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Contents

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(Continued overleaf)

[1] Text with EEA relevance

EN

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

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

EN

(1) Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) No 348/2011

of 8 April 2011

implementing Regulation (EC) No 560/2005 imposing certain specific restrictive measures directed against certain persons and entities in view of the situation in Côte d'Ivoire

THE COUNCIL OF THE EUROPEAN UNION

Having regard to Council Regulation (EC) No 560/2005 of 12 April 2005 imposing certain specific restrictive measures directed against certain persons and entities in view of the situation in Côte d'Ivoire [1], and in particular Article 11a(2) thereof,

Whereas:

(1) On 12 April 2005, the Council adopted Regulation (EC) No 560/2005.

(2) In view of the developments in Côte d'Ivoire, the list of persons and entities subject to restrictive measures set out in Annex IA to Regulation (EC) No 560/2005 should be amended,

HAS ADOPTED THIS REGULATION:

Article 1

The entities listed in the Annex to this Regulation shall be deleted from the list set out in Annex IA to Regulation (EC) No 560/2005.

Article 2

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

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

Done at Brussels, 8 April 2011.

For the Council
The President
MARTONYI J.

[1] OJ L 95, 14.4.2005, p. 1.

ANNEX

ENTITIES REFERRED TO IN ARTICLE 1

1.	SIR (Ivorian Refining Company)
2.	Autonomous Port of Abidjan
3.	Autonomous Port of San Pedro
4.	CGFCC (Coffee and Cocoa Trade Management Committee)

COMMISSION REGULATION (EU) No 349/2011

of 11 April 2011

implementing Regulation (EC) No 1338/2008 of the European Parliament and of the Council on Community statistics on public health and health and safety at work, as regards statistics on accidents at work

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work [1], and in particular Article 9(1) thereof,

Whereas:

(1) Regulation (EC) No 1338/2008 established a common framework for the systematic production of European statistics on public health and health and safety at work.

(2) Pursuant to Article 9(1) of Regulation (EC) No 1338/2008, implementing measures are necessary to determine the data and metadata to be supplied on accidents at work covered in Annex IV to that Regulation as well as to determine the reference periods, intervals and time limits for data provision.

(3) Confidential data sent by Member States to the Commission (Eurostat) should be handled in accordance with the principle of statistical confidentiality as laid down in Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics [2] and with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data [3].

(4) A cost-benefit analysis has been carried out and evaluated in accordance with Article 6 of Regulation (EC) No 1338/2008.

(5) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(a) 'accident at work' means a discrete occurrence in the course of work which leads to physical or mental harm. The phrase 'in the course of work' means whilst engaged in an occupational activity or during the time spent at work. This includes road traffic accidents that occur in the course of work but excludes commuting accidents, i.e. road accidents that occur during the journey between home and the workplace;

(b) 'a fatal accident' means an accident which leads to the death of a victim within 1 year of the accident;

(c) 'economic activity of the employer' covers the main 'economic' activity of the local unit of the enterprise of the victim;

(d) 'age' means the age of the victim at the time of the accident;

(e) 'type of injury' means the physical consequences for the victim;

(f) 'geographical location' means the territorial unit where the accident has occurred;

(g) 'size of the enterprise' means the number of employees (full-time equivalent) working at the local unit of the enterprise of the victim;

(h) 'nationality of the victim' means the country of citizenship;

(i) 'days lost' means the number of calendar days during which the victim is unfit for work as a result of an accident at work;

(j) 'workstation' means the usual or, alternatively, occasional nature of the place/post occupied by the victim at the time of the accident;

(k) 'working environment' means the workplace, work premises or general environment where the accident happened;

(l) 'working process' means the main type of work or task (general activity) being performed by the victim at the time of the accident;

[1] OJ L 354, 31.12.2008, p. 70.
[2] OJ L 87, 31.3.2009, p. 164.
[3] OJ L 8, 12.1.2001, p. 1.

(m) 'specific physical activity' means the victim's exact physical activity at the instant of the accident;

(n) 'material agent associated with the specific physical activity' means the tool, object or instrument being used by the victim when the accident happened;

(o) 'deviation' means the last event deviating from normality and leading to the accident;

(p) 'material agent associated with the deviation' means the tool, object or instrument involved in the abnormal event;

(q) 'contact — mode of injury' means how the victim was hurt (physical or mental trauma) by the material agent that caused the injury;

(r) 'material agent associated with the contact — mode of injury' means the object, tool or instrument with which the victim came into contact or the psychological mode of injury.

Article 2

Data required

1. Member States shall transmit to the Commission (Eurostat) microdata on persons who had an accident in the course of work during the reference period and the associated metadata. The list of variables to be transmitted to the Commission (Eurostat) as well as the compulsory or optional status of the variable and the first year for data transmission are set out in Annex I.

2. Provision of data on accidents at work relating to the self-employed, family workers and students shall be on a voluntary basis.

3. Provision of data on accidents at work that are subject to confidentiality rules by national legislation as listed in Annex II shall be on a voluntary basis.

4. Data for accidents at work that occurred during the reference year shall preferably be based on registers and other administrative sources. When this is not feasible, estimation and imputation, even if based on survey and not case-by-case data, may be used to fill gaps in data coverage.

Article 3

Reference period

The reference period shall be the calendar year in which the accidents are notified to the competent national authorities.

Article 4

Metadata

1. Member States shall transmit to the Commission (Eurostat) an annual verification and update of the metadata together with the data.

2. The metadata shall be transmitted according to a standard template specified by the Commission (Eurostat) and shall include the items referred to in Annex III.

Article 5

Transmission of data and metadata to the Commission (Eurostat)

1. Member States shall transmit data and metadata in accordance with an exchange standard specified by the Commission (Eurostat), within 18 months after the end of the reference period.

2. Data and metadata shall be transmitted to the Commission (Eurostat) through electronic means, using the single entry point at the Commission (Eurostat).

Article 6

Entry into force

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

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

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX I

LIST OF VARIABLES

European statistics on accidents at work (ESAW) Phases I and II variables

Variables	Specifications	First year for data transmission
Case Number	Unique case number to identify each individual record and to ensure that each record represents a separate accident occurrence at work. The chosen case number must be prefixed by the 4 digits of the year when the accident is notified to the competent national authorities.	2013
Economic Activity of the Employer	4-digit level of the NACE Rev.2 ([1])	2013 for NACE Rev.2 sectors A and C-N 2015 for NACE Rev.2 sectors B and O-S.
Occupation of the Victim	2-digit level of the ISCO-08	2013
Age of the Victim	2-digit number	2013
Sex of the Victim	1-digit code	2013
Type of Injury	3-digit version of the ESAW classification for 'Type of injury' according to the ESAW methodology.	2013
Part of Body Injured	2-digit version of the classification of 'part of body injured' according to the ESAW methodology.	2013
Geographical Location of the Accident	5-digit code according to the NUTS classification. ([2])	2013
Date of the Accident	Numeric variable which is indicated as year, month and day	2013
Time of the Accident	2-digit variable describing time intervals in hours according to the ESAW methodology	optional
Size of the Enterprise	Categories according to the ESAW methodology	optional
Nationality of the Victim	Categories according to the ESAW methodology	optional
Employment Status of the Victim	Categories according to the ESAW methodology	2013
Days Lost (severity)	Categories according to the ESAW methodology. Specific codes are used to denote permanent incapacity and fatal accident.	2013
Weight ESAW collection	To be used when the Member State uses a sample for the data collection on accidents and/or wants to correct for under-reporting. If not applicable the default value 1 is used.	2013

([1]) Regulation (EC) No 1893/2006 of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains (OJ L 393, 30.12.2006, p. 1).

([2]) Regulation (EC) No 1059/2003 of the European Parliament and of the Council of 26 May 2003 on the establishment of a common classification of territorial units for statistics (NUTS). (OJ L 154, 21.6.2003, p. 1).

