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Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

2010/631/EU:

- ★ **Council Decision of 13 September 2010 concerning the conclusion, on behalf of the European Union, of the Protocol on Integrated Coastal Zone Management in the Mediterranean to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean** 1

REGULATIONS

- ★ **Commission Regulation (EU) No 955/2010 of 22 October 2010 amending Regulation (EC) No 798/2008 as regards the use of vaccines against Newcastle disease ⁽¹⁾** 3
- ★ **Commission Regulation (EU) No 956/2010 of 22 October 2010 amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the list of rapid tests ⁽¹⁾** 10
- ★ **Commission Regulation (EU) No 957/2010 of 22 October 2010 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health ⁽¹⁾** 13

Price: EUR 4

(Continued overleaf)

⁽¹⁾ Text with EEA relevance

EN

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

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

- ★ **Commission Regulation (EU) No 958/2010 of 22 October 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health ⁽¹⁾** 18

Commission Regulation (EU) No 959/2010 of 22 October 2010 establishing the standard import values for determining the entry price of certain fruit and vegetables 20

DIRECTIVES

- ★ **Commission Directive 2010/69/EU of 22 October 2010 amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners ⁽¹⁾** 22

DECISIONS

2010/632/EU:

- ★ **Council Decision of 15 October 2010 appointing one Romanian member of the European Economic and Social Committee for the period from 21 September 2010 to 20 September 2015** 32

2010/633/EU:

- ★ **Commission Decision of 22 October 2010 amending Decision 93/152/EEC laying down the criteria for vaccines to be used against Newcastle disease in the context of routine vaccination programmes (notified under document C(2010) 7109) ⁽¹⁾** 33

2010/634/EU:

- ★ **Commission Decision of 22 October 2010 adjusting the Union-wide quantity of allowances to be issued under the Union Scheme for 2013 and repealing Decision 2010/384/EU (notified under document C(2010) 7180)** 34

RECOMMENDATIONS

2010/635/Euratom:

- ★ **Commission Recommendation of 11 October 2010 on the application of Article 37 of the Euratom Treaty** 36



⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 13 September 2010

concerning the conclusion, on behalf of the European Union, of the Protocol on Integrated Coastal Zone Management in the Mediterranean to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean

(2010/631/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1), in conjunction with Article 218(6)(a), thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) The Convention for the Protection of the Mediterranean Sea against Pollution, which was subsequently renamed as the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (hereinafter referred to as 'the Barcelona Convention') was concluded on behalf of the European Community by the Council in Decisions 77/585/EEC ⁽¹⁾ and 1999/802/EC ⁽²⁾.

(2) In accordance with Article 4.3(e) of the Barcelona Convention, the Contracting Parties shall commit themselves to promote the integrated management of the coastal zones, taking into account the protection of areas of ecological and landscape interest and the rational use of natural resources.

(3) The Recommendation of the European Parliament and of the Council of 30 May 2002, concerning the implementation of Integrated Coastal Zone Management in

Europe ⁽³⁾, and in particular Chapter V thereof, encourages the implementation by the Member States of integrated coastal zone management in the context of existing conventions with neighbouring countries, including non-Member States, in the same regional sea.

(4) The European Union promotes integrated management on a larger scale by means of horizontal instruments, including in the field of environmental protection, and by developing a sound scientific base for it, through its research programmes. These activities therefore contribute to integrated coastal zone management.

(5) Integrated Coastal Zone Management is one component of the EU Integrated Maritime Policy as endorsed by the European Council held in Lisbon on 13 and 14 December 2007 and as also detailed in the Commission Communication 'Towards an Integrated Maritime Policy for better governance in the Mediterranean' and later welcomed by the General Affairs Council in its conclusions on Integrated Maritime Policy of 16 November 2009.

(6) By Decision 2009/89/EC of 4 December 2008 ⁽⁴⁾, the Council signed the Protocol on Integrated Coastal Zone Management in the Mediterranean to the Barcelona Convention (hereinafter referred to as 'the ICZM Protocol') on behalf of the Community, subject to the subsequent conclusion of the ICZM Protocol at a later date.

(7) Following the entry into force of the Treaty of Lisbon on 1 December 2009, the European Union notified the Government of Spain as regards the European Union having replaced and succeeded the European Community.

⁽¹⁾ OJ L 240, 19.9.1977, p. 1.

⁽²⁾ OJ L 322, 14.12.1999, p. 32.

⁽³⁾ OJ L 148, 6.6.2002, p. 24.

⁽⁴⁾ OJ L 34, 4.2.2009, p. 17.

- (8) The Mediterranean coastal zones continue to experience severe environmental pressure and degradation of coastal resources. The ICZM Protocol provides a framework to stimulate a more concerted and integrated approach, involving public and private stakeholders including civil society and economic operators. Such an inclusive approach, based on best available scientific observation and knowledge, is required to address these problems more effectively and achieve a more sustainable development of the Mediterranean coastal zones.
- (9) The ICZM Protocol covers a broad range of provisions which will need to be implemented by different levels of administration, having regard to the principles of subsidiarity and proportionality. While it is appropriate for the Union to act in support of integrated coastal zone management, bearing in mind, inter alia, the cross-border nature of most environmental problems, the Member States and their relevant competent authorities will be responsible for the design and implementation on the coastal territory of certain detailed measures laid down in the ICZM Protocol, such as the establishment of zones where construction is not allowed.
- (10) The ICZM Protocol should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Protocol on Integrated Coastal Zone Management in the Mediterranean to the Convention for the Protection of the

Marine Environment and the Coastal Region of the Mediterranean (hereinafter referred to as 'the ICZM Protocol') is hereby approved on behalf of the European Union ⁽¹⁾.

Article 2

The President of the Council shall designate the person(s) empowered to proceed, on behalf of the Union, to the deposit of the instrument of approval, with the Government of Spain which assumes the function of Depositary, provided for in Article 37 of the ICZM Protocol, in order to express the consent of the Union to be bound by the ICZM Protocol.

Article 3

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

The date of entry into force of the ICZM Protocol shall be published in the *Official Journal of the European Union*.

Done at Brussels, 13 September 2010.

For the Council

The President

S. VANACKERE

⁽¹⁾ The ICZM Protocol was published in OJ L 34, 4.2.2009, p. 19, together with the Decision on signature.

REGULATIONS

COMMISSION REGULATION (EU) No 955/2010

of 22 October 2010

amending Regulation (EC) No 798/2008 as regards the use of vaccines against Newcastle disease

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Animal Health (the OIE Manual) sets out requirements for vaccines against Newcastle disease including safety controls at different stages of the manufacturing process.

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

Having regard to Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs⁽¹⁾, and in particular Article 25(1)(b) and Article 26(2) thereof,

- (4) In the interests of safeguarding the health status of poultry in the Union and in order to facilitate trade in poultry and poultry meat, it is appropriate that the requirements for Newcastle disease vaccines and their use in third countries from where poultry and poultry meat may be imported, take into account the requirements for such vaccines set out in the OIE Manual.

Whereas:

- (1) Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements⁽²⁾ lays down veterinary certification requirements for those commodities. Those requirements take into account whether or not additional guarantees or specific conditions are required due to the Newcastle disease status of those third countries, territories, zones or compartments.
- (2) Regulation (EC) No 798/2008 also lays down conditions for determining whether or not a third country, territory, zone or compartment is to be considered as free from Newcastle disease. One such criterion is that no vaccination against that disease is carried out using vaccines that do not comply with the criteria for recognised Newcastle disease vaccines set out in Part I of Annex VI to that Regulation. Point 2 of Part II of that Annex sets out specific criteria for Newcastle disease vaccines including for inactivated vaccines.
- (3) The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for

- (5) For that purpose, the general criteria for recognised Newcastle disease vaccines set out in Part I of Annex VI to Regulation (EC) No 798/2008 should refer to the requirements of the OIE Manual, which should be kept as a dynamic reference to take into account the regular updates to that Manual in the light of new scientific developments.
- (6) In addition, in view of technical progress that has been made in relation to the production of Newcastle disease vaccines, in particular as regards inactivation techniques, as well as the requirements laid down in the OIE Manual, the specific criteria for inactivated Newcastle disease vaccines set out in point 2 of Part II of Annex VI to Regulation (EC) No 798/2008 should be deleted.
- (7) It is necessary to amend certain provisions for meat of poultry set out in Annex VII to Regulation (EC) No 798/2008 and the corresponding model veterinary certificate for meat of poultry (POU) set out in Annex I, in order to take account of the amendments to Annex VI to that Regulation.

- (8) Regulation (EC) No 798/2008 should therefore be amended accordingly.

⁽¹⁾ OJ L 343, 22.12.2009, p. 74.

⁽²⁾ OJ L 226, 23.8.2008, p. 1.

- (9) It is appropriate to lay down a date of application of this Regulation, in order to align it with the date of application of Commission Decision 93/152/EEC ⁽¹⁾, as amended by Decision 2010/633/EU ⁽²⁾, which introduces corresponding amendments for the criteria for inactivated vaccines against Newcastle disease.

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, VI and VII to Regulation (EC) No 798/2008 are amended in accordance with the Annex to this Regulation.

Article 2

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

- (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,

It shall apply from 1 December 2010.

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

Done at Brussels, 22 October 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 59, 12.3.1993, p. 35.

⁽²⁾ See page 33 of this Official Journal.

ANNEX

Annexes I, VI and VII to Regulation (EC) No 798/2008 are amended as follows:

- (a) in Part 2 of Annex I the model veterinary certificate for meat of poultry (POU) is replaced by the following:

Model veterinary certificate for meat of poultry (POU)**COUNTRY:****Veterinary certificate to EU**

Part I: Details of dispatched consignment	I.1. Consignor Name Address Tel.				I.2. Certificate reference No		I.2.a.	
					I.3. Central competent authority			
					I.4. Local competent authority			
	I.5. Consignee Name Address Postal code Tel.				I.6.			
	I.7. Country of origin		ISO code		I.8. Region of origin		Code	
					I.9. Country of destination		ISO code	
							I.10.	
	I.11. Place of origin Name Address Approval number				I.12.			
	I.13. Place of loading				I.14. Date of departure			
	I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references				I.16. Entry BIP in EU			
				I.17.				
I.18. Description of commodity						I.19. Commodity code (HS code)		
						I.20. Quantity		
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐						I.22. Number of packages		
I.23. Seal/Container No						I.24. Type of packaging		
I.25. Commodities certified for: Human consumption ☐								
I.26.						I.27. For import or admission into EU ☐		
I.28. Identification of the commodities Approval number of establishments Species (scientific name) Nature of commodity Treatment type Abattoir Cutting plant Cold store Number of packages Net weight								

COUNTRY		POU (meat of poultry)	
II.	Health information	II.a. Certificate reference number	II.b.
Part II: Certification	II.1.	Public Health Attestation I, the undersigned official veterinarian, declare that I am aware of the relevant provisions of Regulations (EC) Nos 178/2002, 852/2004, 853/2004 and 854/2004 and hereby certify that the meat of poultry ⁽¹⁾ described in this certificate has been obtained in accordance with those requirements, and in particular that: (a) it comes from (an) establishments(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004; (b) it has been produced in compliance with the conditions set out in Sections II and V of Annex III to Regulation (EC) No 853/2004; (c) it has been found fit for human consumption following ante and post-mortem inspections carried out in accordance with Section IV, Chapter V of Annex I to Regulation (EC) No 854/2004; (d) it has been marked with an identification mark in accordance with Section I of Annex II to Regulation (EC) No 853/2004; (e) it satisfies the relevant criteria set out in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs; (f) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled; (2) [(g) it fulfils the requirements of Regulation (EC) No 1688/2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning <i>Salmonella</i> for consignments to Finland and Sweden of certain meat and eggs.]	
	II.2.	Animal health attestation I, the undersigned official veterinarian, hereby certify that the meat of poultry described in this certificate:	
	II.2.1.	comes from:	
	(3) (4) (6) either	[the territory of code;]	
	(4) (5) or	[compartment(s);]	
		which at the date of issue of the certificate was (were) free from:	
		highly pathogenic avian influenza as defined in Regulation (EC) No 798/2008, and Newcastle disease as defined in Regulation (EC) No 798/2008;	
	II.2.2.	has been obtained from poultry which:	
	(4) either	[has not been vaccinated against avian influenza;]	
	(4) or	[has been vaccinated against avian influenza in accordance with vaccination plan under Regulation (EC) No 798/2008 using: (name and type of used vaccine(s)) at the age of weeks;]	
II.2.3.	has been obtained from poultry which has been kept in:		
(3) (4) (6) either	[the territory(ies) of code;]		
(4) (5) (6) or	[compartment(s);]		
	since hatching or has been imported as day-old chicks or slaughter poultry from (a) third country(ies) listed for that commodity in Part 1 of Annex I to Regulation (EC) No 798/2008 under conditions at least equivalent to those in that Regulation;		
II.2.4.	has been obtained from poultry coming from establishments:		
	(a) which are not subject to any animal health restriction;		
	(b) within a 10 km radius of which, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or Newcastle disease for at least the previous 30 days;		
II.2.5.	has been obtained from poultry that:		

COUNTRY

POU (meat of poultry)

II.	Health information	II.a. Certificate reference number	II.b.
	(⁷) (a) has been slaughtered on (dd/mm/yyyy) or between (dd/mm/yyyy) and (dd/mm/yyyy); (b) has not been slaughtered under any animal-health scheme for the control or eradication of poultry diseases; (c) during transport to the slaughterhouse, did not come into contact with poultry infected with highly pathogenic avian influenza or Newcastle disease;		
II.2.6.	(a) comes from approved slaughterhouses which, at the time of slaughter, were not under restrictions owing to a suspected or confirmed outbreak of highly pathogenic avian influenza or Newcastle disease and within a 10 km radius of which there has been no outbreak of highly pathogenic avian influenza or Newcastle disease for at least the previous 30 days; (b) has not been in contact at any time during slaughter, cutting, storage or transport with poultry or meat of lower health status;		
(⁶) II.2.7.	comes from slaughter poultry that: (a) has not been vaccinated with live attenuated vaccines prepared from a Newcastle disease virus master seed showing a higher pathogenicity than lentogenic strains of the virus; (b) underwent a virus isolation test for Newcastle disease, carried out in an official laboratory at the time of slaughter on a random sample of cloacal swabs from at least 60 birds in each flock concerned and in which no avian paramyxoviruses with an Intracerebral Pathogenicity Index (ICPI) of more than 0,4 were found; (c) has not been in contact in 30 days preceding slaughter with poultry that does not fulfil the conditions in (a) and (b).]		
II.3.	Animal welfare attestation I, the undersigned official veterinarian, hereby certify that I have read and understood Directive 93/119/EC and that the meat described in this certificate comes from poultry that has been treated in accordance with the relevant provisions of Directive 93/119/EC in the slaughterhouse before and at the time of slaughter or killing.		
Notes			
Part I:			
— Box I.8: Provide the code for the zone or the compartment of origin, if necessary, as defined under the code in column 2 of Part 1 of Annex I to Regulation (EC) No 798/2008.			
— Box I.11: Name, address and approval number of the establishment of dispatch.			
— Box I.15: Indicate the registration number(s) of railway wagons and lorries, the names of ships and, if known, the flight numbers of aircraft. In the case of transport in containers or boxes, the total number of these and their registration and where there is a serial number of the seal it has to be indicated in box I.23.			
— Box I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: 02.07 or 02.08.90.			
Part II:			
(¹) "Poultry meat" means the edible parts of farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites, which have not undergone any treatment other than cold treatment to ensure preservation; vacuum-wrapped meat or meat wrapped in a controlled atmosphere must also be accompanied by a certificate in accordance with this model. (²) Delete if the consignment is not intended for import to Sweden or Finland. (³) Code of the territory as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 798/2008. (⁴) Keep as appropriate. (⁵) Insert the name of compartment(s). (⁶) For countries or territories with the entry "N" in column 6 of Part 1 of Annex I to Regulation (EC) No 798/2008, for meat of poultry (POU) only, this means that in the case of an outbreak of Newcastle disease as defined in Regulation (EC) No 798/2008 then the country code or territory code shall continue to be used but this will exclude any area under official restrictions, by the third country concerned in relation to Newcastle disease, at the date of issue of this certificate.			

