated with eradicating bluetongue in France in 2004 and 2005 pursuant to Decision 2005/659/EC is fixed at EUR 250 175.

Since a first instalment of EUR 150 000 has already been paid pursuant to Decision 2005/659/EC, the balance of EUR 100 175 shall be paid to France.

Article 2

This Decision is addressed to the French Republic.

Done at Brussels, 11 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

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[1] OJ L 224, 18.8.1990, p. 19. Decision last amended by Council Decision 2006/53/EC (OJ L 29, 2.2.2006, p. 37).

[2] OJ L 244, 20.9.2005, p. 24.

(Acts adopted under Title V of the Treaty on European Union)

COUNCIL JOINT ACTION 2006/918/CFSP

of 11 December 2006

amending and extending Joint Action 2006/304/CFSP on the establishment of an EU Planning Team (EUPT Kosovo) regarding a possible EU crisis management operation in the field of rule of law and possible other areas in Kosovo

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 14 thereof,

Whereas:

(1) On 10 April 2006 the Council adopted Joint Action 2006/304/CFSP [1] establishing an EU Planning Team (EUPT Kosovo) regarding a possible EU crisis management operation in the field of rule of law and possible other areas in Kosovo. This Joint Action expires on 31 December 2006.

(2) On 11 October 2006 the Political and Security Committee recommended that EUPT Kosovo be extended and agreed that the mandate of EUPT Kosovo should be adapted.

(3) Joint Action 2006/304/CFSP should be extended and amended accordingly,

HAS ADOPTED THIS JOINT ACTION:

Article 1

Joint Action 2006/304/CFSP is hereby amended as follows:

1. In Article 1(2), the first indent shall be replaced by the following:

'— to take forward planning and take action to ensure a smooth transition between selected tasks of UNMIK and a possible EU crisis management operation in the field of the rule of law and other areas that might be identified by the Council in the context of the future status process;'.

2. Article 2(5) shall be replaced by the following:

'5. Identifying the needs of the possible future EU crisis management operation regarding its required means of support, including all equipment, services and premises and drawing up related terms of reference or technical specifications. Proposing actions to procure the required equipment, services and premises and conclude those actions, taking into account the possibility to take over suitable equipment, premises and material from available sources, including UNMIK, where relevant, feasible and cost efficient. Launching tender procedures and awarding contracts shall be done where appropriate under suspensive clause and/or framework contracts.

Recruiting personnel that would constitute the core of the possible future ESDP crisis management operation, in view of its rapid deployment.

Issuing a deployment plan for the future possible EU crisis management operation.'

3. Article 4(7) shall be deleted.

4. Article 9(1) shall be replaced by the following:

'1. The financial reference amount intended to cover the expenditure related to EUPT Kosovo from 10 April 2006 to 31 December 2006 shall be EUR 3 005 000.

The financial reference amount intended to cover the expenditure related to EUPT Kosovo from 1 January 2007 to 31 May 2007 shall be EUR 10 545 000.'

5. The following paragraph shall be added to Article 9:

'6. In duly substantiated exceptional cases, notably in relation with suppliers offering particularly advantageous terms, the Commission may grant exceptions to the rules of origin applicable to procurement.'

[1] OJ L 112, 26.4.2006, p. 19.

6. Article 14 shall be replaced by the following:

'*Article 14*

Review

By 15 April 2007 the Council shall evaluate whether EUPT Kosovo should be continued after 31 May 2007, taking into account the necessity of a smooth transition to a possible EU crisis management operation in Kosovo.'

7. Article 15(2) shall be replaced by the following:

'2. It shall expire on 31 May 2007 or on the date of the launching of the EU crisis management operation, whichever is earlier.'

Article 2

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

Article 3

This Joint Action shall be published in the *Official Journal of the European Union*.

Done at Brussels, 11 December 2006.

For the Council
The President
E. TUOMIOJA

CORRIGENDA

Corrigendum to Council Joint Action 2006/867/CFSP of 30 November 2006 extending and amending the mandate of the European Union Monitoring Mission (EUMM)

(Official Journal of the European Union L 335 of 1 December 2006)

On page 48:

for: '*Article 3*

The financial reference amount intended to cover the expenditure related to the EUMM between 1 January 2007 and 31 December 2007 shall be EUR 2 318 000. This amount shall also cover expenditure relating to the closing-down of the EUMM.',

read: '*Article 3*

The financial reference amount intended to cover the expenditure related to the EUMM between 1 January 2007 and 31 December 2007 shall be EUR 3 863 583. This amount shall also cover expenditure relating to the closing-down of the EUMM.'