ESAW phase III variables on causes and circumstances

Variables	Specifications	First year for data transmission
1. Workstation	Categories according to the ESAW methodology	2015 (*)
2. Working Environment	3-digit version of the classification of 'Working Environment' according to the ESAW methodology	2015 (*)
3. Working Process	2-digit version of the classification of 'Working Process' according to the ESAW methodology	2015 (*)
4. Specific Physical Activity	2-digit version of the classification of 'Specific Physical Activity' according to the ESAW methodology	2015 (*)
5. Deviation	2-digit version of the classification of 'Deviation' according to the ESAW methodology	2015 (*)
6. Contact — Mode of injury	2-digit version of the classification of 'Contact — Mode of injury' according to the ESAW methodology	2015 (*)
7. Material Agent associated with the Specific Physical Activity	4-digit version of the classification of 'Material Agent' according to the ESAW methodology	2015 (*)
8. Material Agent associated with the Deviation	4-digit version of the classification of 'Material Agent' according to the ESAW methodology	2015 (*)
9. Material Agent associated with the Contact — Mode of injury	4-digit version of the classification of 'Material Agent' according to the ESAW methodology	2015 (*)
Weight Causes and Circumstances	To be used when the Member State applies an additional sampling for the encoding of the ESAW Phase III variables on causes and circumstances. If not applicable the default value 1 is used	2015

(*) Compulsory transmission of at least 3 of the 9 variables

ANNEX II

LIST OF PROFESSIONS SUBJECT TO CONFIDENTIALITY FOR DELIVERY ON A VOLUNTARY BASIS

According to ISCO-08:

— 0 Armed forces occupations

— 3351 Customs and border inspectors

— 3355 Police inspectors and detectives

— 541 Protective services workers

  a. 5411 Fire-fighters

  b. 5412 Police officers

  c. 5413 Prison guards

  d. 5414 Security guards

  e. 5419 Protective services workers not elsewhere classified

According to NACE Rev.2:

— 84.22 Defence activities

— 84.23 Justice and judicial activities

— 84.24 Public order and safety activities

— 84.25 Fire services activities

ANNEX III

METADATA

Where applicable and relevant to full understanding of the ESAW data, the metadata describe the following items:

— the population covered in terms of NACE Rev.2 sectors, and possibly subsectors, and employment status,

— the information on professions/activities for which data on accidents at work are subject to confidentiality by national legislation and cannot be transmitted,

— the declaration rates for accidents at work which are to be used for correction of under-reporting,

— the coverage of the different types of accidents as explained in the ESAW methodology,

— the sampling method — if applicable — used in the setup of the microdata collection,

— the sampling method — if applicable — which is used for encoding of the variables on causes and circumstances,

— the numbers of fatal road traffic accidents and fatal accidents on board any means of transport during a journey in the course of work for persons employed outside the NACE Rev.2 sector H 'Transportation',

— information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.

COMMISSION REGULATION (EU) No 350/2011

of 11 April 2011

amending Regulation (EC) No 1251/2008 as regards the placing on the market requirements for consignments of Pacific oysters intended for Member States or parts thereof with national measures regarding ostreid herpes virus 1 µvar (OsHV-1 µvar) approved by Decision 2010/221/EU

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals [1], and in particular Article 61(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species [2] lays down placing on the market requirements, including animal health certification requirements, for movements of aquaculture animals into areas covered by national measures approved by Commission Decision 2010/221/EU of 15 April 2010 approving national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Council Directive 2006/88/EC [3].

(2) Since 2008, increased mortality in Pacific oysters (*Crassostrea gigas)* has occurred in several areas in Ireland, France and the United Kingdom. The epidemiological investigations undertaken in 2009 suggested that a newly described strain of ostreid herpesvirus-1 (OsHV-1), namely OsHV-1 µvar, played a major role in the increased mortality.

(3) Commission Regulation (EU) No 175/2010 of 2 March 2010 implementing Council Directive 2006/88/EC as regards measures to control increased mortality in oysters of the species *Crassostrea gigas* in connection with the detection of Ostreid herpesvirus 1 µvar (OsHV-1 µvar) [4] was adopted with the aim of preventing the further spread of OsHV-1 µvar. It introduced measures to control the spread of that disease and it applies until 30 April 2011.

(4) Decision 2010/221/EU, as recently amended by Commission Decision 2011/187/EU [5], allows the Member States listed in Annex III thereto to impose placing on the market requirements on the movement of Pacific oysters into areas covered by approved surveillance programmes, in order to prevent the introduction of OsHV-1 µvar into those areas. In the interests of clarity and simplification of Union legislation, the respective placing on the market requirements should be laid down in Regulation (EC) No 1251/2008.

(5) In order to prevent the introduction of OsHV-1 µvar into Member States or parts thereof listed in Annex III to Decision 2010/221/EU, consignments of Pacific oysters intended for farming or relaying areas, and for dispatch centres, purification centres or similar businesses before human consumption, introduced into such Member States or parts thereof, should originate from an area with an equivalent health status.

(6) To ensure that those requirements are complied with, such consignments should be accompanied by an animal health certificate providing the necessary attestations.

(7) Regulation (EC) No 1251/2008 should therefore be amended accordingly.

(8) It is appropriate to provide for transitional measures to allow Member States and the industry to take the necessary measures to comply with the requirements laid down in this Regulation.

(9) To avoid the further spread of OsHV-1 µvar, this Regulation should apply immediately following the date of expiry of Regulation (EU) No 175/2010.

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

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1251/2008 is amended as follows:

(1) in Article 1, point (b)(ii) is replaced by the following:

‘(ii) aquaculture animals intended for farming, relaying areas, put and take fisheries, open ornamental facilities and restocking, and for dispatch centres, purification centres and similar businesses before human

[1] OJ L 328, 24.11.2006, p. 14.
[2] OJ L 337, 16.12.2008, p. 41.
[3] OJ L 98, 20.4.2010, p. 7.
[4] OJ L 52, 3.3.2010, p. 1.
[5] OJ L 80, 26.3.2011, p. 15.

consumption in Member States and parts thereof with national measures approved by Commission Decision 2010/221/EU (*);

(*) OJ L 98, 20.4.2010, p. 7.';

(2) in Article 8a(1)(a), the following point (iii) is added:

'(iii) Annex III to Decision 2010/221/EU as subject to a surveillance programme for one or more of the diseases listed in the first column of that table;';

(3) the following Article 8b is inserted:

'*Article 8b*

Live molluscs intended for dispatch centres, purification centres or similar businesses before human consumption in Member States and parts thereof with national measures approved by Decision 2010/221/EU

1. Consignments of live molluscs intended for dispatch centres, purification centres or similar businesses before human consumption shall be accompanied by an animal health certificate completed in accordance with the model set out in Part B of Annex II and the explanatory notes set out in Annex V, where the animals:

(a) are introduced into Member States or parts thereof listed in the second and fourth column of the table set out in Annex III to Decision 2010/221/EU as subject to a surveillance programme for one or more of the diseases listed in the first column of that table;

(b) are of species which are listed in Part C of Annex II as species susceptible to the disease(s), for which a surveillance programme applies in accordance with Decision 2010/221/EU, as referred to in point (a).

2. Consignments of live molluscs referred to in paragraph 1 shall comply with the animal health requirements set out in the model animal health certificate and explanatory notes as referred to in that paragraph.

3. This Article shall not apply to consignments intended for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system validated by the competent authority that:

(a) inactivates enveloped viruses; or

(b) reduces the risk of transmitting diseases to the natural waters to an acceptable level.';

(4) Annex II is replaced by the text in the Annex to this Regulation.

Article 2

1. For a transitional period until 15 May 2011, consignments of Pacific oysters accompanied by animal health certificates issued in accordance with Part A or B of Annex II to Regulation (EC) No 1251/2008 before the amendments introduced by the present Regulation, and an animal health certificate issued in accordance with Annex II to Regulation (EU) No 175/2010 may be placed on the market provided that they reach their place of final destination before that date.

2. For a transitional period until 1 July 2012, consignments of aquaculture animals accompanied by animal health certificates issued in accordance with Part A or B of Annex II to Regulation (EC) No 1251/2008 before the amendments introduced by the present Regulation, may continue to be placed on the market provided that the animal health attestations as regards OsHV-1 µvar set out in Part II of those certificates are not applicable and they reach their place of final destination before that date.

Article 3

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

It shall apply from 1 May 2011.