COUNTRY		POU (meat of poultry)
II.	Health information	II.a. Certificate reference number II.b.
(⁷) Indicate date or dates of slaughter. Imports of this meat shall not be allowed when obtained from poultry slaughtered in the territory or the compartment(s) mentioned under II.2.1 during a period where restrictive measures have been adopted by the European Union against imports of this meat from this territory or that (these) compartment(s). (⁸) Applicable only to the countries with the entry "VI" in column 5 of Part 1 of Annex I to Regulation (EC) No 798/2008. (⁹) If the meat comes from slaughter poultry originating from (an) other third country(ies) listed in Part 1 of Annex I to Regulation (EC) No 798/2008 for imports of that commodity into the European Union, then the code(s) of third country(ies) or of territory(ies) of those third country(ies) and of the third country slaughtering the poultry shall be indicated.		
Official veterinarian Name (in capital letters): Date: Stamp: Qualification and title: Signature:'		

(b) Annex VI is replaced by the following:

'ANNEX VI

(as referred to in Article 12(1)(b), Article 12(2)(c)(ii) and Article 13(1)(a))

CRITERIA FOR RECOGNISED NEWCASTLE DISEASE VACCINES

I. General criteria

- Vaccines must comply with the standards set out in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) in the Chapter on Newcastle disease.
- Vaccines must be registered by the competent authorities of the third country concerned before being allowed to be distributed and used. For such registration, the competent authorities of the third country concerned must rely on a complete file containing data on the efficacy and innocuity of the vaccine; for imported vaccines the competent authorities may rely on data checked by the competent authorities of the country where the vaccine is produced, as far as these checks have been carried out in conformity with OIE standards.
- In addition, imports or production and distribution of the vaccines must be controlled by the competent authorities of the third country concerned.
- Before distribution is allowed, each batch of vaccines must be tested on innocuity, in particular regarding attenuation or inactivation and absence of undesired contaminating agents, and on efficacy on behalf of the competent authorities.

II. Specific criteria

Live attenuated Newcastle disease vaccines must be prepared from a Newcastle disease virus strain for which the master seed has been tested and shown to have an intracerebral pathogenicity index (ICPI) of:

- less than 0,4, if not less than 10^7 EID₅₀ are administered to each bird in the ICPI test; or
- less than 0,5, if not less than 10^8 EID₅₀ are administered to each bird in the ICPI test;'

(c) in Annex VII, in Part II, point (a) is replaced by the following:

- '(a) has not been vaccinated with live attenuated vaccines prepared from a Newcastle disease virus master seed showing a higher pathogenicity than lentogenic strains of the virus within the period of 30 days preceding slaughter;'

COMMISSION REGULATION (EU) No 956/2010**of 22 October 2010****amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council
as regards the list of rapid tests****(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, and in particular the first paragraph of Article 23 and the introductory phrase and point (a) of Article 23a thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.
- (2) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out a list of rapid tests to be used for the monitoring of bovine spongiform encephalopathy (BSE) in bovine animals and TSEs in ovine and caprine animals.
- (3) On 18 December 2009 and 29 April 2010, the European Food Safety Authority (EFSA) published two Scientific Opinions on Analytical sensitivity of approved TSE rapid tests. Those opinions were based on studies performed by the European Union Reference Laboratory (EURL) for TSEs. The EURL studies were intended to evaluate the analytical sensitivity of all the currently approved TSE rapid tests in order to produce robust analytical sensitivity data and evaluate each test against the same sample sets for the three main types of ruminant TSE: BSE, classical scrapie and atypical scrapie.

- (4) As regards scrapie, the EFSA concluded in its opinion published on 18 December 2009 that the tests 'Enfer TSE v2', 'Enfer TSE v3', 'Prionics®-Check LIA SR' and 'Prionics®-WB Check Western SR' could fail in identifying atypical scrapie cases that other validated tests would detect and according to the EFSA protocol for evaluation of rapid post mortem tests to detect TSE in small ruminants (EFSA, 2007b) they could not be recommended for use for TSE monitoring in that field. Accordingly, those methods should no longer be included in the list of rapid tests to be used for the monitoring of TSEs in ovine and caprine animals set out in point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001.
- (5) On 2 July 2009, Idexx laboratories informed the Commission that their combined test 'IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA', which was developed both for the monitoring of TSE in small ruminants and BSE in bovine animals, has never been included in the list of rapid tests to be used for the monitoring of BSE in the Union even though it has been officially approved by the EURL for that purpose. That test should therefore be added to the list of rapid tests for BSE monitoring set out in point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001.
- (6) For practical reasons, the amendments introduced by this Regulation should apply from 1 January 2011, as the Member States need sufficient time in order to align their monitoring procedures for TSEs in ovine and caprine animals with the new list of rapid tests.
- (7) Annex X to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (8) 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

Annex X to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

Article 2

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

It shall apply from 1 January 2011.

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

Done at Brussels, 22 October 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex X to Regulation (EC) No 999/2001, in Chapter C, point 4 is replaced by the following:

‘4. *Rapid tests*

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), only the following methods shall be used as rapid tests for the monitoring of BSE in bovine animals:

- the immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrPres (Prionics-Check Western test),
- the chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer test & Enfer TSE Kit version 2.0, automated sample preparation),
- the microplate-based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),
- the sandwich immunoassay for PrPres detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),
- the microplate-based immunoassay (ELISA) which detects Proteinase K-resistant PrPres with monoclonal antibodies (Prionics-Check LIA test),
- the immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA & IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),
- the lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (Prionics Check PrioSTRIP),
- the two-sided immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP^{Sc} (Roboscreen Beta Prion BSE EIA Test Kit),
- the sandwich ELISA for the detection of Proteinase K-resistant PrP^{Sc} (Roche Applied Science PrionScreen).

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), only the following methods shall be used as rapid tests for the monitoring of TSE in ovine and caprine animals:

- the sandwich immunoassay for PrPres detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),
- the sandwich immunoassay for PrPres detection with the TeSeE Sheep/Goat Detection kit carried out following denaturation and concentration steps with the TeSeE Sheep/Goat Purification kit (Bio-Rad TeSeE Sheep/Goat rapid test),
- the immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA).

In all rapid tests, sample tissue on which the test must be applied must comply with the manufacturer's instructions for use.

Producers of rapid tests must have a quality assurance system in place that has been approved by the European Union Reference Laboratory and ensures that the test performance does not change. Producers must provide the European Union Reference Laboratory with the test protocols.

Changes to rapid tests and to test protocols may only be made after prior notification to the European Union Reference Laboratory and provided that the European Union Reference Laboratory finds that the change does not alter the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.’

COMMISSION REGULATION (EU) No 957/2010**of 22 October 2010****on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health****(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 17(3) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on food are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as the Authority.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission of the application, and to deliver an opinion on a health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Two opinions referred to in this Regulation are related to applications for reduction of disease risk claims, as referred to in Article 14(1)(a) of Regulation (EC) No 1924/2006 and three opinions are related to applications for health claims referring to children's development and health, as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006.

(6) Following an application from Association de la Transformation Laitière Française (ATLA), submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the

Authority was required to deliver an opinion on a health claim related to the effects of iodine on normal growth of children (Question No EFSA-Q-2008-324) ⁽²⁾. The claim proposed by the applicant was worded as follows: 'Iodine is necessary for the growth of children'.

(7) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 20 November 2009 that a cause and effect relationship had been established between the intake of iodine and the claimed effect. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Union list of permitted claims.

(8) Following an application from Association de la Transformation Laitière Française (ATLA), submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of iron on cognitive development of children (Question No EFSA-Q-2008-325) ⁽³⁾. The claim proposed by the applicant was worded as follows: 'Iron is necessary for the cognitive development of children'.

(9) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 20 November 2009 that a cause and effect relationship had been established between the intake of iron and the claimed effect. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Union list of permitted claims.

(10) Article 16(4) of Regulation (EC) No 1924/2006 provides that an opinion in favour of authorising a health claim should include certain particulars. Accordingly, those particulars should be set out in the Annex I to the present Regulation as regards the authorised claims and include, as the case may be, the revised wording of the claims, specific conditions of use of the claims, and, where applicable, conditions or restrictions of use of the food and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ The EFSA Journal (2009) 7(11):1359.

⁽³⁾ The EFSA Journal (2009) 7(11):1360.

- (11) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording and presentation are taken into account in that respect. Therefore, where the wording of claims has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use, as indicated in Annex I.
- (12) Following an application from GP International Holding BV, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of OPC PremiumTM on reduction of blood cholesterol (Question No EFSA-Q-2009-00454) ⁽¹⁾. The claim proposed by the applicant was worded as follows: 'OPC have been shown to reduce blood cholesterol levels and may therefore reduce the risk of cardiovascular disease'.
- (13) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 26 October 2009 that a cause and effect relationship had not been established between the intake of OPC PremiumTM and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (14) Following an application from Valosun AS, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Uroval® on urinary tract infections (Question No EFSA-Q-2009-00600) ⁽²⁾. The claim proposed by the applicant was worded as follows: 'Cranberry extract and D-mannose, the main active ingredients of the food supplement Uroval®, eliminate the adhesion of harmful bacteria to the bladder wall. The adhesion of harmful bacteria to the bladder wall is the main risk factor in the development of urinary tract infections'.
- (15) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 22 December 2009 that a cause and effect relationship had not been established between the intake of Uroval® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (16) Following an application from Töpfer GmbH, submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of bifidobacteria (*Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium longum*) on decreasing potentially pathogenic intestinal micro-organisms (Question No EFSA-Q-2009-00224) ⁽³⁾. The claim proposed by the applicant was worded as follows: 'Probiotic bifidobacteria lead to a healthy intestinal flora comparable to the composition of the intestinal flora of breast-fed infants' intestine'.
- (17) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 22 December 2009 that a cause and effect relationship had not been established between the intake of the combination of bifidobacteria and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (18) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.
- (19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

The health claims set out in Annex I to this Regulation may be made on foods on the European Union market in compliance with the conditions set out in that Annex.

Those health claims shall be included in the Union list of permitted claims referred to in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

The health claims set out in Annex II to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

⁽¹⁾ The EFSA Journal (2009) 7(10):1356.

⁽²⁾ The EFSA Journal (2009) 7(12):1421.

⁽³⁾ The EFSA Journal (2009) 7(12):1420.

Health claims as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006 and set out in Annex II to this Regulation may continue to be used for six months after the entry into force of this Regulation.

Article 3

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, 22 October 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Permitted health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Applicant — Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(b) health claim referring to children's development and health	Association de la Transformation Laitière Française (ATLA), 42 rue de Châteaudun, 75314 Paris Cedex 09, France	Iodine	Iodine contributes to the normal growth of children	The claim can be used only for food which is at least a source of iodine as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-324
Article 14(1)(b) health claim referring to children's development and health	Association de la Transformation Laitière Française (ATLA), 42 rue de Châteaudun, 75314 Paris Cedex 09, France	Iron	Iron contributes to normal cognitive development of children	The claim can be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-325

ANNEX II

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	OPC Premium™	OPC have been shown to reduce blood cholesterol levels and may therefore reduce the risk of cardiovascular disease	Q-2009-00454
Article 14(1)(a) health claim referring to a reduction of a disease risk	Uroval®	Cranberry extract and D-mannose, the main active ingredients of the food supplement Uroval®, eliminate the adhesion of harmful bacteria to the bladder wall. The adhesion of harmful bacteria to the bladder wall is the main risk factor in the development of urinary tract infections	Q-2009-00600
Article 14(1)(b) health claim referring to children's development and health	Combination of bifidobacteria (<i>Bifidobacterium bifidum</i> , <i>Bifidobacterium breve</i> , <i>Bifidobacterium infantis</i> , <i>Bifidobacterium longum</i>)	Probiotic bifidobacteria lead to a healthy intestinal flora comparable to the composition of the intestinal flora of breast-fed infants' intestine	Q-2009-00224

COMMISSION REGULATION (EU) No 958/2010**of 22 October 2010****refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health****(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 18(5) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on food are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.
- (3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission and to deliver an opinion on a health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Rudolf Wild GmbH & Co. KG, submitted on 10 June 2008 pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Immune Balance Drink on strengthening body's defences (Question No EFSA-Q-2009-00517) ⁽²⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'The Immune Balance Drink activates body's defence'.

- (6) On 4 November 2009, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of Immune Balance Drink and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) The comments from the applicant and the members of the public received by the Commission, pursuant to Article 16(6) of Regulation (EC) No 1924/2006, have been considered when setting the measures provided for in this Regulation.
- (8) Health claims referred to in Article 13(1)(a) of Regulation (EC) No 1924/2006 are subject to the transition measures laid down in Article 28(5) of that Regulation only if they comply with the conditions therein mentioned, among which that they have to comply with the Regulation. As for the claim subject to the present Regulation, the Authority concluded that a cause and effect relationship had not been established between the consumption of the food and the claimed effect and thus it does not comply with the Regulation (EC) No 1924/2006 and it could not benefit from the transition period foreseen in Article 28(5) of that Regulation. A transition period of six months is provided for to enable food business operators to adapt to the requirements laid down in this Regulation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim set out in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

However, it may continue to be used for six months after the entry into force of this Regulation.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ The EFSA Journal (2009) 7 (11):1357.