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

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

'ANNEX II

PART A

Model animal health certificate for the placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking

EUROPEAN UNION **Intra trade certificate**

Part I: Details of consignment presented

I.1. Consignor Name Address Postal code		I.2. Certificate reference No	I.2.a. Local reference No
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code		I.6.	
		I.7.	
I.8. Country of origin	ISO code / I.9.	I.10. Country of destination	ISO code / I.11.
I.12. Place of origin Approved aquaculture holding ☐ Other ☐ Name Approval number Address Postal code		I.13. Place of destination Approved aquaculture holding ☐ Other ☐ Name Approval number Address Postal code	
I.14. Place of loading Postal code		I.15. Date and time of departure	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification		I.17. Transporter Name Approval number Address Postal code Member State	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24. Type of packaging	
I.25. Commodities certified for: Breeding ☐ Game restocking ☐ Relaying ☐ Pets ☐ Quarantine ☐ Other ☐			
I.26. Transit through third country ☐ Third country ISO code Exit point Code Entry point BIP No		I.27. Transit through Member States ☐ Member State ISO code Member State ISO code Member State ISO code	
I.28. Export ☐ Third country ISO code Exit point Code		I.29.	
I.30.			
I.31. Identification of the commodities Species (Scientific name) Quantity			

EUROPEAN UNION

Placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking

Part II: Certification

II.	Health information	II.a. Certificate reference No	II.b.

II.1 General requirements

I, the undersigned official inspector, hereby certify that the aquaculture animals referred to in Part I of this certificate:

II.1.1 *either* (1)[have been inspected within (1)(2)[72] (1)[24] hours of loading, and showed no clinical signs of disease]

or (1)[in the case of eggs and molluscs, come from a farm or mollusc farming area where, according to the records of the farm or mollusc farming area, there is no indication of disease problems]

or (1)(3)[in the case of wild aquatic animals, according to the best of my knowledge and belief are clinically healthy];

II.1.2 are not subject to any prohibitions due to unresolved increased mortality;

II.1.3 are not intended for destruction or slaughter for the eradication of diseases;

II.1.4 comply with the requirements for placing on the market laid down in Directive 2006/88/EC;

II.1.5 (1)[in the case of molluscs, were subject to an individual visual check of each part of the consignment, and no molluscs species other than those specified in Part I of the certificate were detected.]

II.2 (1)(4)(5)**[Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease**

I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above:

either (1)(6)[originate from a Member State, zone or compartment declared free from (1)[VHS] (1)[IHN] (1)[ISA] (1)[KHV] (1)[Marteilia refringens] (1)[Bonamia ostreae] (1)[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC.]

or (1)(5)(6)[in the case of wild aquatic animals, have been subject to quarantine in accordance with Decision 2008/946/EC.]]

II.3 (1)(7)**[Requirements for vector species to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease**

I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above which are to be regarded as possible vectors to (1)[VHS] (1)[IHN] (1)[ISA] (1)[KHV] (1)[Marteilia refringens] (1)[Bonamia ostreae] (1)[White spot disease] as they are of species listed in Column 2 and fulfil the conditions set out in Column 3 of the table in Annex I to Regulation (EC) No 1251/2008:

either (1)(6)[originate from a Member State, zone or compartment declared free from (1)[VHS] (1)[IHN] (1)[ISA] (1)[KHV] (1)[Marteilia refringens] (1)[Bonamia ostreae] (1)[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC.]

or (1)(6)(7)[have been subject to quarantine in accordance with Decision 2008/946/EC.]]

II.4 Transport and labelling requirements

I, the undersigned official inspector, hereby certify that:

II.4.1 the aquaculture animals referred to above,

(i) are placed under conditions, including with a water quality, that do not alter their health status,

(ii) as appropriate, comply with the general conditions for the transport of animals laid down in Article 3 of Regulation (EC) No 1/2005;

EUROPEAN UNION **Placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking**

II.	Health information	II.a. Certificate reference No	II.b.
II.4.2	the transport container or well boat prior to loading is clean and disinfected or previously unused; and		
II.4.3	the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.8 to I.13 of Part I of this certificate, and the following statement:		
	either (1)["(1)[Wild] (1)[Fish] (1)[Molluscs] (1)[Crustaceans] intended for farming in the European Union"],		
	or (1)["(1)[Wild] (1)[Molluscs] intended for relaying in the European Union"],		
	or (1)["(1)[Wild] (1)[Fish] (1)[Molluscs] (1)[Crustaceans] intended for put and take fisheries in the European Union"],		
	or (1)["(1)[Wild] (1)[Ornamental fish] (1)[Ornamental molluscs] (1)[Ornamental crustaceans] intended for open ornamental facilities in the European Union"],		
	or (1)["(1)[Fish] (1)[Molluscs] (1)[Crustaceans] intended for restocking in the European Union"],		
	or (1)["(1)[Wild] (1)[Fish] (1)[Molluscs] (1)[Crustaceans] intended for quarantine in the European Union"],		
II.5	(1)(8)**[Attestation for consignments originating from an area subject to disease control measures as provided for in Section 3 to 6 of Chapter V of Directive 2006/88/EC**		
	I, the undersigned official inspector, hereby certify that:		
II.5.1	the animals referred to above originate from an area subject to disease control measures regarding (1)[Epizootic ulcerative syndrome (EUS)] (1)[Epizootic haematopoietic necrosis (EHN)] (1)[Viral haemorrhagic septicaemia (VHS)] (1)[Infectious haematopoietic necrosis (IHN)] (1)[Infectious salmon anaemia (ISA)] (1)[Koi herpes virus (KHV)] (1)[Bonamia exitiosa] (1)[Perkinsus marinus] (1)[Mikrocytos mackini] (1)[Marteilia refringens] (1)[Bonamia ostreae] (1)[Taura syndrome] (1)[Yellowhead disease] (1)[White spot disease] (1)(9)[the following emerging disease: .....]; II.5.2 the animals referred to above are allowed to be placed on the market according to the control measures laid down; and II.5.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.8 to I.13 of Part I of this certificate, and the following statement: "(1)[Wild] (1)[Fish] (1)[Molluscs] (1)[Crustaceans] originating from an area subject to disease control measures".]		
II.6	(1)(10)**[Requirements for species susceptible to Spring viraemia of carp (SVC), Bacterial kidney disease (BKD), Infectious pancreatic necrosis virus (IPN) and Infection with Gyrodactylus salaris (GS)**		
	I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above,		
either	(1)[originate from a Member State or part thereof: (a) where (1)[SVC] (1)[GS] (1)[BKD] (1)[IPN] are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority, (b) where all aquaculture animals of species susceptible to the relevant disease(s) introduced into that Member State or part thereof comply with the requirements set out in II.6 of this certificate, (c) where species susceptible to the relevant diseases are not vaccinated against the relevant diseases, and		

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II.	Health information	II.a. Certificate reference No	II.b.

(d) *either* (1)[which, in the case of (1)[IPN](1)[BKD], complies with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC.]

and/or (1)[which, in the case of (1)[SVC] (1)[GS], comply with requirements for disease freedom laid down in the relevant OIE Standard.]

and/or (1)[which, in the case of (1)[SVC] (1)[IPN] (1)[BKD], comprises one individual farm which under the supervision of the competent authority:

(i) has been emptied, cleansed and disinfected, and fallowed in at least 6 weeks,

(ii) has been restocked with animals from areas certified free from the relevant disease by the competent authority.]]

and/or (1)[in the case of wild aquatic animals susceptible to (1)[SVC] (1)[IPN] (1)[BKD], have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]

and/or (1)[in the case of consignments for which GS requirements apply, have been held, immediately prior to the placing on the market, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days and no other live aquatic animals of the species susceptible to GS have been introduced during that period.]

and/or (1)[in the case of eyed fish eggs for which GS requirements apply, have been disinfected by a method demonstrated to be effective against GS.]]

II.7 (1)(11)**[Requirements for species susceptible to OsHV-1 µvar**

I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above,

either (1)[originate from a Member State or compartment:

(a) where OsHV-1 µvar is notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,

(b) where all aquaculture animals of species susceptible to OsHV-1 µvar introduced into that Member State or compartment comply with the requirements set out in II.7 of this certificate,

(c) *either* (1)[which comply with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC,]

and/or (1)[in the case of consignments intended for a Member State or compartment covered by a programme approved by Decision 2010/221/EU, which itself is also covered by a surveillance programme approved by Decision 2010/221/EU,]

and/or (1)[have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]

Notes

Part I:

— Box I.12: If appropriate, use the authorisation number for the farm or mollusc farming area in question. Use “other” if wild aquatic animals,

— Box I.13: If appropriate, use the authorisation number for the farm or mollusc farming area in question. Use “other” if intended for restocking,

— Box I.19: Use the appropriate HS codes: 0301, 0306, 0307, 030110 or 030270,

— Box I.20 and I. 31: As regards quantity, give the total number,

— Box I.25: Use the option “Breeding” if intended for farming, “Relaying” if intended for relaying, “Pets” if intended for open ornamental facilities, “Game restocking” if intended for restocking, “Quarantine” if the aquaculture animals are intended for a quarantine facility, and “Other” if intended for put and take fisheries.

Part II:

(1) Keep as appropriate.

(2) The 24-hour option applies only to consignments of aquaculture animals which according to Article 8 of Regulation (EC) No 1251/2008 must be accompanied by a certificate and which in compliance with the placing on the market requirements of Directive 2006/88/EC are allowed by the competent authority to leave an area subject to control provisions provided for in Sections 3 to 6 of Chapter V of Directive 2006/88/EC or a Member State, zone or compartment with an eradication programme approved in accordance with Article 44(2) of that Directive. In all other cases the 72-hour option applies.

EUROPEAN UNION

Placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking

II. Health information	II.a. Certificate reference No	II.b.

(3) Only applicable to consignments of aquaculture animals caught in the wild and immediately transported to a farm or mollusc farming area without any temporary storage.

(4) Part II.2 of this certificate applies to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC.

(5) Consignments of wild aquatic animals may be placed on the market regardless of the requirements in Part II.2 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.

(6) To be authorised into a Member State, zone or compartment declared free from VHS, IHN, ISA, KHV, Marteilia refringens, Bonamia ostreae, or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain susceptible or vector species to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Union are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm

(7) Part II.3 of this certificate applies to vector species to one or more of the diseases referred to in the title. Possible vector species and the conditions, under which consignments of such species are to be considered vector species, are listed in Annex I to Regulation (EC) No 1251/2008. Consignments of possible vector species may be placed on the market regardless of the requirements in Part II.3 if the conditions set out in Column 4 of the table in Annex I to Regulation (EC) No 1251/2008 are not fulfilled or they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.

(8) Part II.5 of this certificate applies to consignments of aquaculture animals which according to Article 8 of Regulation (EC) No 1251/2008 must be accompanied by a certificate and which in compliance with the placing on the market requirements of Directive 2006/88/EC are allowed by the competent authority to leave an area subject to control provisions provided for in Sections 3 to 6 of Chapter V of Directive 2006/88/EC or a Member State, zone or compartment with an eradication programme approved in accordance with Article 44(2) of that Directive.

(9) Applicable when measures are taken in accordance with Article 41 of Directive 2006/88/EC.

(10) Part II.6 of this certificate only applies to consignments intended for a Member State or part thereof which is regarded as disease-free, or for which an programme is approved in accordance with Decision 2010/221/EU as regards SVC, BKD, IPN or GS, and the consignment comprises species listed in Part C of Annex II as susceptible to the disease(s) for which the disease-free status or programme(s) apply(ies).

Part II.6 shall also apply to consignments of fish of any species originating from waters where species listed in Part C of Annex II as species susceptible to infection with GS, are present, where those consignments are intended for a Member State or part thereof listed in Annex I to Decision 2010/221/EU as free of GS.

Consignments of wild aquatic animals for which SVC, IPN and/or BKD related requirements are applicable, may be placed on the market regardless of the requirements in Part II.6 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.

(11) Part II.7 of this certificate only applies to consignments intended for a Member State or compartment which is regarded as disease-free, or for which a programme is approved by Decision 2010/221/EU as regards OsHV-1 µvar, and the consignment comprises species listed in Part C of Annex II to Regulation (EC) No 1251/2008 as susceptible to OsHV-1 µvar.

The requirements set out in part II.7 shall not apply to consignments intended for a quarantine facility complying with the requirements at least equivalent to those laid down in Decision 2008/946/EC.

Official veterinarian or official inspector

Name (in capital letters): Qualification and title:

Local veterinary unit: LVU No:

Date: Signature:

Stamp:

PART B

Model animal health certificate for the placing on the market of aquaculture animals or products thereof intended for further processing, dispatch centres and purification centres and similar businesses before human consumption

EUROPEAN UNION **Intra trade certificate**

Part I: Details of consignment presented

I.1. Consignor Name Address Postal code		I.2. Certificate reference No	I.2.a. Local reference No
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code		I.6.	
		I.7.	
I.8. Country of origin ISO code	I.9.	I.10. Country of destination ISO code	I.11.
I.12. Place of origin Approved aquaculture holding ☐ Other ☐ Name Approval number Address Postal code		I.13. Place of destination Approved aquaculture holding ☐ Other ☐ Name Approval number Address Postal code	
I.14. Place of loading Postal code		I.15. Date and time of departure	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification		I.17. Transporter Name Approval number Address Postal code Member State	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24. Type of packaging	
I.25. Commodities certified for: Human consumption ☐			
I.26. Transit through third country ▭ Third country ISO code Exit point Code Entry point BIP No		I.27. Transit through Member States ▭ Member State ISO code Member State ISO code Member State ISO code	
I.28. Export ▭ Third country ISO code Exit point Code		I.29.	
I.30.			
I.31. Identification of the commodities Species (Scientific name) Quantity			

EUROPEAN UNION — **Placing on the market of aquaculture animals or products thereof for human consumption**

Part II: Certification

II.	Health information	II.a. Certificate reference No	II.b.

II.1 **General requirements**

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:

II.1.1 comply with the requirements for placing on the market laid down in Council Directive 2006/88/EC.

II.2 (1)(2)**[Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease**

I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to above:

II.2.1 (1)originate from a Member State, zone or compartment declared free from (1)[VHS] (1)[IHN] (1)[ISA] (1)[KHV] (1)[Marteilia refringens] (1)[Bonamia ostreae] (1)[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC.]

II.3 **Transport and labelling requirements**

I, the undersigned official inspector, hereby certify that:

II.3.1 the aquaculture animals or products thereof referred to above,

(i) are placed under conditions, including with a water quality, that do not alter their health status;

(ii) as appropriate, comply with the general conditions for the transport of animals laid down in Article 3 of Council Regulation (EC) No 1/2005;

II.3.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and

II.3.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.8 to I.13 of Part I of this certificate, and the following statement:

"(1)[Fish] (1)[Molluscs] (1)[Crustaceans] intended for (1)[further processing] (1)[dispatch centres or similar businesses] (1)[purification centres or similar businesses] before human consumption in the European Union".

II.4 (1)(3)**[Attestation for consignments originating from an area subject to disease control measures**

I, the undersigned official inspector, hereby certify that:

II.4.1 *either* (1)[the animals referred to above have been inspected within 24 hours of loading, and showed no clinical signs of disease],

or (1)[in the case of eggs and molluscs, come from a farm or mollusc farming area where, according to the records of the farm or mollusc farming area, there is no indication of disease problems];

II.4.2 the animals referred to above originate from an area subject to disease control measures regarding (1)[Epizootic ulcerative syndrome (EUS)] (1)[Epizootic haematopoietic necrosis (EHN)] (1)[Viral haemorrhagic septicaemia (VHS)] (1)[Infectious haematopoietic necrosis (IHN)] (1)[Infectious salmon anaemia (ISA)] (1)[Koi herpes virus (KHV)] (1)[Bonamia exitiosa] (1)[Perkinsus marinus] (1)[Mikrocytos mackini] (1)[Marteilia refringens] (1)[Bonamia ostreae] (1)[Taura syndrome] (1)[Yellowhead disease] (1)[White spot disease] (1)(4)[the following emerging disease: .....];

II.4.3 the animals referred to above are allowed to be placed on the market according to the control measures laid down; and

II.4.4 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship manifest, with the relevant information referred to in boxes I.8 to I.13 of Part I of this certificate, and the following statement:

"(1)[Fish] (1)[Molluscs] (1)[Crustaceans] originating from an area subject to disease control measures"]

II.5 (1)(5)**[Requirements for species susceptible to OsHV-1 µvar**

I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above,

either (1)[originate from a Member State or compartment:

(a) where OsHV-1 µvar is notifiable to the competent authority and reports of suspicion of infection of that disease must be immediately investigated by the competent authority,

EUROPEAN UNION

Placing on the market of aquaculture animals or products thereof for human consumption

II.	Health information	II.a. Certificate reference No	II.b.

(b) where all aquaculture animals of species susceptible to OsHV-1 µvar introduced into that Member State or compartment comply with the requirements set out in II.5 of this certificate,

(c) *either* [1][which comply with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC,]

and/or [1][in the case of consignments intended for a Member State or compartment covered by a programme is approved by Decision 2010/221/EU, which itself is also covered by a surveillance programme approved by Decision 2010/221/EU,]

or [1][have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]

Notes

Part I

— Box I.12 and I.13: If appropriate, use the authorisation number for the farm, mollusc farming area or establishment in question,

— Box I.19: Use the appropriate HS codes: 0301, 0302, 030270, 0303, 0306 or 0307,

— Box I.20 and I.31: As regards quantity, give the total number,

Part II

(1) Keep as appropriate.

(2) Part II.2 of this certificate applies to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC.