Article 2

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, 22 October 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

Rejected health claim

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Immune Balance drink	The Immune Balance Drink activates body's defence	Q-2009-00517

COMMISSION REGULATION (EU) No 959/2010**of 22 October 2010****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 23 October 2010.

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

Done at Brussels, 22 October 2010.

*For the Commission,
On behalf of the President,**Jean-Luc DEMARTY
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	MA	78,7
	MK	74,3
	XS	73,2
	ZZ	75,4
0707 00 05	MK	87,5
	TR	158,2
	ZZ	122,9
0709 90 70	TR	149,0
	ZZ	149,0
0805 50 10	AR	62,3
	BR	68,9
	CL	67,2
	IL	91,2
	TR	92,5
	UY	61,0
	ZA	60,4
	ZZ	71,9
0806 10 10	BR	214,6
	TR	133,8
	US	155,2
	ZA	64,2
	ZZ	142,0
0808 10 80	AR	77,6
	BR	59,6
	CL	103,4
	CN	64,2
	NZ	91,5
	US	82,6
	ZA	88,4
	ZZ	81,0
0808 20 50	CN	72,2
	ZA	88,6
	ZZ	80,4

⁽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'.

DIRECTIVES

COMMISSION DIRECTIVE 2010/69/EU

of 22 October 2010

amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 31 thereof,

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 ⁽²⁾, and in particular Article 53 thereof,

After consulting the Scientific Committee on Food and the European Food Safety Authority,

Whereas:

- (1) European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners ⁽³⁾ lays down a list of food additives that may be used in the European Union and the conditions for their use.
- (2) There have been technical developments in the field of food additives since the adoption of Directive 95/2/EC. This Directive should be adapted to take into account those developments.
- (3) In accordance with Article 31 of Regulation (EC) No 1333/2008 until the establishment of the Union lists of food additives as provided for in Article 30 of that Regulation is completed, the Annexes to Directive 95/2/EC shall be amended, where necessary, by measures adopted by the Commission.
- (4) The following stabilisers agar (E 406), carrageenan (E 407), locust bean gum (E 410), guar gum (E 412),

xanthan gum (E 415), pectins (E 440), cellulose (E 460), carboxy methyl cellulose (E 466), oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxyl propyl starch (E 1440), hydroxy propyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and emulsifier mono- and diglycerides of fatty acids (E 471) are currently authorised under Directive 95/2/EC for a variety of uses. These food additives have been allocated an acceptable daily intake (ADI) 'not specified' by the Scientific Committee on Food (hereinafter SCF) and therefore do not present any hazard to the health of consumers. There is a technological need to extend their uses to unflavoured live fermented cream products and substitute products with a fat content of less than 20 % to ensure the stability and integrity of the emulsion. This use would benefit the consumer by providing the choice of reduced fat fermented cream products with similar properties as to the ordinary product. It is therefore appropriate to authorise this additional use.

- (5) In 1990, the SCF evaluated sodium and potassium salts of lactate (E 325 and E 326), potassium acetate (E 261), sodium acetate (E 262i) and sodium hydrogen acetate (E 262ii) and came to the conclusion that they are all naturally present as constituents in food and estimates of their intake are likely to be insignificant compared to the intake from natural sources. Therefore they were all allocated a 'group ADI not specified'. Consequently, these food additives are generally permitted for use in all foodstuffs, other than those referred to in Article 2(3) of Directive 95/2/EC. There is a proposal to extend the use of these food additives into pre-packed preparations of fresh minced meat to control the growth of microbial pathogens, e.g. *Listeria*, *E. coli* O157. Based on this technological justification, and taking into account that this use raises no safety concern, it is appropriate to permit the additional use of these food additives in pre-packed preparations of fresh minced meat.
- (6) Sorbates (E 200, E 202, E 203) and benzoates (E 210, E 211, E 212, E 213) are currently permitted as food additives under Directive 95/2/EC. An additional use as preservative of these food additives is proposed in seaweed-based fish product analogues (caviar analogues

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 31, 1.2.2002, p. 1.

⁽³⁾ OJ L 61, 18.3.1995, p. 1.

made of seaweed) as topping on various foods in order to prevent the growth of moulds and yeasts and the formation of mycotoxins. These salts are allocated an ADI of 0-25 mg/kg bw and 0-5 mg/kg/ bw respectively. On the basis of a worst case scenario where the maximum concentrations were used, the intake estimates are very low compared to the ADI. The exposure of the consumer as a result of this use does not give rise to safety concern. It is therefore appropriate to permit the additional use of sorbates and benzoates in seaweed based fish analogue products, bearing in mind the technological justification and the fact that this new product represents a niche market.

- (7) The use of sorbates (E 200, E 202, E 203) and benzoates (E 210, E 211, E 212, E 213) is requested for beers in keg to which more than 0,5 % fermentable sugars and/or fruit juices or concentrates have been added and which are directly served on draft. These beers in keg may stay connected to the beer tap for a longer time. As the connection of the keg to the tap cannot be performed under sterile conditions, microbiological contamination of the keg is possible. This is a problem for beers which still contain fermentable sugars because this may lead to the growth of hazardous microorganisms. Therefore antimicrobial agents are required in draft beers and to which fermentable sugars and/or fruit juices or concentrates have been added. From an intake point of view, the consumption on draft of such fruit beers remains marginal and the intake estimates for sorbates and benzoates, on the grounds of a 'worst case approach', should be below their respective ADIs. Therefore it is appropriate to permit the additional use of sorbates and benzoates in beer in kegs containing more than 0,5 % added fermentable sugar and/or fruit juices or concentrates.
- (8) To prevent the development of moulds on citrus fruit, their post harvest treatment with pesticides such as imazalil and thiabendazole is authorised. Sorbates (E 200, E 202, E 203) could be used to replace these pesticides partly or completely for the treatment of citrus fruit. Sorbates can be applied on the surface of the unpeeled fresh citrus fruit via the authorised waxes: beeswax, candelilla wax, carnauba wax and shellac (E 901, E 902, E 903 and E 904 respectively). The exposure of the consumer to these additives due to this use is not a cause of safety concern. It is therefore appropriate to authorise its additional use.
- (9) Consumers may choose to supplement their intake of some nutrients with food supplements. For that purpose, vitamin A and combinations of vitamins A and D can be added to food supplements, as defined by Directive 2002/46/EC of the European Parliament and of the Council⁽¹⁾. For reasons of safe handling, vitamin A and combinations of vitamins A and D have

to be formulated into preparations that may require high humidity and high temperature, in the presence of starches and sugars. Such processing may favour the development of microorganisms. In order to prevent the growth of these microorganisms, the addition of sorbates (E 200, E 202, E 203) and benzoates (E 210, E 211, E 212 and E 213) should be authorised in vitamin A and in combinations of vitamins A and D when used in food supplements supplied in dried form.

- (10) Sulphur dioxide and sulphites (E 220, E 221, E 222, E 223, E 224, E 226, E 227, E 228) are food additives authorised under Directive 95/2/EC which act primarily as antimicrobial agents and controlling chemical spoilage. Nowadays, transport of fresh fruit has become very important, in particular by sea freight. Such transport may be several weeks. The use of sulphur dioxide and sulphites will protect fresh blueberries against fungi growth. The additional use of sulphur dioxide and sulphites should be authorised in order to help preserve fresh blueberries against fungi growth, bearing in mind that this is likely to represent a niche market. Taking also into consideration the sound technological reasons for including these new authorisations, the need to facilitate worldwide trade and its negligible impact in term of sulphur and sulphite intake, it is therefore appropriate to authorise the additional use of sulphur dioxide in blueberries at the concentration level indicated in the Annex to this Directive.
- (11) For the production of cinnamon sticks (*Cinnamomum ceylanicum* only), also known as 'quills', the fresh peels of the inner bark of the cinnamon tree is used. The peel is exposed to microbial contamination and insect attacks, particularly under tropical and humid climatic conditions, in the producing country. Sulphur dioxide fumigation is an appropriate treatment against such microbial contamination and insect attacks. In 1994, the SCF established an ADI of 0-0,7 mg/kg bw and considered that the use of sulphur dioxide and other sulphiting agents should be limited in order to limit the occurrence of severe asthmatic reactions. Although the use of sulphur dioxide and sulphites should be limited, this specific use represents a negligible contributor in relation to the intake of sulphur dioxide and sulphites. It is therefore appropriate to authorise the additional use of sulphur dioxide and sulphites (E 220, E 221, E 222, E 223, E 224, E 226, E 227, E 228) only in this particular type of cinnamon.
- (12) The European Food Safety Authority (hereinafter EFSA) assessed the information on the safety of use of nisin in an additional food category of liquid eggs, and on the safety of nisin produced using a modified production process. The EFSA confirmed in its opinion on 26 January 2006⁽²⁾ the previously established ADI of 0-0,13 mg/kg for the nisin produced using a new manufacturing and extraction process based on

⁽¹⁾ OJ L 183, 12.7.2002, p. 51.

⁽²⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of nisin (E 234) as a food additive, *The EFSA Journal* (2006) 314, p. 1.

fermentation of a sugar medium as a replacement for the traditionally milk-based medium. In this opinion, the EFSA also confirmed that the development of antibiotic resistance should not be expected from the use of nisin in food. According to the EFSA, there are no reports of nisin resistant bacterial mutants showing cross-resistance to therapeutic antibiotic. It considered that this is probably due to the differences between therapeutic antibiotics and nisin in terms of the antimicrobial mode of action. The EFSA furthermore confirmed in its opinion issued on 20 October 2006 ⁽¹⁾ that the additional use of nisin in pasteurised liquid eggs under the intended conditions of use (maximum limit at 6,25 mg/l) is not a safety concern and is justified from a technological point of view to extend the shelf life of the product and also to prevent the growth of food poisoning spore-forming species, like *Bacillus cereus*, which may survive from pasteurisation treatment. It is therefore appropriate to authorise this additional use of nisin in pasteurised liquid egg.

- (13) Dimethyl dicarbonate (DMDC, E 242) is a food additive permitted under Directive 95/2/EC which acts as a preservative in non-alcoholic flavoured drinks, alcohol-free wine and liquid-tea concentrate. The authorisation of this additive was decided on the basis of a positive opinion issued by the SCF in 1990 and confirmed in 1996. The SCF was unable to set an ADI, as DMDC rapidly decomposes into carbon dioxide and methanol. In 2001, the SCF was requested to investigate the safety of use of DMDC in wine. At that time the SCF considered that the formation of methanol and other reaction products, such as methylcarbamate resulting from the use of DMDC for the treatment of alcoholic beverages and wine is similar to that formed in non-alcoholic beverages, and even a heavy consumption of wine would not pose any hazard from methanol and methylcarbamate. The use of DMDC has been requested in order to prevent spoilage as a result of fermentation in unopened non-sterile filled bottles of cider, perry and fruit wines, alcohol-reduced wine, wine-based drinks and all other products covered by Council Regulation (EEC) No 1601/91 ⁽²⁾. These additional uses are not considered as being of safety concern for the consumer. Moreover, the use of DMDC could contribute to the reduction of the sulphur dioxide exposure. It is therefore appropriate to authorise the additional uses of DMDC in cider, perry and fruit wines, alcohol-reduced wine, wine-based drinks and other products covered by Regulation (EEC) No 1601/91.

- (14) The EFSA assessed the information on the safety of use of extracts of rosemary when used as an antioxidant in

foodstuffs. Extracts of rosemary are derived from *Rosmarinus officinalis* L. and contain several compounds which exert antioxidative functions (mainly phenolic acids, flavonoids, diterpenoids and triterpenes). Although the toxicological data on extracts of rosemary were insufficient for the EFSA to establish a numerical ADI, the EFSA considered in its opinion on 7 March 2008 ⁽³⁾ that the margin of safety was high enough to conclude that dietary exposure resulting from the proposed uses and use levels were of no safety concern. Extracts of rosemary can therefore be authorised where there is a technological justification for their use. The proposed uses of extracts of rosemary as antioxidant should be authorised and E 392 should be assigned as E number for extracts of rosemary.

- (15) Whey is a by-product of cheese manufacturing. Some whey protein containing drinks have been developed in order to provide a diet sufficiently rich in proteins. To keep the proteins in suspension during the heat treatment of such drinks, the phosphates must be at levels that are higher than for normal non-alcoholic flavoured drinks. Phosphates should be authorised in whey protein containing sport drinks.
- (16) Beeswax (E 901) is currently authorised as a glazing agent for use in small products of fine bakery wares coated with chocolate. This authorisation does not cover ice cream wafers that are not coated with chocolate. In addition to the fact that beeswax can be considered as an alternative to chocolate in pre-packed ice cream wafers, the coating of the wafers with beeswax would prevent the migration of water to the wafer and ensure its crunchiness and the extension of the shelf life of the product and is therefore considered technologically justified. Therefore beeswax should be authorised as a glazing agent to replace fully or partly the in-layer chocolate in pre-packed wafers containing ice-cream.
- (17) The EFSA assessed the information on the safety of use of beeswax considering its additional use as a carrier of flavourings in non-alcoholic flavoured drinks. Although the available data on beeswax itself were insufficient to establish an ADI, the EFSA came to the conclusion that, due to the low toxicological profile of beeswax, the existing food uses and the proposed new use of beeswax do not raise safety concern. It is therefore appropriate to authorise this additional use of beeswax as a carrier of flavourings in non-alcoholic flavoured drinks.

⁽¹⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on the safety in use of nisin as a food additive in an additional category of liquid eggs and on the safety of nisin produced using a modified production process as a food additive, *The EFSA Journal* (2006) 314b, p. 1.

⁽²⁾ OJ L 149, 14.6.1991, p. 1.

⁽³⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of rosemary extracts as a food additive, *The EFSA Journal* (2008) 721, p. 1.