To be authorised into a Member State, zone or compartment declared free from VHS, IHN, ISA, KHV, Marteilia refringens, Bonamia ostreae, or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, this statement must be kept if the consignment contains species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies), unless the consignment is intended for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.

Data on the disease status of each farm and mollusc farming area in the European Union are accessible at http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm

(3) Part II.4 of this certificate applies to consignments of aquaculture animals and products thereof which according to Article 8 of Regulation (EC) No 1251/2008 must be accompanied by a certificate and which in compliance with the placing on the market requirements of Directive 2006/88/EC are allowed by the competent authority to leave an area subject to control provisions provided for in Sections 3 to 6 of Chapter V of Directive 2006/88/EC or a Member State, zone or compartment with an eradication programme approved in accordance with Article 44(2) of that Directive.

(4) Applicable when measures are taken in accordance with Article 41 of Directive 2006/88/EC.

(5) Part II.5 of this certificate only applies to consignments intended for dispatch centres, purification centres or similar businesses in Member States or compartments which are regarded as disease-free, or for which a programme is approved by Decision 2010/221/EU as regards OsHV-1 µvar, and the consignment comprises species listed in Part C of Annex II to Regulation (EC) No 1251/2008 as susceptible to OsHV-1 µvar.

The requirements set out in part II.5 shall not apply to consignments intended for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system validated by the competent authority that inactivates enveloped viruses or reduces the risk of transmitting diseases to the natural waters to an acceptable level.

Official veterinarian or official inspector

Name (in capital letters): Qualification and title:

Local veterinary unit: LVU No:

Date: Signature:

Stamp:

PART C

List of species susceptible to diseases for which national measures are approved under Decision 2010/221/EU

Disease	Susceptible species
Spring Viraemia of Carp (SVC)	Bighead carp (*Aristichthys nobilis*), goldfish (*Carassius auratus*), crucian carp (*Carassius carassius*), grass carp (*Ctenopharyngodon idellus*), common carp and koi carp (*Cyprinus carpio*), silver carp (*Hypophthalmichthys molitrix*), sheatfish (*Silurus glanis*), and tench (*Tinca tinca*), Orfe (*Leuciscus idus*)
Bacterial kidney disease (BKD)	Family: *Salmonidae*
Infectious pancreatic necrosis virus (IPN)	Rainbow trout (*Oncorhynchus mykiss*), brook torut (*Salvelinus fontinalis*), brown trout (*Salmo trutta*), Atlantic salmon (*Salmo salar*) and (*Oncorhynchus spp.*), whitefish (*Coregonus lavaretus*)
Infection with Gyrodactilys salaris	Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), Arctic char (*Salvelinus alpinus*), North American brook trout (*Salvelinus fontinalis*), grayling (*Thymallus thymallus*), North American lake trout (*Salvelinus namaycush*) and brown trout (*Salmo trutta*)
Ostreid herpesvirus 1 µvar (OsHV-1 µvar)	Pacific oyster (*Crassostrea gigas*)'

COMMISSION IMPLEMENTING REGULATION (EU) No 351/2011

of 11 April 2011

amending Regulation (EU) No 297/2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1], and in particular Article 53 (1) (b)(ii) thereof,

Whereas:

(1) Article 53 of Regulation (EC) No 178/2002 provides for the possibility to adopt appropriate Union emergency measures for food and feed imported from a third country in order to protect public health, animal health or the environment, where the risk cannot be contained satisfactorily by means of measures taken by the Member States individually.

(2) Following the accident at the Fukushima nuclear power station on 11 March 2011, the Commission was informed that radionuclide levels in certain food products originating in Japan such as milk and spinach exceeded the action levels in food applicable in Japan. Such contamination may constitute a threat to public and animal health within the Union and therefore Commission Implementing Regulation (EU) No 297/2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station [2] was adopted on 25 March 2011.

(3) Regulation (EU) No 297/2011 provides for the requirement for pre-export control by the competent authorities of Japan. Action levels for iodine, caesium and plutonium in food have been established by the competent authorities of Japan. The Commission was informed on 17 March 2011 of these action levels applicable in Japan but it was indicated that these action levels were adopted for the time being as provisional regulation values. The authorities from Japan also informed the Commission that products that are not allowed to be placed on the Japanese market, are also not allowed to be exported. It becomes now evident that these action levels will be applied in Japan for a longer term. It is therefore appropriate in order to provide consistency between the pre-export controls performed by the Japanese authorities and the controls on the level of radionuclides performed on feed and food originating in or consigned from Japan at the entry into the EU, to apply on a provisional basis the same maximum levels in the EU for radionuclides in feed and food from Japan as the action levels applicable in Japan as long as these are lower than the EU values.

(4) This Regulation is without prejudice to the scientifically established levels laid down in Council Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90 for application in case of a future nuclear accident or any other case of radiological emergency affecting the EU territory. This Regulation applies for isotopes of strontium the values established in Regulation (Euratom) No 3954/87, since there are no such values laid down in Japan.

(5) Given that for the time being, there is evidence that feed and food from certain regions from Japan is contaminated by the radionuclides iodine-131, caesium-134 and caesium 137 and that there is no indication that feed and food originating in or consigned from Japan is contaminated with other radionuclides, it is appropriate to restrict the obligatory controls to iodine-131, caesium-134 and caesium-137. Member States may also perform analysis on a voluntary basis for the presence of other radionuclides in view of gathering information on the possible presence of these other radionuclides. It is therefore appropriate to mention the existing maximum levels in EU legislation or action levels applied in Japan for the radionuclides strontium, plutonium and trans-plutonium elements in Annex II to this Regulation.

(6) It is therefore appropriate to amend Regulation (EU) 297/2011 accordingly.

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

[1] OJ L 31, 1.2.2002, p. 1.
[2] OJ L 80, 26.3.2011, p. 5.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 297/2011 is amended as follows

(1) Article 2 is amended as follows:

(a) In Paragraph 3, the third indent is replaced by the following:

'— in case the product is originating in or consigned from the prefectures Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Yamagata, Niigata, Nagano, Yamanashi, Saitama, Tokyo and Chiba, the product does not contain levels of the radionuclides iodine-131, caesium-134 and caesium-137 above the maximum levels provided for in Annex II to this Regulation. This provision applies also to products originating in the coastal waters of these prefectures, irrespective of where such products are landed.'

(b) Paragraph 4 is replaced by the following:

'4. The model of the declaration referred to in paragraph 3 is set out in the Annex I. The declaration shall be signed by an authorised representative of the Japanese competent authorities and shall for the products falling under paragraph 3, third indent be accompanied by an analytical report.'

(2) Article 7 is replaced by the following:

'*Article 7*

Non-compliant products

Feed and food originating in or consigned from Japan which do not comply with the maximum levels referred to in Annex II, shall not be placed on the market. Such non-compliant feed and food shall be safely disposed of or returned to the country of origin.'

(3) The Annex is replaced by the text in Annex I to this Regulation.

(4) A new Annex II, the text of which is set out in Annex II to this Regulation, is added.

Article 2

Entry into force

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

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

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Declaration for the import into the European Union of

..... (*)

Consignment Code ..... **Declaration Number** .....

According to the provisions of the Commission Implementing Regulation (EU) No 297/2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station the

.....

..... (competent authority referred to in Article 2(4))

DECLARES that the .....

..... (products referred to in Article 1)

of this consignment composed of: .....

.....

..... (description of consignment, product, number and type of packages, gross or net weight)

embarked at ..... (embarkation place)

on ..... (date of embarkation)

by ..... (identification of transporter)

going to ..... (place and country of destination)

which comes from the establishment .....

..... (name and address of establishment)

☐ has been harvested and/or processed before 11 March 2011

☐ is originating in or consigned from a prefecture other than Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Yamagata, Niigata, Nagano, Yamanashi, Saitama, Tokyo and Chiba

☐ is originating in or consigned from the prefectures Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Yamagata, Niigata, Nagano, Yamanashi, Saitama, Tokyo and Chiba and has been sampled on ..... (date), subjected to laboratory analysis on .....

(date) in the .....

(name of laboratory), to determine the level of the radionuclides, iodine-131, cesium-134 and caesium-137, and the analytical results are in compliance with the maximum levels referred to in Article 2 (3). The analytical report is attached.

Done at ..... on .....

Stamp and signature of
authorised representative of competent authority referred to in Article 2(4)

Part to be completed by the competent authority at the BIP or DPE

☐ The consignment has been accepted to be presented for release for free circulation by the custom authorities in the European Union

☐ The consignment has NOT been accepted to be presented for release for free circulation by the custom authorities in the European Union

.....

(Competent authority, Member State)

.....

Date Stamp Signature

(*) Product and country of origin.

ANNEX II

Maximum levels for foodstuffs [1] **(Bq/kg)**

	Foods for infants and young children	Milk and dairy products	Other foodstuffs, except liquid foodstuffs	Liquid foodstuffs
Sum of Isotopes of strontium, notably Sr-90	75	125	750	125
Sum of Isotopes of iodine, notably I-131	100 [1]	300 [2]	2 000	300 [2]
Sum of Alpha-emitting isotopes of plutonium and trans-plutonium elements, notably Pu-239, Am-241	1	1 [2]	10 [2]	1 [2]
Sum of all other nuclides of half-life greater than 10 days, notably Cs-134 and Cs-137, except C-14 and H-3	200 [2]	200 [2]	500 [2]	200 [2]

[1] In order to ensure consistency with action levels currently applied in Japan, these values replace on a provisional basis the values laid down in Council Regulation (Euratom) 3954/87.
[2] In order to ensure consistency with action levels currently applied in Japan, this value replaces on a provisional basis the value laid down in Commission Regulation (Euratom) No 770/90.

Maximum levels for feedingstuffs [2] **(Bq/kg)**

	Feedingstuffs
Sum of Cs-134 and Cs-137	500 [1]
Sum of Isotopes of iodine, notably I-131	2 000 [2]

[1] In order to ensure consistency with action levels currently applied in Japan, this value replaces on a provisional basis the value laid down in Commission Regulation (Euratom) No 770/90.
[2] This value is laid down on a provisional basis and taken to be the same as for foodstuffs, pending an assessment of transfer factors of iodine from feedingstuffs to food products.

[1] The level applicable to concentrated or dried products is calculated on the basis of the reconstituted product as ready for consumption.
[2] Maximum level is relative to a feed with a moisture content of 12 %.

COMMISSION IMPLEMENTING REGULATION (EU) No 352/2011

of 11 April 2011

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

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2], and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 12 April 2011.

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

Done at Brussels, 11 April 2011.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.

ANNEX

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

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	JO	68,6
	MA	44,0
	TN	106,6
	TR	88,7
	ZZ	77,0
0707 00 05	EG	152,2
	TR	116,5
	ZZ	134,4
0709 90 70	MA	80,0
	TR	85,5
	ZA	15,5
	ZZ	60,3
0805 10 20	EG	48,0
	IL	78,6
	MA	46,4
	TN	48,9
	TR	73,9
	ZZ	59,2
0805 50 10	TR	53,4
	ZZ	53,4
0808 10 80	AR	77,8
	BR	71,5
	CA	91,3
	CL	85,3
	CN	96,7
	MK	50,2
	NZ	123,1
	US	131,4
	UY	65,6
	ZA	84,4
	ZZ	87,7
0808 20 50	AR	89,4
	CL	108,4
	CN	73,5
	US	72,1
	ZA	103,4
	ZZ	89,4

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

COMMISSION IMPLEMENTING REGULATION (EU) No 353/2011

of 11 April 2011

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EU) No 867/2010 for the 2010/11 marketing year

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector ([2]), and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2010/11 marketing year are fixed by Commission Regulation (EU) No 867/2010 ([3]). These prices and duties have been last amended by Commission Regulation (EU) No 347/2011 ([4]).

(2) The data currently available to the Commission indicate that those amounts should be amended in accordance with the rules and procedures laid down in Regulation (EC) No 951/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EU) No 867/2010 for the 2010/11, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 12 April 2011.

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

Done at Brussels, 11 April 2011.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 178, 1.7.2006, p. 24.
([3]) OJ L 259, 1.10.2010, p. 3.
([4]) OJ L 96, 9.4.2011, p. 21.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 12 April 2011

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 11 10 (1)	47,82	0,00
1701 11 90 (1)	47,82	0,56
1701 12 10 (1)	47,82	0,00
1701 12 90 (1)	47,82	0,26
1701 91 00 (2)	48,51	2,92
1701 99 10 (2)	48,51	0,00
1701 99 90 (2)	48,51	0,00
1702 90 95 (3)	0,49	0,22

(1) For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.
(2) For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.
(3) Per 1 % sucrose content.

DIRECTIVES

COMMISSION IMPLEMENTING DIRECTIVE 2011/38/EU

of 11 April 2011

amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/98/EC of the European Parliament and the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [1], and in particular point (f) of the second paragraph of Article 29 thereof,

Whereas:

(1) Point 2.4 of Annex V to Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [2] sets minimum (6,4) and maximum (7,4) pH levels for units of platelets at the end of the shelf life. Therefore, platelet units that do not meet these minimum or maximum values have to be discarded.

(2) Recent scientific evidence and field practice experience has demonstrated that values higher than pH 7,4 do not affect the quality and safety of stored platelets, contrary to pH levels below 6,4 that systematically result in damaging the platelets, and that a maximum pH value for platelet concentrates is thus not necessary.

(3) Discarding platelets that exceed the maximum pH value as set out in Annex V to Directive 2004/33/EC leads to considerable losses. These losses may increase in the future due to new collection methods and storage bags, which both generate higher pH values at the end of the shelf life.

(4) Therefore the maximum (7,4) pH value for all platelet concentrates listed in Annex V to Directive 2004/33/EC should be removed.

(5) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 28 of Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex V to Directive 2004/33/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2011 at the latest. 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 91, 30.3.2004, p. 25.

ANNEX

In point 2.4 of Annex V to Directive 2004/33/EC, for the entries:

— 'Platelets, apheresis',

— 'Platelets, aphaeresis, leucocyte-depleted',

— 'Platelets, recovered, pooled',

— 'Platelets, recovered, pooled, leucocyte-depleted',

— 'Platelets, recovered, single unit', and

— 'Platelets, recovered, single unit, leucocyte-depleted',

the acceptable results for quality measurements for pH are replaced by the following:

'Minimum 6,4 corrected for 22 °C, at the end of the shelf life'.

COMMISSION IMPLEMENTING DIRECTIVE 2011/39/EU

of 11 April 2011

amending Council Directive 91/414/EEC to include fenazaquin as active substance and amending Commission Decision 2008/934/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 Regulations (EC) No 451/2000 ([2]) and (EC) No 1490/2002 ([3]) lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish 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 included fenazaquin.

(2) In accordance with Article 11e of Regulation (EC) No 1490/2002 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances ([4]) was adopted on the non-inclusion of fenazaquin.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ([5]).

(4) The application was submitted to Greece, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) Greece evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 28 January 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on fenazaquin to the Commission on 28 October 2010 ([6]). The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 March 2011 in the format of the Commission review report for fenazaquin.

(6) It has appeared from the various examinations made that plant protection products containing fenazaquin may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include fenazaquin in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(7) 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.

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 55, 29.2.2000, p. 25.
([3]) OJ L 224, 21.8.2002, p. 23.
([4]) OJ L 333, 11.12.2008, p. 11.
([5]) OJ L 15, 18.1.2008, p. 5.

([6]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fenazaquin. EFSA Journal 2010; 8(11):1892. [74 pp.]. doi:10.2903/j.efsa.2010.1892. Available online: www.efsa.europa.eu

(8) 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 6 months after inclusion to review existing authorisations of plant protection products containing fenazaquin 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.

(9) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I.

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

(11) Decision 2008/934/EC provides for the non-inclusion of fenazaquin and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning fenazaquin in the Annex to that Decision.

(12) It is therefore appropriate to amend Decision 2008/934/EC accordingly.

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

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

The line concerning fenazaquin in the Annex to Decision 2008/934/EC is deleted.

Article 3

Member States shall adopt and publish by 30 November 2011 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 December 2011.

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 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing fenazaquin as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to fenazaquin 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 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing fenazaquin as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2011 at the latest, 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 fenazaquin. 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.

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

Following that determination Member States shall:

(a) in the case of a product containing fenazaquin as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or

(b) in the case of a product containing fenazaquin as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 5

This Directive shall enter into force on 1 June 2011.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry 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
'345	Fenazaquin CAS No: 120928-09-8 CIPAC No: 693	4-tert-butylphenethyl quinazolin-4-yl ether	≥ 975 g/kg	1 June 2011	31 May 2021	PART A Only uses as acaricide on ornamentals in greenhouses may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenazaquin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: (1) pay particular attention to the protection of aquatic organisms; (2) pay particular attention to the risk to operators and ensure that conditions of use include the application of adequate personal protective equipment; (3) pay particular attention to the protection of bees and ensure that conditions of use include risk mitigation measures, where appropriate; (4) provide for conditions of use which ensure that there are no residues of fenazaquin in crops for human and animal consumption.'