- (18) Triethyl citrate (E 1505) is currently authorised within the EU under Directive 95/2/EC as a carrier in flavourings, and in dried egg white. Its ADI was established by the SCF in 1990 at 0-20 mg/kg. An extension of use of triethyl citrate has been proposed as glazing agent of food supplement tablets. Triethyl citrate would increase the film resistance of the coating, protecting the tablet from external environment and also increase the duration of release of the product. According to the worst case scenario, this additional source of triethyl citrate intake is negligible (0,25 % of the ADI) compared to the full ADI. Therefore it is appropriate to authorise the additional use of triethyl citrate at EU level as a glazing agent for food supplement tablets.
- (19) The EFSA assessed the information on the safety of polyvinyl alcohol (PVA) as a film-coating agent for food supplements and expressed its opinion on 5 December 2005 ⁽¹⁾. The EFSA found the use of PVA in the coating of food supplements that are in the form of capsules and tablets to be of no safety concern. The EFSA considered that the potential human exposure to PVA under the intended conditions of use is expected to be low. PVA is reported to be minimally absorbed following oral administration. The maximum limit of use has been fixed at 18 g/kg based on the worst case scenario and on the basis of which the EFSA has undertaken its risk assessment. Due to the good adhesion qualities and film strength of polyvinyl alcohol, this new food additive is expected to play a technological role as film coating agent for food supplements, in particular in applications where moisture barrier and moisture protection properties are required. It is therefore appropriate to authorise this use at EU level. This new food additive should be assigned the E number E 1203.
- (20) The EFSA assessed the information on the safety of use of six grades of polyethylene glycols (PEG 400, PEG 3000, PEG 3350, PEG 4000, PEG 6000, PEG 8000) as film coating agents for use in food supplement products and expressed its opinion on 28 November 2006 ⁽²⁾. The EFSA found the use of these grades of polyethylene glycol as a glazing agent in film-coating formulations for food supplement tablets and capsules under the intended conditions of use of no safety concern. The EFSA has also taken into consideration in its risk assessment the additional source of exposure to these PEGs originating from the use of pharmaceutical products and considered that only a limited additional intake may result from the already approved use of PEG 6000 as carrier for sweeteners, as well as from the use of PEG in food contact materials. It is therefore appropriate to authorise this new use at EU level. In addition, due to the limited intake from PEG 6000 as carrier of sweeteners and its similar toxicological profile with respect to the other PEG grades (the six PEGs have been allocated a group tolerable daily intake (TDI), it is also appropriate to authorise the use of the PEGs evaluated by the EFSA as alternatives to PEG 6000 as carrier of sweeteners. All these PEGs should be assigned E 1521 as E number.
- (21) The EFSA assessed the information on the safety of use of cassia gum as a new food additive acting as gelling agent and thickener and expressed its opinion on 26 September 2006 ⁽³⁾. The EFSA found the use of cassia gum as indicated under the conditions specified raised no safety concern. Although the EFSA considered the available toxicological data on cassia gum as insufficient to derive an ADI, they did not consider that the existing data gave cause for concern. In particular the EFSA highlighted the specific low absorption of cassia gum and the fact that, if hydrolysed at all, cassia gum would be degraded to compounds that will enter the normal metabolic pathways. There is a technological justification for the use of cassia gum through its synergistic gelling effects when added to other regular food gums. It is therefore appropriate to authorise these uses at EU level and to assign E 427 as E number for cassia gum.
- (22) The EFSA evaluated the safety of neotame as a flavour enhancer and expressed its opinion on 27 September 2007 ⁽⁴⁾. The EFSA concluded that neotame is of no safety concern with respect to the proposed uses as a flavour enhancer and established an ADI of 0-2 mg/kg bw/day. Therefore it is necessary to authorise the use of neotame as a flavour enhancer.
- (23) The EFSA assessed the information on the safety of use of L-cysteine (E 920) in certain foodstuffs intended for infants and young children. The EFSA concluded in
- ⁽¹⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyvinyl alcohol as a coating agent for food supplement, *The EFSA Journal* (2005) 294, p. 1.
- ⁽²⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyethylene glycol (PEG) as a film coating agent for use in food supplement products, *The EFSA Journal* (2006) 414, p. 1.
- ⁽³⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to an application on the use of cassia gum as a food additive, *The EFSA Journal* (2006) 389, p. 1.
- ⁽⁴⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission on neotame as a sweetener and flavour enhancer, *The EFSA Journal* (2007) 581, p. 1.

its opinion on 26 September 2006 ⁽¹⁾ that its proposed use in processed cereal-based foods and foods (specifically baby biscuits) for infants and young children is of no safety concern. Biscuits for infants and young children are required to have a suitable composition, including a controlled content of sugar and fat. However, biscuits with a low fat content have increased brittleness with an associated risk of choking and suffocation due to the biscuit breaking in the child's mouth. The function of the L-cysteine is to act as a dough improver to control the texture of the final product. It is therefore appropriate to authorise the use of L-cysteine in biscuits for infants and young children at EU level.

- (24) EFSA assessed the safety of use of an enzyme preparation based on thrombin with fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food and concluded in its opinion on 26 April 2005 that this use of the enzyme preparation when produced as outlined in the opinion is of no safety concern ⁽²⁾. However, the European Parliament in its Resolution of 19 May 2010 on the draft Commission Directive amending the Annexes to the European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners, considered that the inclusion in Annex IV to Directive 95/2/EC of this enzyme preparation as a food additive for reconstituting food was not compatible with the aim and content of Regulation (EC) No 1333/2008, as it does not meet the general criteria of Article 6 of Regulation (EC) No 1333/2008, especially in paragraph 1(c) of Article 6.
- (25) Commission Decision 2004/374/EC ⁽³⁾ suspended the placing on the market and import of jelly mini-cups containing gel-forming food additives derived from seaweed and certain gums (E 400, E 401, E 402, E 403, E 404, E 405, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417, E 418) due to the risk of choking posed by these products. Directive 95/2/EC was amended accordingly by Directive 2006/52/EC of the European Parliament and of the Council ⁽⁴⁾. Commission Decision 2004/374/EC should therefore be repealed as its provisions have been included in Directive 95/2/EC.
- (26) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II to VI to Directive 95/2/EC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 March 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with Article 1 of this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 April 2011 at the latest.

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

Commission Decision 2004/374/EC is repealed.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 22 October 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of L-cysteine in foods intended for infants and young children, *The EFSA Journal* (2006) 390, p. 1.

⁽²⁾ Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to the use of an enzyme preparation based on thrombin: fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food, *The EFSA Journal* (2005) 214, p. 1.

⁽³⁾ OJ L 118, 23.4.2004, p. 70.

⁽⁴⁾ OJ L 204, 26.7.2006, p. 10.

ANNEX

Annexes II to VI to Directive 95/2/EC are amended as follows:

(1) Annex II is amended as follows:

(a) the entry concerning 'Pre-packed preparations of fresh minced meat' is replaced by the following:

'Pre-packed preparations of fresh minced meat	E 261	Potassium acetate	<i>quantum satis</i>
	E 262i	Sodium acetate	
	E 262ii	Sodium hydrogen acetate	
	E 300	Ascorbic acid	
	E 301	Sodium ascorbate	
	E 302	Calcium ascorbate	
	E 325	Sodium lactate	
	E 326	Potassium lactate	
	E 330	Citric acid	
	E 331	Sodium citrates	
	E 332	Potassium citrates	
	E 333	Calcium citrates	

(b) at the end of the Annex, the following entry is added:

'Unflavoured live fermented cream products and substitute products with a fat content of less than 20 %	E 406	Agar	<i>quantum satis</i>
	E 407	Carrageenan	
	E 410	Locust bean gum	
	E 412	Guar gum	
	E 415	Xanthan gum	
	E 440	Pectins	
	E 460	Cellulose	
	E 466	Carboxy methyl cellulose	
	E 471	Mono- and diglycerides of fatty acids	
	E 1404	Oxidised starch	
	E 1410	Monostarch phosphate	
	E 1412	Distarch phosphate	
	E 1413	Phosphated distarch phosphate	
	E 1414	Acetylated distarch phosphate	
	E 1420	Acetylated starch	
	E 1422	Acetylated distarch adipate	
	E 1440	Hydroxyl propyl starch	

	E 1442	Hydroxy propyl distarch phosphate	
	E 1450	Starch sodium octenyl succinate	
	E 1451	Acetylated oxidised starch	

(2) Annex III is amended as follows:

(a) at the end of Part A, the following entries are added:

'Seaweed-based fish analogue products	1 000	500				
Beer in kegs containing more than 0,5 % added fermentable sugar and/or fruit juices or concentrates	200	200		400		
Unpeeled fresh citrus fruit (surface treatment only)	20					
Food supplements as defined in Directive 2002/46/EC supplied in dried form containing preparations of vitamin A and of combinations of vitamin A and D				1 000 in the product ready for consumption'		

(b) at the end of Part B, the following entries are added:

'Blueberries (<i>Vaccinium corymbosum</i> only)	10
Cinnamon (<i>Cinnamomum ceylanicum</i> only)	150'

(c) Part C is amended as follows:

(i) the entry concerning the additive E 234 is replaced by the following:

'E 234	Nisin (*)	Semolina and tapioca puddings and similar products	3 mg/kg
		Ripened cheese and processed cheese	12,5 mg/kg
		Clotted cream	10 mg/kg
		Mascarpone	10 mg/kg
		Pasteurised liquid egg (white, yolk or whole egg)	6,25 mg/l

(*) This substance may be present in certain cheeses as a result of fermentation process.'

(ii) the entry concerning the additive E 242 is replaced by the following:

'E 242	Dimethyl dicarbonate	Non-alcoholic flavoured drinks Alcohol-free wine Liquid-tea concentrate	250 mg/l ingoing amount, residues not detectable
		Cider, perry, fruit wines Alcohol-reduced wine Wine-based drinks and products covered by Regulation (EEC) No 1601/91	250 mg/l ingoing amount, residues not detectable'

(d) in Part D the following entry is inserted after the entry concerning additive E 316:

E 392	Extracts of rosemary	Vegetable oils (excluding virgin oils and olive oils) and fat where content of polyunsaturated fatty acids is higher than 15 % w/w of the total fatty acid, for the use in non heat treated food products	30 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Fish oils and algal oil	50 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Lard, beef, poultry, sheep and porcine fat Fats and oils for the professional manufacture of heat-treated foodstuffs Frying oil and frying fat, excluding olive oil and olive pomace oil Snack foods (snack based on cereals, potatoes or starch)	50 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Sauces	100 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Fine bakery wares	200 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Food supplements as defined in Directive 2002/46/EC	400 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dehydrated potatoes Egg products Chewing gum	200 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Milk powder for vending machines Seasoning and condiments Processed nuts	200 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Dehydrated soups and broths	50 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dehydrated meat	150 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Meat and fish products, excluding dehydrated meat and dried sausage	150 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Dried sausage	100 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Flavourings	1 000 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dried milk for the manufacturing of ice cream	30 mg/kg (expressed as the sum of carnosol and carnosic acid)

(3) Annex IV is amended as follows:

- (a) in the entry concerning additives E 338, E 339, E 340, E 341, E 343, E 450, E 451 and E 452, the following row is inserted after the row concerning 'vegetable protein drinks':

		'Whey protein containing sport drinks	4 g/kg'
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- (b) the following entry is inserted before the entry concerning additives E 432, E 433, E 434, E 435 and E 436:

'E 427	Cassia gum	Edible ices	2 500 mg/kg
		Fermented milk products with the exception of unflavoured live fermented milk products	
		Dairy-based dessert and similar products	
		Filling, topping and coating for fine bakery wares and dessert	
		Processed cheese	
		Sauces and salads dressing	
		Dehydrated soups and broths	
		Heat-treated meat products	1 500 mg/kg'

- (c) in the entry for E 901, E 902, and E 904, in the third column, under the use 'As glazing agent only for', the following entry is added:

		'— Pre-packed wafers containing ice cream (only for E 901)	<i>quantum satis</i>
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- (d) in the entry for E 901, E 902, and E 904, in the third column, below the use as 'Peaches and pineapples (surface treatment only)', the following entry is added:

		'Flavourings in non-alcoholic flavoured drinks (only for E 901)	0,2 g/kg in the flavoured drinks'
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- (e) the following entry is inserted after the entry concerning the additive E 959:

'E 961	Neotame	Water-based flavoured drinks, energy-reduced or with no added sugar	2 mg/l as flavour enhancer
		Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	2 mg/l as flavour enhancer
		"Snacks": certain flavours of ready-to-eat, pre-packed, dry, savoury starch products and coated nuts	2 mg/kg as flavour enhancer
		Starch-based confectionery, energy-reduced or with no added sugar	3 mg/kg as flavour enhancer
		Breath-freshening micro-sweets, with no added sugar	3 mg/kg as flavour enhancer
		Strongly flavoured throat pastilles with no added sugar	3 mg/kg as flavour enhancer
		Chewing gum with added sugar	3 mg/kg as flavour enhancer
		Energy-reduced jams, jellies and marmalades	2 mg/kg as flavour enhancer

		Sauces	2 mg/kg as flavour enhancer
		Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	2 mg/kg as flavour enhancer
		Food supplements as defined in Directive 2002/46/EC supplied in a solid form	2 mg/kg as flavour enhancer
		Food supplements as defined in Directive 2002/46/EC based on vitamins and/or mineral elements and supplied in a syrup-type or non-chewable form	2 mg/kg as flavour enhancer'

(f) the following entry is inserted after the entry concerning additive E 1202:

'E 1203	Polyvinyl alcohol	Food supplements as defined in Directive 2002/46/EC in capsule and tablet form	18 g/kg'
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(g) after the entry concerning the additive E 1202, the entry concerning only the food additive E 1505 is replaced by the following:

'E 1505	Triethyl citrate	Food supplements as defined in Directive 2002/46/EC in capsule and tablet form	3,5 g/kg
		Dried egg white	<i>quantum satis</i>

(h) the following entry is inserted after the entry concerning the additive E 1452:

'E 1521	Polyethylene glycol	Food supplements as defined in Directive 2002/46/EC in capsule and tablet form	10 g/kg'
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(4) In Annex V, the entry concerning the additive 'Polyethyleneglycol 6000' is replaced by the following:

'E 1521	Polyethylene glycol	Sweeteners'
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(5) In Part 3 of Annex VI, the following entry is added after the entry concerning additive E 526:

'E 920	L-cysteine	Biscuits for infants and young children	1 g/kg'
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DECISIONS

COUNCIL DECISION

of 15 October 2010

appointing one Romanian member of the European Economic and Social Committee for the period from 21 September 2010 to 20 September 2015

(2010/632/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 300(2) and Article 302 thereof, in conjunction with Article 7 of the Protocol on Transitional Provisions annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community,

Having regard to the proposal made by Romania,

Having regard to the opinion of the European Commission,

Whereas:

- (1) The term of office of the members of the European Economic and Social Committee expired on 20 September 2010.
- (2) On 13 September 2010, the Council adopted Decision 2010/570/EU, Euratom appointing the members of the European Economic and Social Committee for the period from 21 September 2010 to 20 September 2015 ⁽¹⁾, except for one Romanian member, whom the Romanian authorities reserved the right to nominate at a later stage.

- (3) By a letter which reached the Council on 28 September 2010, the Romanian authorities proposed to the Council a candidate for appointment as a member of the European Economic and Social Committee during the abovementioned period, in order to complete the list of members allocated to Romania by the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

Mr Eugen LUCAN is hereby appointed as a member of the European Economic and Social Committee, for the period from 21 September 2010 to 20 September 2015.

Article 2

This Decision shall take effect on the day of its adoption.

Done at Luxembourg, 15 October 2010.

For the Council
The President
E. SCHOUPE

⁽¹⁾ OJ L 251, 25.9.2010, p. 8.

COMMISSION DECISION
of 22 October 2010
amending Decision 93/152/EEC laying down the criteria for vaccines to be used against Newcastle
disease in the context of routine vaccination programmes

(notified under document C(2010) 7109)

(Text with EEA relevance)

(2010/633/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs ⁽¹⁾, and in particular point 2 of Annex III thereto,

Whereas:

- (1) Commission Decision 93/152/EEC ⁽²⁾ lays down certain rules concerning the vaccines to be used in routine vaccination programmes against Newcastle disease.
- (2) In particular, that Decision sets out the criteria that have to be met for the intracerebral pathogenicity index (ICPI) in respect of the Newcastle disease virus strain used in live attenuated and inactivated vaccines against that disease.
- (3) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ⁽³⁾ provides for certain requirements for immunological veterinary medicinal products, including requirements for safety tests.
- (4) In view of the technical progress which has been made in relation to the manufacture of vaccines, in particular as regards inactivation techniques and the requirements of Directive 2001/82/EC and the European Pharmacopoeia, it is therefore appropriate to delete the specific requirement for inactivated vaccines regarding the intracerebral pathogenicity index (ICPI) in respect of the

Newcastle disease virus strain used in such vaccines currently laid down in point (b) of Article 1 of Decision 93/152/EEC.

- (5) Decision 93/152/EEC should therefore be amended accordingly.
- (6) It is appropriate to lay down a date of application of this Decision, in order to align it with the date of application of Commission Regulation (EC) No 798/2008 ⁽⁴⁾, as amended by Regulation (EU) No 955/2010 ⁽⁵⁾, which introduces corresponding amendments for the criteria for inactivated vaccines against Newcastle disease used in third countries,

HAS ADOPTED THIS DECISION:

Article 1

Point (b) of Article 1 of Decision 93/152/EEC is deleted.

Article 2

This Decision shall apply from 1 December 2010.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 22 October 2010.

For the Commission
John DALLI
Member of the Commission

⁽¹⁾ OJ L 343, 22.12.2009, p. 74.

⁽²⁾ OJ L 59, 12.3.1993, p. 35.

⁽³⁾ OJ L 311, 28.11.2001, p. 1.

⁽⁴⁾ OJ L 226, 23.8.2008, p. 1.

⁽⁵⁾ See page 3 of this Official Journal.

COMMISSION DECISION

of 22 October 2010

adjusting the Union-wide quantity of allowances to be issued under the Union Scheme for 2013 and repealing Decision 2010/384/EU

(notified under document C(2010) 7180)

(2010/634/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC ⁽¹⁾, and in particular Article 9 and Article 9a(3) thereof,

Whereas:

- (1) In accordance with Article 9a of Directive 2003/87/EC, the Union-wide quantity of allowances should be adjusted to reflect allowances issued in respect of installations that were included in the EU Emission Trading Scheme during the period from 2008 to 2012 pursuant to Article 24(1) of Directive 2003/87/EC. The Union-wide quantity of allowances should also be adjusted in respect of installations that carry out activities listed in Annex I to the Directive and that are only included in the Union scheme from 2013 onwards.
- (2) In accordance with Article 9 of Directive 2003/87/EC, Commission Decision 2010/384/EU of 9 July 2010 on the Community-wide quantity of allowances to be issued under the EU Emission Trading Scheme for 2013 ⁽²⁾ based the absolute Union-wide quantity of allowances for 2013 on the total quantities of allowances issued or to be issued by the Member States in accordance with the Commission decisions on their national allocation plans for the period from 2008 to 2012. As additional information has become available since the adoption of that Decision, it should be repealed and replaced.
- (3) Further to applications by Member States for the unilateral inclusion of additional activities and gases in the Union scheme under Article 24(1) of Directive

2003/87/EC, activities previously not included in the Union scheme were included in the scheme by Commission Decisions C(2008) 7867, C(2009) 3032 and C(2009) 9849. For the purpose of this Decision, applications pursuant to Article 24(1) of Directive 2003/87/EC should be taken into account where the Commission has approved their inclusion before 31 August 2010. It will remain possible to reflect in future adjustments to the Union-wide quantity of allowances for 2013 inclusions approved by the Commission after this date. Pursuant to Article 9a(1) of Directive 2003/87/EC, the Union-wide quantity of allowances is to be adjusted by the linear factor referred to in Article 9 of the Directive from 2010 onwards.

- (4) In accordance with Article 2(1) of Directive 2009/29/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 2003/87/EC so as to improve and extend the greenhouse gas emission allowance trading scheme of the Community ⁽³⁾ Member States have brought into force national law, regulations and administrative provisions to ensure that the operators of installations carrying out activities listed in Annex I to Directive 2003/87/EC that are only included in the Union scheme from 2013 onwards, were able to submit to the relevant competent authority duly substantiated and independently verified emissions data. Such data is necessary, if it is to be taken into account for the adjustment of the Union-wide quantity of allowances. Member States were required to notify duly substantiated emission data to the Commission by 30 June 2010.
- (5) To provide a level playing field for all installations, emissions data notified by Member States to the Commission should be adjusted to take into account the emission reduction effort that would have been expected from installations only included in the Union scheme as from 2013, had they been included in the Union scheme as from 2005. The Union-wide quantity of allowances is also to be adjusted pursuant to Article 9a(2) of the Directive by the linear factor referred to in Article 9 of the Directive from 2010 onwards. In the event that new Member States join the Union, it will remain possible to reflect additional information in future adjustments to the Union-wide quantity of allowances.

⁽¹⁾ OJ L 275, 25.10.2003, p. 32.

⁽²⁾ OJ L 175, 10.7.2010, p. 36.

⁽³⁾ OJ L 140, 5.6.2009, p. 63.

- (6) Where Member States notified emissions from installations producing ammonia or soda ash, which will only be included in the Union scheme as from 2013, emissions serving as the basis for the calculation of the adjustment of the Union-wide quantity of allowances determined in this Decision, were taken into account assuming that these emissions represent emissions in the sense of Article 3(b) of Directive 2003/87/EC. To guarantee consistency between the total quantity of allowances in the Union scheme, and the emissions for which allowances have to be surrendered, it will remain possible to revise the Union-wide quantity of allowances, if the Regulation to be adopted pursuant to Article 14(1) of Directive 2003/87/EC deviates from this approach.
- (7) To avoid double counting, only notified emissions with respect to activities listed in Annex I to Directive 2003/87/EC included in the scope of the Union scheme as from 2013, should be taken into account for the adjustment of the Union-wide quantity of allowances.
- (8) Pursuant to Article 27 of Directive 2003/87/EC, Member States may exclude certain installations from the Union-wide scheme, if they notify the Commission of each of those installations by not later than 30 September 2011 and the Commission does not object. To date, the Commission has not received notifications from Member States in this respect. It will remain possible to reflect such exclusions in future adjustments to the Union-wide quantity of allowances for 2013.
- (9) It may be necessary to take into account additional information concerning the Union-wide quantity of allowances pursuant to Article 9 of Directive 2003/87/EC, as determined by Decision 2010/384/EU when it becomes available. It will remain possible to reflect such additional information in future adjustments to the Union-wide quantity of allowances for 2013.
- (10) On the basis of information available since the adoption of Decision 2010/384/EU, the average annual total quantity of allowances issued by Member States in accordance with the Commission decisions on their national allocation plans for the period from 2008 to 2012, which is taken into account for the calculation of the Union-wide quantity of allowances pursuant to Article 9 of Directive 2003/87/EC amounts to 2 037 227 209.
- (11) For 2013, the absolute Union-wide quantity of allowances referred to in Article 9 of Directive 2003/87/EC amounts to 1 930 883 949.
- (12) For 2013, the quantity of allowances issued in respect of installations that were included in the Union scheme during the period from 2008 to 2012 pursuant to Article 24(1) of Directive 2003/87/EC and adjusted by the linear factor referred to in Article 9 of this Directive amounts to 1 328 218.
- (13) For 2013, the quantity of allowances issued in respect of installations that are included in the Union scheme from 2013 onwards and adjusted by the linear factor referred to in Article 9 of this Directive amounts to 106 940 715.
- (14) On the basis of Article 9 and Article 9a, the total quantity of allowances to be issued from 2013 onwards is to annually decrease by a linear factor of 1,74 %, amounting to 37 435 387 allowances,
- HAS ADOPTED THIS DECISION:
- Article 1*
- For 2013, the total absolute Union-wide quantity of allowances referred to in Article 9 and Article 9a(1) and (2) of Directive 2003/87/EC amounts to 2 039 152 882.
- Article 2*
- Decision 2010/384/EU is repealed.
- Article 3*
- This Decision is addressed to the Member States.
- Done at Brussels, 22 October 2010.
- For the Commission*
Connie HEDEGAARD
Member of the Commission
-

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 11 October 2010

on the application of Article 37 of the Euratom Treaty

(2010/635/Euratom)

THE EUROPEAN COMMISSION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 37 thereof in conjunction with Article 106a referring to Article 292 of the Treaty on the Functioning of the European Union,

Having consulted the group of persons appointed in accordance with Article 31 of the Euratom Treaty by the Scientific and Technical Committee,

Whereas:

- (1) Article 37 requires that each Member State is to provide the Commission with such general data relating to any plan for the disposal of radioactive waste in whatever form as will make it possible to determine whether the implementation of such plan is liable to result in the radioactive contamination of the water, soil or airspace of another Member State. The Commission is to deliver its opinion within six months, after consulting the group of experts referred to in Article 31.
- (2) Experience has been acquired in the application of the Commission Recommendations of 16 November 1960 ⁽¹⁾, 82/181/Euratom ⁽²⁾ 91/4/Euratom ⁽³⁾ and 1999/829/Euratom ⁽⁴⁾ concerning the application of Article 37 of the Treaty.
- (3) The Court of Justice of the European Union, in its judgment of 22 September 1988 in Case 187/87 ⁽⁵⁾, ruled that Article 37 of the Euratom Treaty must be interpreted as meaning that the European Commission shall be provided with general data before the discharge authorisation of radioactive effluents is granted by the Member State concerned, in order to make it possible for the Commission to issue its opinion before such discharges are authorised so that the Commission's opinion can be taken into account.
- (4) Article 37 has as its objective to forestall any possibility of radioactive contamination of another Member State. The Commission, having consulted the abovementioned group of experts has deemed the disposal of radioactive waste associated with certain operations not to be liable to result in the radioactive contamination of another Member State.
- (5) In exceptional cases due to information received, the Commission may call for general data to be submitted for a plan for the disposal of radioactive waste, otherwise deemed not to be liable to result in the radioactive contamination of another Member State on the basis of the present Recommendation; the Commission's opinion may then pertain to an authorisation which has been granted at an earlier stage.
- (6) To appraise disposal plans in a consistent manner, it is necessary to specify which types of operation may result in the disposal of radioactive waste within the meaning of Article 37 of the Treaty, and to specify for the different types of operation which information is to be supplied as the general data.
- (7) Mixed-oxide fuel fabrication plants process large amounts of plutonium oxide, a submission of general data for the dismantling of such plants should be required as is already the case for the dismantling of nuclear reactors and reprocessing plants.
- (8) Trivial operations having no or negligible radiological impact in other Member States should not be submitted to the Commission.
- (9) Member States may communicate an integrated submission for a complex site where major changes are scheduled to be carried out over a long period of time, involving several steps and including the operation of new facilities, and the completeness of the information contained in the initial general data should allow the Commission to fulfil its obligations pursuant to Article 37 of the Euratom Treaty and deliver a sound opinion.

⁽¹⁾ OJ 81, 21.12.1960, p. 1893/60.

⁽²⁾ OJ L 83, 29.3.1982, p. 15.

⁽³⁾ OJ L 6, 9.1.1991, p. 16.

⁽⁴⁾ OJ L 324, 16.12.1999, p. 23.

⁽⁵⁾ [1988] ECR 5013.

- (10) In view of the number of existing nuclear plants on which no opinion has already been issued within the meaning of Article 37 of the Treaty and which may be subject to modifications or dismantling operations, it is necessary to specify which information is to be supplied as the general data to allow the Commission to fulfil its obligation without prejudice to the principle of equity between installations subject to modifications and those which are not.
- (11) In cases where the exposure of the population in the vicinity of the site of interest is very low, this information may be sufficient for the assessment of the impact on other Member States.
- (12) To appraise in a consistent manner the radiological impact on other Member States of accidental situations, information requested in the general data on unplanned releases from nuclear reactors and reprocessing plants should be extended beyond the reference accidents to accidents taken into consideration for the establishment of the site related national emergency plan.
- (13) To clarify and limit the information required by the Commission pertaining to the predisposal management of radioactive waste and to modifications of a plan on which no opinion has already been issued by the Commission, two new annexes have been included.
- (14) All Member States have now declared that they will desist from sea dumping and no Member State intends to carry out sub-seabed burial of radioactive waste,
- (6) the storage of irradiated nuclear fuel⁽¹⁾ in dedicated facilities (except storage of irradiated nuclear fuel in casks licensed for transport or storage, on existing nuclear sites);
- (7) the handling and processing of artificial radioactive substances on an industrial scale;
- (8) the predisposal management⁽²⁾ of radioactive waste arising from operations (1) to (7) and (9);
- (9) the dismantling⁽³⁾ of nuclear reactors, mixed-oxide⁽⁴⁾ fuel fabrication plants and reprocessing plants (except research reactors whose maximum power does not exceed 50 MW continuous thermal load);
- (10) the emplacement of radioactive waste above or under the ground without the intention of retrieval;
- (11) the industrial processing of naturally occurring radioactive materials subject to a discharge authorisation;
- (12) all other relevant operations.
2. 'General data' within the meaning of Article 37 of the Treaty should be understood to mean:
- for operations referred to in point 1(1) to (7), the information set out in Annex I,
 - for operations referred to in point 1(8), the information set out in Annex II,
 - for operations referred to in point 1(9), the information set out in Annex III,
 - for operations referred to in point 1(10), the information set out in Annex IV,
 - for operations referred to in point 1(11), the relevant parts of the information set out in Annex I (Sections 6 and 7 of Annex I are in most cases not applicable).