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

COMMISSION IMPLEMENTING DIRECTIVE 2011/40/EU

of 11 April 2011

amending Council Directive 91/414/EEC to include sintofen as active substance and amending Commission Decision 2008/934/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 Regulations (EC) No 451/2000 [2] and (EC) No 1490/2002 [3] lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish 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 included sintofen.

(2) In accordance with Article 11e of Regulation (EC) No 1490/2002 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances [4] was adopted on the non-inclusion of sintofen.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I [5].

(4) The application was submitted to France, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) France evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 14 January 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on sintofen to the Commission on 26 November 2010 [6]. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 March 2011 in the format of the Commission review report for sintofen.

(6) It has appeared from the various examinations made that plant protection products containing sintofen may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include sintofen in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(7) Without prejudice to that conclusion, 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 the applicant submit further information confirming: the specification of the technical material, the relevance of the impurities present in the technical specifications, the relevance of the test material used in the toxicity and ecotoxicity dossiers and the metabolic profile of sintofen in rotational crops.

(8) 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.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 55, 29.2.2000, p. 25.
[3] OJ L 224, 21.8.2002, p. 23.
[4] OJ L 333, 11.12.2008, p. 11.
[5] OJ L 15, 18.1.2008, p. 5.

[6] European Food Safety Authority: Conclusion on the peer review of the pesticide risk assessment of the active substance sintofen. EFSA Journal 2010;8(12): [49 pp.]. doi:10.2903/j.efsa.2010.1931. Available online: www.efsa.europa.eu/efsajournal.htm

(9) 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 6 months after inclusion to review existing authorisations of plant protection products containing sintofen 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.

(10) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I.

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

(12) Decision 2008/934/EC provides for the non-inclusion of sintofen and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning sintofen in the Annex to that Decision.

(13) It is therefore appropriate to amend Decision 2008/934/EC accordingly.

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

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

The line concerning sintofen in the Annex to Decision 2008/934/EC is deleted.

Article 3

Member States shall adopt and publish by 30 November 2011 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 December 2011.

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 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing sintofen as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to sintofen 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 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing sintofen as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2011 at the latest, 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 sintofen. 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:

(a) in the case of a product containing sintofen as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or

(b) in the case of a product containing sintofen as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

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

Article 5

This Directive shall enter into force on 1 June 2011.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry 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
'347	Sintofen CAS No 130561-48-7 CIPAC No 717	*1-(4-chlorophenyl)-1,4-dihydro-5-(2-methoxyethoxy)-4-oxocinnoline-3-carboxylic acid*	≥ 980 g/kg Impurities: 2-methoxyethanol, not more than 0,25 g/kg N,N-dimethylformamide, not more than 1,5 g/kg	1 June 2011	31 May 2021	PART A Only uses as a plant growth regulator on wheat for hybrid seed production not intended for human consumption may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sintofen, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate risk mitigation measures. They shall ensure that wheat treated with sintofen does not enter the food and feed chain. The Member States concerned shall request the submission of confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data; (2) the relevance of the impurities present in the technical specifications, except of the impurities 2-methoxyethanol and N,N-dimethylformamide; (3) the relevance of the test material used in the toxicity and ecotoxicity dossiers in view of the specification of the technical material; (4) the metabolic profile of sintofen in rotational crops. The Member States concerned shall ensure that the applicant submits to the Commission: the information set out in points (1) (2) and (3) by 1 December 2011 and the information set out in point (4) by 31 May 2013.'

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

COMMISSION IMPLEMENTING DIRECTIVE 2011/41/EU

of 11 April 2011

amending Council Directive 91/414/EEC to include dithianon as active substance and amending Commission Decision 2008/934/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 Regulations (EC) No 451/2000 [2] and (EC) No 1490/2002 [3] lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish 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 included dithianon.

(2) In accordance with Article 11e of Regulation (EC) No 1490/2002 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances [4] was adopted on the non-inclusion of dithianon.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I [5].

(4) The application was submitted to Greece, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) Greece evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 27 January 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on dithianon to the Commission on 15 November 2010 [6]. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 March 2011 in the format of the Commission review report for dithianon.

(6) It has appeared from the various examinations made that plant protection products containing dithianon may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include dithianon in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(7) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that the applicant submit information confirming the storage stability and the nature of residues in processed products, the aquatic and groundwater exposure assessment for phthalic acid and the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 55, 29.2.2000, p. 25.
[3] OJ L 224, 21.8.2002, p. 23.
[4] OJ L 333, 11.12.2008, p. 11.
[5] OJ L 15, 18.1.2008, p. 5.

[6] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon. EFSA Journal 2010; 8(11):1904. [121 pp.]. doi:10.2903/j.efsa.2010.1904. Available online: www.efsa.europa.eu

(8) 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.

(9) 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 6 months after inclusion to review existing authorisations of plant protection products containing dithianon 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.

(10) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties, it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I.

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

(12) Decision 2008/934/EC provides for the non-inclusion of dithianon and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning dithianon in the Annex to that Decision.

(13) It is therefore appropriate to amend Decision 2008/934/EC accordingly.

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

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

The line concerning dithianon in the Annex to Decision 2008/934/EC is deleted.

Article 3

Member States shall adopt and publish by 30 November 2011 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 December 2011.

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 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing dithianon as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to dithianon 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 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing dithianon as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2011 at the latest, 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 dithianon. 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.

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

Following that determination Member States shall:

(a) in the case of a product containing dithianon as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or

(b) in the case of a product containing dithianon as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 5

This Directive shall enter into force on 1 June 2011.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry 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
'344	Dithianon CAS No: 3347-22-6 CIPAC No: 153	5,10-dihydro-5,10-dioxonaphtho[2,3-*b*]-1,4-dithiine-2,3-dicarbonitrile	≥ 930 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dithianon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: (a) pay particular attention to the protection of aquatic organisms; conditions of use shall include risk mitigation measures, where appropriate; (b) pay particular attention to the operator safety; conditions of use shall include the application of adequate personal protective equipment, where appropriate; (c) pay particular attention to the long-term risks to birds; conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the storage stability and the nature of residues in processed products; (b) the aquatic and groundwater exposure assessment for phthalic acid; (c) the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013.'

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

COMMISSION IMPLEMENTING DIRECTIVE 2011/42/EU

of 11 April 2011

amending Council Directive 91/414/EEC to include flutriafol as active substance and amending Commission Decision 2008/934/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 Regulations (EC) No 451/2000 [2] and (EC) No 1490/2002 [3] lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish 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 included flutriafol.

(2) In accordance with Article 11e of Regulation (EC) No 1490/2002 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances [4] was adopted on the non-inclusion of flutriafol.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I [5].

(4) The application was submitted to the United Kingdom, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) The United Kingdom evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 15 January 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on flutriafol to the Commission on 14 October 2010 [6]. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 March 2011 in the format of the Commission review report for flutriafol.

(6) It has appeared from the various examinations made that plant protection products containing flutriafol may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include flutriafol in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(7) Without prejudice to that conclusion, 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 the applicant submit further information confirming the relevance of the impurities present in the technical specifications, the assessment as regards the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin, and the long-term risk to insectivorous birds.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 55, 29.2.2000, p. 25.
[3] OJ L 224, 21.8.2002, p. 23.
[4] OJ L 333, 11.12.2008, p. 11.
[5] OJ L 15, 18.1.2008, p. 5.

[6] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance flutriafol. EFSA Journal 2010;8(10):1868. [50 pp.] doi:10.2903/j.efsa.2010.1868. Available online: www.efsa.europa.eu/efsajournal.htm

(8) 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.

(9) 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 6 months after inclusion to review existing authorisations of plant protection products containing flutriafol 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.

(10) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.

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

(12) Decision 2008/934/EC provides for the non-inclusion of flutriafol and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning flutriafol in the Annex to that Decision.

(13) It is therefore appropriate to amend Decision 2008/934/EC accordingly.

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

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

The line concerning flutriafol in the Annex to Decision 2008/934/EC is deleted.

Article 3

Member States shall adopt and publish by 30 November 2011 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 December 2011.

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 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing flutriafol as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to flutriafol 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 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing flutriafol as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2011 at the latest, 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 flutriafol. 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.