HAS ADOPTED THIS RECOMMENDATION:

1. The 'disposal of radioactive waste' within the meaning of Article 37 of the Treaty should cover any planned or accidental release of radioactive substances associated with the operations listed below, in gaseous, liquid or solid form in or to the environment:

- (1) the operation of nuclear reactors (except research reactors whose maximum power does not exceed 1 MW continuous thermal load);
- (2) the reprocessing of irradiated nuclear fuel;
- (3) the mining, milling and conversion of uranium and thorium;
- (4) U-235 enrichment of uranium;
- (5) the fabrication of nuclear fuel;

⁽¹⁾ Provided that the operation is not incorporated in a plan submitted under another heading.

⁽²⁾ The term 'predisposal management' includes storage of radioactive waste.

⁽³⁾ Decommissioning comprises all technical and administrative procedures, activities and measures taken after the final shut-down of a facility and up to the release of the site for unrestricted or other licensed use. Within these activities 'dismantling' comprises disassembling, cutting and demolition of contaminated or activated components, systems and structures including their packaging and transfer off-site.

⁽⁴⁾ Oxides of uranium and plutonium.

3. Operations falling within the scope of point 1(12) should be deemed not to be liable to result in the radioactive contamination of another Member State, significant from the point of view of health, unless in any specific case the Commission calls for general data to be provided.
4. For operations falling within the scope of point 1(9), the submission of general data should be governed by the following conditions:
 - (a) submission of general data is necessary if
 - a new licence or authorisation for a plan for the disposal of radioactive waste in whatever form for the dismantling is envisaged by the Member State, or
 - dismantling of the contaminated or activated parts of the plant will be started;
 - (b) if a Member State envisages dismantling an installation referred to in point 1(9) on which no opinion has already been given under the terms of Article 37, the general data should be submitted in the form of Annex III;
 - (c) if a Member State envisages dismantling a plant referred to in point 1(9) on which an opinion has already been given under the terms of Article 37, the general data should be submitted in the form of Annex III. However, with regard to the description of the site and its surroundings, the emergency plans and the environmental monitoring, reference to the general data submitted for the earlier procedure is sufficient if all appropriate additional information is provided as regards possible changes.
5. If a Member State envisages modifying ⁽¹⁾ a plan for the disposal of radioactive waste, the submission of general data should be governed by the following conditions:
 - (a) if a Member State envisages modifying a plan for the disposal of radioactive waste, on which an opinion has already been given under the terms of Article 37, a submission of general data containing at least the information set out in a standard form in Annex V is necessary if the authorised limits or the associated requirements for the disposal of radioactive waste are less restrictive than in the existing plan or if the potential consequences of the unplanned releases which may follow the accident(s) evaluated in the licensing procedure are increased;
 - (b) unless the Commission calls for general data to be communicated, no submission of general data is necessary if no new authorisation or licence is required;
 - (c) unless the Commission calls for general data to be communicated, no submission of general data is necessary if:
 - the modification of the plan for the disposal of radioactive waste envisages unchanged or more restrictive authorised limits and associated requirements than in the existing plan, and
 - the potential consequences of the unplanned releases which may follow the reference accident(s) evaluated in the licensing procedure are unchanged or decreased;
 - (d) in the case of a plan for the disposal of radioactive waste on which no opinion has already been given under the terms of Article 37, a submission of the general data is necessary unless the Member State provides the Commission with a statement demonstrating that the conditions outlined in point (b) and (c) are met. If any of these conditions are not met, the general data should contain the relevant information set out in Annex VI.
6. The general data should be submitted to the Commission:
 - (a) after the plan for the disposal of radioactive waste is firmly established, and whenever possible one year but not less than six months:
 - before any authorisation for the discharge of radioactive waste is granted by competent authorities, and
 - before start-up of those operations for which no authorisation for the discharge of radioactive waste is foreseen;
 - (b) in cases where the Commission has called for general data in accordance with point 3, no later than six months after the request, without prejudice to any authorisation duly granted by the competent authorities pending receipt of the Commission's request. Any authorisation granted before the Commission called for general data should be reviewed in the light of the Commission's subsequent opinion.

⁽¹⁾ Modifications of a plan might also include preparatory work in view of the operations referred to in point 1(9).

7. Where Member States communicate an integrated submission of general data for a complex site where major changes are scheduled to be carried out over long periods of time, involving several steps and including, inter alia, the operation of new facilities, the initial submission should contain a complete and detailed overview of the planned operations, to be updated by subsequent submissions in case of any modifications to the existing plan. As regards the accident scenarios in the initial submission, the general data should include at least information on estimated amounts and physico-chemical forms of radionuclides present in each of the facilities on the site as well as quantities assumed to be released in the event of the accident considered for each of those facilities. The general data may provide background on past and current operations on the site, bearing in mind that the Commission's opinions will relate only to future operations.
 8. Since submission of a plan for the disposal of radioactive waste is the responsibility of the relevant Member State, that State should accept responsibility for all information submitted to the Commission in respect of such a plan.
 9. Following receipt of an opinion, the Member State concerned should inform the Commission of the actions it envisages in response to any recommendation given in the Commission opinion on a disposal plan.
 10. Following receipt of an opinion, the Member State concerned should communicate to the Commission the discharge authorisation as well as any later amendments for comparison with the information in the general data on which the Commission opinion was based.
- This Recommendation is addressed to the Member States.
- It replaces Recommendation 1999/829/Euratom.
- Done at Brussels, 11 October 2010.
- For the Commission*
Günther OETTINGER
Member of the Commission
-

ANNEX I

General data applicable to the operations referred to in point 1(1) to (7)

Introduction

- general presentation of the plan,
- present stage of licensing procedure, envisaged commissioning steps.

1. THE SITE AND ITS SURROUNDINGS**1.1. Geographical, topographical and geological features of the site and the region with**

- a map of the region showing the location and geographical coordinates (degrees, minutes) of the site,
- the relevant features of the region, including geological features,
- the location of the installation in relation to such other installations, the discharges from which need to be considered in conjunction with those from the installation in question,
- the location of the site with regard to other Member States giving the distances from frontiers and relevant conurbations, together with their populations.

1.2. Seismology

- the degree of seismic activity in the region; probable maximum seismic activity and designed seismic resistance of the installation.

1.3. Hydrology

For an installation situated near to a waterbody providing a potential contamination pathway to another Member State, a brief description of appropriate hydrological features, extending to the other Member State(s), for example:

- brief description of the path(s), tributaries, estuary, water abstraction, floodplains, etc.,
- average, maximum and minimum water flows and their frequency of occurrence,
- underground water table, levels and flows,
- brief description of the littoral areas,
- direction and force of currents, tides, circulation patterns, both local and regional,
- flood risk and protection of the installation.

1.4. Meteorology

Local climatology with frequency distributions of:

- wind directions and speeds,
- precipitation intensity and duration,
- for each wind sector, atmospheric dispersion conditions, duration of temperature inversions,
- extreme weather phenomena (for example, tornadoes, severe storms, heavy rainfall, droughts).

1.5. Natural resources and foodstuffs

Brief description of:

- water utilisation in the region and as appropriate in neighbouring Member States,
- principal food resources in the region and as appropriate in other Member States: crops, stock breeding, fishing and, for discharges into sea, data on fishing in territorial and extraterritorial waters,
- foodstuff distribution system and particularly the export to other Member States from the regions concerned, in so far as they are related to the risk of exposure from discharges through the significant exposure pathways.

1.6. Other activities in the vicinity of the site

- where appropriate, other nuclear facilities and any hazardous industrial or military activities, surface and aerial traffic, pipelines, storages and any other factors which may have an influence on the safety of the installation,
- protection measures.

2. THE INSTALLATION

2.1. Main features of the installation

- brief description of the installation,
- type, purpose and main features of the processes,
- site layout plan,
- safety provisions.

2.2. Ventilation systems and the treatment of gaseous and airborne wastes

Description of ventilation, decay, filtration and discharge systems, in normal conditions and in the case of an accident, including flow diagrams

2.3. Liquid waste treatment

Description of liquid waste treatment facilities, storage capacities and discharge systems, including flow diagrams

2.4. Solid waste treatment

Description of solid waste treatment facilities and storage capacities

2.5. Containment

Description of systems and provisions to confine radioactive substances

2.6. Decommissioning and dismantling

- envisaged period of operation of the installation,
- consideration given to decommissioning and dismantling,
- outline of regulatory and administrative provisions for decommissioning and dismantling.

3. RELEASE FROM THE INSTALLATION OF AIRBORNE RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

3.1. Authorisation procedure in force

- outline of the procedure in force,
- discharge limits and associated requirements envisaged by the authorities, including the assumed radionuclide composition.

3.2. Technical aspects

- annual discharges foreseen,
- origins of the radioactive effluents, their composition and physico-chemical forms,
- management of these effluents, methods and paths of release.

3.3. Monitoring of discharges

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of the monitoring equipment,
- for operations listed under (1) and (2), key radionuclides and associated detection limits should at least fulfil the specifications laid down in Commission Recommendation 2004/2/Euratom ⁽¹⁾,
- alarm levels, intervention actions (manual and automatic).

3.4. Evaluation of transfer to man

Except for operations listed under (1) and (2), if the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 µSv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected ⁽²⁾ Member States are required if doses to the reference groups in the vicinity of the plant are provided.

⁽¹⁾ Commission Recommendation of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation (OJ L 2, 6.1.2004, p. 36).

⁽²⁾ Affected Member States are to be selected by taking into account distance from the installation, wind direction for gaseous effluent releases and the route of water courses for liquid effluent releases.

3.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the plant and for other affected Member States:

- atmospheric dispersion of the effluents,
- ground deposition and re-suspension,
- food chains, inhalation, external exposure etc.,
- living habits (diet, exposure time etc.),
- other parameter values used in the calculations.

3.4.2. Evaluation of concentration and exposure levels associated with the envisaged discharge limits cited in 3.1 above:

- annual average concentrations of activity in the atmosphere near the ground and surface contamination levels, for the most exposed areas in the vicinity of the plant and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States, corresponding annual exposure levels: effective dose to adults, children and infants, taking account of all significant exposure pathways.

3.5. **Radioactive discharges to atmosphere from other installations**

Procedures for coordination with radioactive discharges from other installations referred to in 1.1, third indent

4. **RELEASE FROM THE INSTALLATION OF LIQUID RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS**

4.1. **Authorisation procedure in force**

- outline of the general procedure involved,
- discharge limits and associated requirements envisaged by the authorities, including the assumed radionuclide composition.

4.2. **Technical aspects**

- annual discharges foreseen,
- origins of the radioactive effluents, their composition and physico-chemical forms,
- management of the effluents, methods and paths of release.

4.3. **Monitoring of discharges**

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of monitoring equipment,
- for operations listed under (1) and (2), key radionuclides and associated detection limits should at least fulfil the specifications laid down in Recommendation 2004/2/Euratom,
- alarm levels, intervention actions (manual and automatic).

4.4. **Evaluation of transfer to man**

Except for operations listed under (1) and (2), if the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 µSv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected Member States are required if doses to reference groups in the vicinity of the plant are provided.

4.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the plant and for other affected Member States:

- aquatic dispersion of the effluents,
- their transfer by sedimentation and ion exchange,
- food chains, inhalation of sea spray, external exposure etc.,
- living habits (diet, exposure time etc.),
- other parameter values used in the calculations.

4.4.2. Evaluation of concentration and exposure levels associated with the discharge limits cited in 4.1 above:

- annual average concentrations of activity in surface waters, at the points where such concentrations are highest, in the vicinity of the plant and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States: effective dose to adults, children and infants, taking account of all significant exposure pathways.

4.5. **Radioactive discharges into the same receiving waters from other installations**

Procedures for coordination with discharges from other installations referred to in 1.1, third indent

5. DISPOSAL OF SOLID RADIOACTIVE WASTE FROM THE INSTALLATION

5.1. **Solid radioactive waste**

- categories of solid radioactive waste and estimated amounts,
- processing and packaging,
- storage arrangements on site.

5.2. **Radiological risks to the environment**

- assessment of risks to the environment,
- precautions taken.

5.3. **Off-site arrangements for the transfer of waste**

5.4. **Release of materials from the requirements of the basic safety standards**

- national strategy, criteria and procedures for the release of contaminated and activated materials,
- clearance levels established by competent authorities for disposal, recycling and reuse,
- envisaged types and amounts of released materials.

6. UNPLANNED RELEASES OF RADIOACTIVE EFFLUENTS

6.1. **Review of accidents of internal and external origin which could result in unplanned releases of radioactive substances**

List of the accidents studied in the safety report

6.2. **Reference accident(s) taken into consideration by the competent national authorities for evaluating possible radiological consequences in the case of unplanned releases**

In addition, for operations (1) and (2) accidents taken into consideration by the competent authorities for the establishment of the site related national emergency plan.

Outline of the accident(s) considered and reasons for its (their) choice

6.3. **Evaluation of the radiological consequences of the reference accident(s) and for operations (1) and (2), the accident(s) taken into consideration by the competent authorities for the establishment of the site related national emergency plan**

6.3.1. Accidents entailing releases to atmosphere

Except for operations listed under (1) and (2), if the assessed maximum exposure levels from the reference accident to adults, children and infants in the vicinity of the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the releases to atmosphere,
- release paths; time patterns of the releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameter values used to calculate for the releases their atmospheric dispersion, ground deposition, re-suspension and transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways in the vicinity of the plant and for other affected Member States,

- maximum time-integrated concentrations of radioactivity in the atmosphere near the ground and maximum surface contamination levels (in dry and wet weather) for the most exposed areas in the vicinity of the plant and for relevant areas in other affected Member States,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

6.3.2. Accidents entailing releases into an aquatic environment

Except for operations listed under (1) and (2), if the assessed maximum exposure levels from the reference accident to adults, children and infants close to the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the liquid release,
- release paths, time pattern of releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameters used to calculate for the releases their aquatic dispersion, their transfer by sedimentation and ion exchange, their transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

7. EMERGENCY PLANS, AGREEMENTS WITH OTHER MEMBER STATES

In relation to possible radiological emergencies which may affect other Member States in order to facilitate the organisation of radiological protection in these States:

Brief description of:

- intervention levels established for different types of countermeasures,
- emergency planning arrangements, including the emergency planning zones adopted for the installation,
- arrangements in place for the early exchange of information with other Member States, bilateral or multilateral agreements on transfrontier information, coordination of emergency plans and their implementation and mutual assistance,
- emergency plan testing arrangements with particular reference to the involvement of other Member States.

8. ENVIRONMENTAL MONITORING

- external radiation monitoring,
- monitoring of radioactive substances in air, water, soil and the food chains, whether undertaken by the operator or by competent authorities.

With reference to 3.1 and 4.1 above, monitoring programs as approved by the competent national authorities, organisation, sample forms and frequency, type of monitoring instruments used in normal and accident circumstances; where appropriate, any collaboration arrangements in this respect with neighbouring Member States.

ANNEX II

General data applicable to the operation referred to in point 1(8)**The predisposal management of radioactive waste arising from the operations referred to in point 1(1) to (7) and (9)**

Introduction

- general presentation of the plan,
- present stage of licensing procedure, and
- envisaged commissioning steps.

1. THE SITE AND ITS SURROUNDINGS

1.1. **Geographical, topographical and geological features of the site and the region with**

- a map of the region showing the location and geographical coordinates (degrees, minutes) of the site,
- the relevant features of the region, including geological features,
- the location of the installation in relation to such other installations, the discharges from which need to be considered in conjunction with those from the installation in question,
- the location of the site with regard to other Member States giving the distances from frontiers and relevant conurbations, together with their populations.

1.2. **Seismology**

- the degree of seismic activity in the region; probable maximum seismic activity and designed seismic resistance of the installation.

1.3. **Hydrology**

For an installation situated near to a waterbody providing a potential contamination pathway to another Member State, a brief description of appropriate hydrological features, extending to the other Member State(s), for example:

- brief description of the path(s), tributaries, estuary, water abstraction, floodplains, etc.,
- average, maximum and minimum water flows and their frequency of occurrence,
- underground water table, levels and flows,
- brief description of the littoral areas,
- direction and force of currents, tides, circulation patterns, both local and regional,
- flood risk and protection of the installation.

1.4. **Meteorology**

Local climatology with frequency distributions of:

- wind directions and speeds,
- precipitation intensity and duration,
- for each wind sector, atmospheric dispersion conditions, duration of temperature inversions,
- extreme weather phenomena (for example, tornadoes, severe storms, heavy rainfall, droughts).

1.5. **Natural resources and foodstuffs**

Brief description of:

- water utilisation in the region and as appropriate in neighbouring Member States,
- principal food resources in the region and as appropriate in other Member States: crops, stock breeding, fishing and, for discharges into sea, data on fishing in territorial and extraterritorial waters,

- foodstuff distribution system and particularly the export to other Member States from the regions concerned, in so far as they are related to the risk of exposure from discharges through the significant exposure pathways.

1.6. Other activities in the vicinity of the site

- where appropriate, other nuclear facilities and any hazardous industrial or military activities, surface and aerial traffic, pipelines, storages and any other factors which may have an influence on the safety of the installation,
- protection measures.

2. THE INSTALLATION

2.1. Main features of the installation

- brief description of the installation,
- type, purpose and main features of the processes,
- description of radioactive waste to be received for storage and processing, facilities and storage capacities, categories and types of radioactive waste (for example, low or intermediate level, metal, combustible waste) to be stored and processed, including volumes and radionuclide content,
- site layout plan,
- safety provisions.

2.2. Ventilation systems and the treatment of gaseous and airborne wastes

Description of ventilation, decay, filtration and discharge systems, in normal conditions and in the case of an accident, including flow diagrams

2.3. Liquid waste treatment

Description of secondary liquid waste treatment facilities, storage capacities and discharge systems, including flow diagrams

2.4. Solid waste treatment

Description of secondary solid waste treatment facilities and storage capacities

2.5. Containment

Description of systems and provisions to confine radioactive substances

2.6. Decommissioning and dismantling

- envisaged period of operation of the installation,
- consideration given to decommissioning and dismantling,
- outline of regulatory and administrative provisions for decommissioning and dismantling.

3. RELEASE FROM THE INSTALLATION OF AIRBORNE RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

3.1. Authorisation procedure in force

- outline of the procedure in force,
- discharge limits and associated requirements envisaged by the authorities, including the assumed radionuclide composition.

3.2. Technical aspects

- annual discharges expected,
- origins of the radioactive effluents, their composition and physico-chemical forms,
- management of these effluents, methods and paths of release.

3.3. Monitoring of discharges

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,

- principal features of the monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

3.4. Evaluation of transfer to man

If the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 µSv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected ⁽¹⁾ Member States are required if doses to the reference groups in the vicinity of the plant are provided.

3.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the plant and for other affected Member States:

- atmospheric dispersion of the effluents,
- ground deposition and re-suspension,
- food chains, inhalation, external exposure etc.,
- living habits (diet, exposure time etc.),
- other parameter values used in the calculations.

3.4.2. Evaluation of the concentration and exposure levels associated with the envisaged discharge limits cited in 3.1 above:

- annual average concentrations of activity in the atmosphere near the ground and surface contamination levels, for the most exposed areas in the vicinity of the installation and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States, corresponding annual exposure levels: effective dose to adults, children and infants, taking account of all significant exposure pathways.

3.5. Radioactive discharges to atmosphere from other installations

Procedures for coordination with radioactive discharges from other installations referred to in 1.1, third indent

4. RELEASE FROM THE INSTALLATION OF LIQUID RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

4.1. Authorisation procedure in force

- outline of the general procedure involved,
- discharge limits and associated requirements envisaged by the authorities, including the assumed radionuclide composition.

4.2. Technical aspects

- annual discharges expected,
- origins of the radioactive effluents, their composition and physico-chemical forms,
- management of the effluents, methods and paths of release.

4.3. Monitoring of discharges

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

4.4. Evaluation of transfer to man

If the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 µSv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected Member States are required if doses to reference groups in the vicinity of the plant are provided.

⁽¹⁾ Affected Member States are to be selected by taking into account distance from the installation, wind direction for gaseous effluent releases and the route of water courses for liquid effluent releases.

4.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the plant and for other affected Member States:

- aquatic dispersion of the effluents,
- their transfer by sedimentation and ion exchange,
- food chains, inhalation of sea spray, external exposure etc.,
- living habits (diet, exposure time etc.),
- other parameter values used in the calculations.

4.4.2. Evaluation of concentration and exposure levels associated with the discharge limits cited in 4.1 above:

- annual average concentrations of activity in surface waters, at the points where such concentrations are highest, in the vicinity of the plant and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States: effective dose to adults, children and infants, taking account of all significant exposure pathways.

4.5. **Radioactive discharges into the same receiving waters from other installations**

Procedures for coordination with discharges from other installations referred to in 1.1, third indent

5. DISPOSAL OF SOLID RADIOACTIVE WASTE FROM THE INSTALLATION

5.1. **Solid radioactive waste**

- categories of solid radioactive waste and estimated amounts,
- processing and packaging,
- storage arrangements on site.

5.2. **Radiological risks to the environment**

- assessment of risks to the environment,
- precautions taken.

5.3. **Off-site arrangements for the transfer of waste**

5.4. **Release of materials from the requirements of the basic safety standards**

- national strategy, criteria and procedures for the release of contaminated and activated materials,
- clearance levels established by competent authorities for disposal, recycling and reuse,
- envisaged types and amounts of released materials.

6. UNPLANNED RELEASES OF RADIOACTIVE EFFLUENTS

6.1. **Review of accidents of internal and external origin which could result in unplanned releases of radioactive substances**

List of the accidents studied in the safety report

6.2. **Reference accident(s) taken into consideration by the competent national authorities for evaluating possible radiological consequences in the case of unplanned releases**

Outline of the accident(s) considered and reasons for its (their) choice

6.3. **Evaluation of the radiological consequences of the reference accident(s)**

6.3.1. Accidents entailing releases to atmosphere

If the assessed maximum exposure levels from the reference accident to adults, children and infants in the vicinity of the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the releases to atmosphere,
- release paths; time patterns of the releases,

- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameter values used to calculate for the releases their atmospheric dispersion, ground deposition, re-suspension and transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways in the vicinity of the plant and for other affected Member States,
- maximum time-integrated concentrations of radioactivity in the atmosphere near the ground and maximum surface contamination levels (in dry and wet weather) for the most exposed areas in the vicinity of the plant and for relevant areas in other affected Member States,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

6.3.2. Accidents entailing releases into an aquatic environment

If the assessed maximum exposure levels from the reference accident to adults, children and infants close to the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the liquid release,
- release paths, time pattern of releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameters used to calculate for the releases their aquatic dispersion, their transfer by sedimentation and ion exchange, their transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

7. EMERGENCY PLANS, AGREEMENTS WITH OTHER MEMBER STATES

In relation to possible radiological emergencies which may affect other Member States in order to facilitate the organisation of radiological protection in these States:

Brief description of:

- intervention levels established for different types of countermeasures,
- emergency planning arrangements, including the emergency planning zones adopted for the installation,
- arrangements in place for the early exchange of information with other Member States, bilateral or multilateral agreements on transfrontier information, coordination of emergency plans and their implementation and mutual assistance,
- emergency plan testing arrangements with particular reference to the involvement of other Member States.

8. ENVIRONMENTAL MONITORING

- external radiation monitoring,
- monitoring of radioactive substances in air, water, soil and the food chains, whether undertaken by the operator or by competent authorities.

With reference to 3.1 and 4.1 above, monitoring programs as approved by the competent national authorities, organisation, sample forms and frequency, type of monitoring instruments used in normal and accident circumstances; where appropriate, any collaboration arrangements in this respect with neighbouring Member States.

ANNEX III

General data applicable to the operations referred to in point 1(9)**The dismantling of nuclear reactors, mixed-oxide fuel fabrication plants and reprocessing plants (except research reactors whose maximum power does not exceed 50 MW continuous thermal load)**

Introduction

- general presentation of the plan,
- description of the different decommissioning and dismantling phases envisaged,
- decommissioning and dismantling licensing procedures.

1. THE SITE AND ITS SURROUNDINGS

1.1. **Geographical, topographical and geological features of the site and region with**

- a map of the region showing the location and geographical coordinates (degrees, minutes) of the site,
- the relevant features of the region, including geological features,
- the location of the installation in relation to such installations, the discharges from which need to be considered in conjunction with those from the installation in question,
- the location of the site with regard to other Member States giving the distances from frontiers and relevant conurbations, together with their populations.

1.2. **Hydrology**

For an installation situated near to a waterbody providing a potential contamination pathway to another Member State, a brief description of appropriate hydrological features, extending to the other Member State(s), for example:

- brief description of the path(s), tributaries, estuary, water abstraction, floodplains, etc.,
- average, maximum and minimum water flows and their frequency of occurrence,
- underground water table, levels and flows,
- brief description of the littoral areas,
- direction and force of currents, tides, circulation patterns, both local and regional,
- flood risk and protection of the installation.

1.3. **Meteorology**

Local climatology with frequency distributions of:

- wind directions and speeds,
- precipitation intensity and duration,
- for each wind sector, atmospheric dispersion conditions, duration of temperature inversions,
- extreme weather phenomena (for example, tornadoes, severe storms, heavy rainfall, droughts).

1.4. **Natural resources and foodstuffs**

Brief description of:

- water utilisation in the region and as appropriate in neighbouring Member States,
- principal food resources in the region and as appropriate in other Member States: crops, stock breeding, fishing and, for discharges into sea, data on fishing in territorial and extraterritorial waters,
- foodstuff distribution system and particularly the export to other Member States from the regions concerned, in so far as they are related to the risk of exposure from discharges through the significant exposure pathways.

2. THE INSTALLATION

2.1. Brief description and history of the installation to be dismantled

2.2. Ventilation systems and the treatment of gaseous and airborne wastes

Description of ventilation, decay, filtration and discharge systems during dismantling, in normal conditions and in the case of an accident, including flow diagrams

2.3. Liquid waste treatment

Description of liquid waste treatment facilities during dismantling, storage capacities and discharge systems, including flow diagrams

2.4. Solid waste treatment

Description of solid waste treatment facilities and storage capacities at the site during dismantling

2.5. Containment

Description of systems and provisions to confine radioactive substances

3. RELEASE FROM THE INSTALLATION OF AIRBORNE RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

3.1. Authorisation procedure in force

- outline of the procedure in force,
- discharge limits and associated requirements envisaged by the authorities for the dismantling operations, including the assumed radionuclide composition,
- for comparison: discharge limits and associated requirements in force for the time before the envisaged dismantling operations, including the radionuclide composition.

3.2. Technical aspects

- annual discharges expected during dismantling,
- origins of the radioactive effluents, their composition and physico-chemical forms,
- management of these effluents, methods and paths of release.

3.3. Monitoring of discharges

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of the monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

3.4. Evaluation of transfer to man

If the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 µSv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected ⁽¹⁾ Member States are required if doses to the reference groups in the vicinity of the plant are provided.

3.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the plant and for other affected Member States:

- atmospheric dispersion of the effluents,
- ground deposition and re-suspension,
- food chains, inhalation, external exposure etc.,
- living habits (diet, exposure time etc.),
- other parameter values used in the calculations.

⁽¹⁾ Affected Member States are to be selected by taking into account distance from the installation, wind direction for gaseous effluent releases and the route of water courses for liquid effluent releases.

3.4.2. Evaluation of the concentration and exposure levels associated with the envisaged discharge limits for the dismantling operations cited in 3.1 above:

- annual average concentrations of activity in the atmosphere near the ground and surface contamination levels, for the most exposed areas in the vicinity of the plant and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States, corresponding annual exposure levels: effective dose to adults, children and infants, taking account of all significant exposure pathways.

4. RELEASE FROM THE INSTALLATION OF LIQUID RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

4.1. **Authorisation procedure in force**

- outline of the general procedure involved,
- discharge limits and associated requirements envisaged by the authorities for the dismantling operations, including the assumed radionuclide composition,
- for comparison: discharge limits and associated requirements in force before the envisaged dismantling operations, including the radionuclide composition.

4.2. **Technical aspects**

- annual discharges expected during dismantling,
- origins of the radioactive effluents, their composition and physico-chemical forms,
- management of the effluents, methods and paths of release.

4.3. **Monitoring of discharges**

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

4.4. **Evaluation of transfer to man**

If the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 µSv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected Member States are required if doses to reference groups in the vicinity of the plant are provided.

4.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the plant and for other affected Member States:

- aquatic dispersion of the effluents,
- their transfer by sedimentation and ion exchange,
- food chains, inhalation of sea spray, external exposure, etc.,
- living habits (diet, exposure time etc.),
- other parameter values used in the calculations.

4.4.2. Evaluation of the concentration and exposure levels associated with the envisaged discharge limits for the dismantling operations cited in 4.1 above:

- annual average concentrations of activity in surface waters, at the points where such concentrations are highest, in the vicinity of the plant and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States, corresponding annual exposure levels: effective dose to adults, children and infants, taking account of all significant exposure pathways.