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

Following that determination Member States shall:

(a) in the case of a product containing flutriafol as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or

(b) in the case of a product containing flutriafol as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 5

This Directive shall enter into force on 1 June 2011.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 11 April 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry 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
'346	Flutriafol CAS No: *76674-21-0* CIPAC No: 436	*(RS)-2,4′-difluoro-α-(1H-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol*	≥ 920 g/kg (racemate) Relevant impurities: dimethyl sulphate: max content 0,1 g/kg dimethylformamide: max content 1 g/kg methanol: max content 1 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on flutriafol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, shall be taken into account. In this overall assessment Member States shall: (1) pay particular attention to the protection of the workers' safety and ensure that conditions of use include the application of adequate personal protective equipment; (2) pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) pay particular attention to the long-term risk to insectivorous birds. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards: (a) the relevance of the impurities present in the technical specifications; (b) the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; (c) the long-term risk to insectivorous birds. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 1 December 2011, the information set out in points (b) and (c) by 31 May 2013.'

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

DECISIONS

COUNCIL IMPLEMENTING DECISION 2011/230/CFSP

of 8 April 2011

implementing Decision 2010/656/CFSP renewing the restrictive measures against Côte d'Ivoire

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Council Decision 2010/656/CFSP of 29 October 2010 renewing the restrictive measures against Côte d'Ivoire [1], and in particular Article 6(2) thereof, in conjunction with Article 31(2) of the Treaty on European Union,

Whereas:

(1) On 29 October 2010, the Council adopted Decision 2010/656/CFSP.

(2) In view of the developments in Côte d'Ivoire, the list of persons and entities subject to restrictive measures set out in Annex II to Decision 2010/656/CFSP should be amended,

HAS ADOPTED THIS DECISION:

Article 1

The entities listed in the Annex to this Decision shall be deleted from the list set out in Annex II to Decision 2010/656/CFSP.

Article 2

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

Done at Brussels, 8 April 2011.

For the Council
The President
MARTONYI J.

[1] OJ L 285, 30.10.2010, p. 28.

ANNEX

ENTITIES REFERRED TO IN ARTICLE 1

1.	SIR (Ivorian Refining Company)
2.	Autonomous Port of Abidjan
3.	Autonomous Port of San Pedro
4.	CGFCC (Coffee and Cocoa Trade Management Committee)

COMMISSION DECISION

of 11 April 2011

granting derogations to certain Member States with respect to the transmission of statistics pursuant to Regulation (EC) No 1338/2008 of the European Parliament and of the Council on Community statistics on public health and health and safety at work, as regards statistics on accidents at work

(notified under document C(2011) 2403)

(Only the German, Greek, English, French, Latvian and Dutch texts are authentic)

(2011/231/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work [1], and in particular Article 9(2) thereof,

Having regard to the requests made by the Kingdom of Belgium, the Federal Republic of Germany, Ireland, the Hellenic Republic, the French Republic, the Republic of Latvia, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland,

Whereas:

(1) In accordance with Article 2 of Regulation (EC) No 1338/2008, it applies to the production of statistics on accidents at work as defined in Annex IV.

(2) Article 9(2) of Regulation (EC) No 1338/2008 provides, if necessary, for derogations and transition periods for Member States, both to be based upon objective grounds.

(3) It emerges from the information provided to the Commission that the requests for derogations made by Belgium, Germany, Ireland, Greece, France, Latvia, the Netherlands and the United Kingdom result from the need for major adaptations to national administrative and statistical systems in order to comply in full with Regulation (EC) No 1338/2008.

(4) Such derogations should therefore be granted as requested to those Member States.

(5) The measures provided for in this Decision are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS DECISION:

Article 1

Derogations as set out in the Annex are granted to the Member States listed therein.

Article 2

This Decision is addressed to the Kingdom of Belgium, the Federal Republic of Germany, Ireland, the Hellenic Republic, the French Republic, the Republic of Latvia, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 11 April 2011.

For the Commission

Olli REHN

Member of the Commission

[1] OJ L 354, 31.12.2008, p. 70.

ANNEX

Derogations from Regulation (EC) No 1338/2008, as implemented by the Commission, concerning statistics on accidents at work

Member State	Derogation	End of derogation
Belgium	First delivery of data on accidents at work for employees of the public sector (NACE O): 2016 (data in respect of 2014).	30 June 2016
	First delivery of the variable ISCO-08: 2014 (data in respect of 2012).	30 June 2014
Germany	First delivery of variables 'days lost', ISCO-08 and NACE Rev.2 on 4-digit level: 2016 (data in respect of 2014).	30 June 2016
	First delivery of data on accidents at work for civil servants: 2016 (data in respect of 2014).	30 June 2016
Ireland	First delivery of data on road traffic accidents (increased level of road traffic accident data): 2016 (data in respect of 2014).	30 June 2016
Greece	First delivery of variables 'days lost', 'type of injury' and phase III variables on causes and circumstances: 2016 (data in respect of 2014).	30 June 2016
	First delivery of data for the employees of the public sector (NACE O) and for employees of the branches of the NACE Rev.2 which are not insured by the Social Insurance Foundation (IKA): 2016 (data in respect of 2014).	30 June 2016
France	First delivery of phase III variables on causes and circumstances: 2016 (data in respect of 2014).	30 June 2016
	Full coverage of all employees in the NACE Rev.2 sectors A-S: 2016 (for data in respect of 2014).	30 June 2016
Latvia	First delivery of variables 'days lost', 'economic activity of the employer' with the detailed 4-digit code of NACE Rev.2 and the geographical location according to NUTS: 2014 (data in respect of 2012).	30 June 2014
Netherlands	First delivery of variables 'occupation', 'type of injury', 'part of body injured', 'date of the accident', 'days lost' and phase III variables on causes and circumstances: 2016 (data in respect of 2014).	30 June 2016
United Kingdom	First delivery of variable 'days lost': 2015 (data in respect of 2013).	30 June 2015
	First delivery of data on road traffic accidents: 2015 (data in respect of 2013).	30 June 2015
	First delivery of data on accidents involving aircrew and sailors: 2016 (data in respect of 2014).	30 June 2016

COMMISSION DECISION

of 11 April 2011

amending Decision 2000/367/EC establishing a classification system for resistance-to-fire performance for construction products, construction works and parts thereof

(notified under document C(2011) 2417)

(Text with EEA relevance)

(2011/232/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products [1], and in particular Article 20(2) thereof,

After consulting the Standing Committee on Construction,

Whereas:

(1) Commission Decision 2000/367/EC of 3 May 2000 implementing Council Directive 89/106/EEC as regards the classification of the resistance to fire performance of construction products, construction works and parts thereof [2] should be amended to take into account technical progress in the development of the relevant test methods and in order to include cavity barriers.

(2) Decision 2000/367/EC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2000/367/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 11 April 2011.

For the Commission
Antonio TAJANI
Vice-President

[1] OJ L 40, 11.2.1989, p. 12.
[2] OJ L 133, 6.6.2000, p. 26.

ANNEX

The Annex to Decision 2000/367/EC is amended as follows:

(1) in Section 3 'Products and systems for protecting load-bearing elements or parts of works', the classification table that relates to 'ceilings with no independent fire resistance' is replaced by the following table:

'Applies to	ceilings with no independent fire resistance
Standard(s)	EN 13501-2; prEN 13381-1
Classification: expressed in the same terms as the load-bearing element being protected	
Notes	If also fulfilling the requirement with regard to the "semi-natural" fire, the symbol "sn" is added to the classification.'

(2) in Section 3 'Products and systems for protecting load-bearing elements or parts of works', the classification table that relates to 'fire protective coatings, boards, renderings, claddings and screens' is replaced by the following table:

'Applies to	fire protective coatings, boards, renderings, claddings and screens
Standard(s)	EN 13501-2; prEN 13381-2 to 8
Classification: expressed in the same terms as the load-bearing element being protected	
Notes	—'

(3) in Section 4 'Non-load bearing elements or parts of works and products therefor', the classification table that relates to 'partitions (including those incorporating uninsulated portions)' is replaced by the following table:

'Applies to	partitions (including partitions incorporating uninsulated portions, and cavity barriers)									
Standard(s)	EN13501-2; EN 1364-1 (*); EN 1992-1-2; EN 1993-1-2; EN 1994-1-2; EN 1995-1-2; EN 1996-1-2; EN 1999-1-2									
Classification: -										
E		20	30		60	90	120			
EI	15	20	30	45	60	90	120	180	240	
EI-M			30		60	90	120	180	240	
EW		20	30		60	90	120			
Notes	—									
(*) For cavity barriers this standard is complemented by EOTA TR 031.'										

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