5. DISPOSAL OF SOLID RADIOACTIVE WASTE FROM THE INSTALLATION

5.1. Solid radioactive wastes

- categories of solid radioactive wastes and estimated amounts,
- processing and packaging,
- storage arrangements on site.

5.2. Radiological risks to the environment

- assessment of risks to the environment,
- precautions taken.

5.3. Off-site arrangements for the transfer of waste

5.4. Release of materials from the requirements of the basic safety standards

- national strategy, criteria and procedures for the release of contaminated and activated materials,
- clearance levels established by competent authorities for disposal, recycling or reuse,
- envisaged types and amounts of released materials.

6. UNPLANNED RELEASES OF RADIOACTIVE EFFLUENTS

6.1. Review of accidents of internal and external origin which could result in unplanned releases of radioactive substances

List of the accidents studied in the safety report

6.2. Reference accident(s) taken into consideration by the competent national authorities for evaluating possible radiological consequences in the case of unplanned releases

Outline of the accident(s) considered and reasons for its (their) choice

6.3. Evaluation of the radiological consequences of the reference accident(s)

6.3.1. Accidents entailing releases to atmosphere

If the assessed maximum exposure levels from the reference accident to adults, children and infants in the vicinity of the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the releases to atmosphere,
- release paths; time patterns of the releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameter values used to calculate for the releases their atmospheric dispersion, ground deposition, re-suspension and transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways in the vicinity of the plant and for other affected Member States,
- maximum time-integrated concentrations of radioactivity in the atmosphere near the ground and maximum surface contamination levels (in dry and wet weather) for the most exposed areas in the vicinity of the plant and for relevant areas in other affected Member States,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

6.3.2. Accidents entailing releases into an aquatic environment

If the assessed maximum exposure levels from the reference accident to adults, children and infants close to the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the liquid release,
- release paths, time pattern of releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameters used to calculate for the releases their aquatic dispersion, their transfer by sedimentation and ion exchange, their transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

7. EMERGENCY PLANS, AGREEMENTS WITH OTHER MEMBER STATES

In relation to possible radiological emergencies which may affect other Member States in order to facilitate the organisation of radiological protection in these States:

Brief description of:

- intervention levels established for different types of countermeasures,
- emergency planning arrangements, including the emergency planning zones adopted for the installation,
- arrangements in place for the early exchange of information with other Member States, bilateral or multilateral agreements on transfrontier information, coordination of emergency plans and their implementation and mutual assistance,
- emergency plan testing arrangements with particular reference to the involvement of other Member States.

In the case of reactors no data are required if all nuclear fuel has been transferred off-site to a licensed facility or to an on-site storage facility, on which an opinion has already been given under the terms of Article 37.

8. ENVIRONMENTAL MONITORING

- external radiation monitoring,
- monitoring of radioactive substances in air, water, soil and the food chains, whether undertaken by the operator or by competent authorities.

With reference to 3.1 and 4.1 above, monitoring programs as approved by the competent national authorities, organisation, sample forms and frequency, type of monitoring instruments used in normal and accident circumstances; where appropriate, any collaboration arrangements in this respect with neighbouring Member States.

ANNEX IV

General data applicable to the operations referred to in point 1(10)**The emplacement of radioactive waste above or under the ground without intention of retrieval**

Introduction

- general presentation of the waste emplacement plan,
- general presentation of the repository, type and class of waste,
- present stage of project and licensing procedure, envisaged commissioning and licensing steps,
- timescale, envisaged starting date, operational period and closure date.

1. THE SITE AND ITS SURROUNDINGS

1.1. **Geographical, topographical and geological features of the site and the region with**

- a map of the region showing the location and geographical coordinates (degrees, minutes) of the site,
- the relevant features of the region, including geological features,
- the location of the repository in relation to such other installations, the discharges from which need to be considered in conjunction with those from the installation in question,
- the location of the site with regard to other Member States giving the distances from frontiers and closest conurbations, together with their populations,
- anticipated changes in geography and topography over the time period considered for the assessment of post-closure impact.

1.2. **Geology and seismology**

- geological setting,
- active tectonic processes, historical earthquakes, the degree of seismic activity in the region; probable maximum seismic activity,
- structural and geotechnical soil characteristics, soil liquefaction (*as appropriate*),
- surface processes (landslides and erosion) ⁽⁴⁾,
- anticipated changes in geology over the time period considered for the assessment of post-closure impact.

1.3. **Hydrology and hydrogeology**

A brief description of hydrological features providing a potential contamination pathway to another Member State:

- regional and local water tables and their seasonal variations,
- ground water flow direction and velocity, water discharge and extraction points,
- existing and projected major water users, location of the repository with respect to potential potable water aquifers,
- brief description of the surface water bodies (rivers, lakes, estuary, water abstraction, floodplains, etc.) and littoral areas (*as appropriate*),
- average, maximum and minimum water flows and their frequency of occurrence (*as appropriate*),
- chemical composition of ground water,
- flood risk and protection of the installation (*as appropriate*),
- anticipated changes in hydrology, hydrogeology over the time period considered for the assessment of post-closure impact.

1.4. Meteorology and climate

A brief description of climate and meteorological features:

- wind directions and speeds,
- precipitation intensity (rain and snow) and duration,
- temperature (average, minimal and maximal),
- atmospheric dispersion conditions,
- extreme weather phenomena (for example, tornadoes, severe storms, heavy rainfalls, droughts) ^(a),
- anticipated changes of climate (for example, glacial effects, potential impact of global warming), and, for coastal sites, sea level changes and coastal erosion over the time period considered for the assessment of post-closure impact.

1.5. Natural resources and foodstuffs

A brief description of:

- water utilisation in the region and as appropriate in neighbouring Member States,
- principal food resources in the region and as appropriate in other Member States: crops, stock breeding, fishing and, for discharges into sea, data on fishing in territorial and extraterritorial waters,
- foodstuff distribution system and particularly the export to other Member States from the regions concerned, in so far as they are related to the risk of exposure from discharges through the significant exposure pathways,
- assumptions made on future population patterns, habits and food sources.

1.6. Other activities in the vicinity of the site

- where appropriate, other nuclear facilities and any hazardous industrial or military activities, surface and aerial traffic, pipelines, storages and any other factors which may have an influence on the safety of the installation,
- protection measures *(as appropriate)*,
- anticipated evolution of activities over the time period considered for the assessment of long-term impact.

2. THE REPOSITORY

2.1. Conceptual approach and design

- disposal concept,
- depth and location in relation to geological strata *(as appropriate)* ^(b),
- design criteria for natural phenomena,
- waste emplacement methods, backfill and sealing strategy and methods,
- safety approach: role of the geological and engineered barriers,
- closure of repository,
- approach to retrievability of waste (if applicable),
- auxiliary waste treatment, conditioning and buffer storage facilities to be constructed at the site of the repository.

2.2. Wastes to be disposed of in the repository

- types of waste,
- waste form, applied conditioning methods and characteristics of waste packages (*as appropriate*),
- waste inventory; amounts and radionuclide activities,
- potential heat generation, potential gas generation, potential criticality (*as appropriate*),
- waste acceptance requirements/criteria, waste package verification procedure and techniques to ensure compliance with established waste acceptance criteria.

2.3. Ventilation systems and the treatment of gaseous and airborne wastes

Description of ventilation, filtration and discharge systems, in normal conditions and in the case of an accident (*as appropriate*)

2.4. Drainage system and the treatment of liquid effluents

Description of potentially contaminated water collection, drainage and discharge systems, in normal conditions and in the case of an accident (*as appropriate*)

2.5. Management of secondary solid and liquid waste in normal conditions and in the case of an accident

- categories of secondary liquid and solid radioactive waste and estimated amounts,
- storage and transportation of waste,
- treatment of waste.

3. RELEASE FROM THE INSTALLATION OF AIRBORNE RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

During normal operation of waste disposal facilities only very minor releases of radioactive substances, if any, are expected and significant exposure of members of the public is not anticipated. Therefore this section is not applicable if there is no authorisation for radioactive discharges granted. However, if radionuclide discharge limits are prescribed and discharge monitoring is in place, the general data must be submitted according requirements specified in Section 3 of Annex II.

4. RELEASE FROM THE INSTALLATION OF LIQUID RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

During normal operation of waste disposal facilities only very minor releases of radioactive substances, if any, are expected and significant exposure of members of the public is not anticipated. Therefore this section is not applicable if there is no authorisation for radioactive discharges granted. However, if radionuclide discharge limits are prescribed and discharge monitoring is in place, the general data must be submitted according requirements specified in Section 4 of Annex II.

5. DISPOSAL OF SOLID RADIOACTIVE WASTE FROM THE INSTALLATION

This section is normally not applicable.

6. UNPLANNED RELEASES OF RADIOACTIVE EFFLUENTS**6.1. Review of accidents of internal and external origin which could result in unplanned releases of radioactive substances. Accidents studied in the safety assessment report and evaluated radiological consequences in the case of unplanned releases.****6.2. Evaluation of the radiological consequences of releases to atmosphere**

If the assessed maximum exposure levels from the reference accident to adults, children and infants in the vicinity of the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected ⁽¹⁾ Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the releases to atmosphere,
- release paths; time patterns of the releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,

⁽¹⁾ Affected Member States are to be selected by taking into account distance from the installation, wind direction for gaseous effluent releases and the route of water courses for liquid effluent releases.

- models and parameter values used to calculate for the releases their atmospheric dispersion, ground deposition, re-suspension and transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways in the vicinity of the plant and for other affected Member States,
- maximum time-integrated concentrations of radioactivity in the atmosphere near the ground and maximum surface contamination levels (in dry and wet weather) for the most exposed areas in the vicinity of the plant and for relevant areas in other affected Member States,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

6.3. Evaluation of the radiological consequences of releases into an aquatic environment

If the assessed maximum exposure levels from the reference accident to adults, children and infants close to the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the liquid release,
- release paths, time pattern of releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameters used to calculate for the releases their aquatic dispersion, their transfer by sedimentation and ion exchange, their transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

7. EMERGENCY PLANS; AGREEMENTS WITH OTHER MEMBER STATES

In relation to possible radiological emergencies which may affect other Member States in order to facilitate the organisation of radiological protection in these States:

Brief description of:

- intervention levels established for different types of countermeasures,
- emergency planning arrangements, including the emergency planning zones adopted for the installation,
- arrangements in place for the early exchange of information with other Member States, bilateral or multilateral agreements on crossfrontier information, coordination of emergency plans and their implementation and mutual assistance,
- emergency plan testing arrangements with particular reference to the involvement of other Member States.

8. POST-CLOSURE PERIOD

The different post-closure phases (e.g. active and passive institutional control phases) should be taken into account where appropriate.

8.1. Regulatory and administrative provisions

- plans for the repository closure,
- time periods considered (periods of active and passive institutional control),
- description of measures foreseen for active institutional control period,
- description of measures foreseen for passive institutional control period,

- record-keeping,
- dismantling programme for auxiliary installations,
- periodical safety reviews before closure.

8.2. Radiological impact during post-closure period

If the assessed maximum exposure levels from releases resulting from normal evolution and from early degradation of barriers to adults, children and infants in the vicinity of the installation are below 1 mSv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected Member States are required if doses to reference groups in the vicinity of the plant are provided.

- redundancy and performance of barriers (if relevant),
- time periods considered,
- analysed features, events and processes, description of scenarios assumed (brief descriptions of the normal evolution scenario, most relevant degraded evolution scenarios and human intrusion scenarios),
- methods and techniques used for assessment of radiological impact,
- parameters and assumptions,
- main exposure pathways in vicinity of repository and other affected Member States resulting from normal evolution and for early degradation of barriers,
- activity and timing of radionuclide release,
- corresponding maximum exposure levels: effective doses and/or estimated risks to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways,
- evaluation of the uncertainties.

9. ENVIRONMENTAL MONITORING

- operational monitoring of external radiation and radioactive substances in air, water, soil and the food chains, whether undertaken by the operator or by competent authorities (sample forms and frequency, type of monitoring instruments used in normal and accident circumstances),
- guidelines for post-closure monitoring of radioactive substances in air, water, soil and the food chains, whether undertaken by the operator or by competent authorities ^(a),
- any collaboration arrangements with neighbouring Member States in respect of environmental monitoring.

Notes:

^(a) Relevant for new surface repositories only.

^(b) Relevant for geological repositories only.

ANNEX V

General data applicable to modifications of a plan on which an opinion has already been given

STANDARD FORM

1. Name and location of the facility concerned:
 2. Date of the Commission's Opinion:
 3. Brief description of the planned modifications:
 4. Authorised discharge limits in the existing plan, and other relevant conditions:
 - 4.1. Gaseous effluents:
 - 4.2. Liquid effluents:
 - 4.3. Solid waste:
 5. New discharge limits envisaged by the authorities, including modifications in the assumed radionuclide composition, and other relevant conditions:
 - 5.1. Gaseous effluents:
 - 5.2. Liquid effluents:
 - 5.3. Solid waste:
 6. Consequences of the new discharge limits and associated requirements (gaseous and/or liquid effluents) in relation to the evaluation of the exposure of the population in other Member States:
 7. Consequences of the modifications in relation to the disposal of solid waste:
 8. Consequences of the modifications in relation to the reference accident(s) taken into account in the previous opinion:
 9. In the case of new reference accident(s): description and evaluation of the radiological consequences:
 10. Implications of the modifications in relation to the current emergency plans and the current environmental monitoring:
-

ANNEX VI

General data applicable to modifications of a plan on which no opinion has been given yet

Introduction

- general presentation of the plan,
- present stage of licensing procedure.

1. THE SITE AND ITS SURROUNDINGS

1.1. **Geographical, topographical and geological features of the site and the region with**

- a map of the region showing the location and geographical coordinates (degrees, minutes) of the site,
- the relevant features of the region, including geological features,
- the location of the installation in relation to such other installations, the discharges from which need to be considered in conjunction with those from the installation in question,
- the location of the site with regard to other Member States giving the distances from frontiers and closest conurbations, together with their populations.

1.2. **Hydrology**

Data mentioned in this section 1.2 are required only if the modification of the discharges from the plant of liquid radioactive effluents in normal conditions envisages less restrictive authorised limits or associated requirements than in the existing plan or if the potential consequences of the reference accident(s) entailing releases into an aquatic environment are increased.

For an installation situated near to a waterbody providing a potential contamination pathway to another Member State, a brief description of appropriate hydrological features, extending to the other Member State(s), for example:

- brief description of the path(s), tributaries, estuary, water abstraction, floodplains, etc.,
- average, maximum and minimum water flows and their frequency of occurrence,
- brief description of the littoral areas,
- direction and force of currents, tides, circulation patterns, both local and regional.

1.3. **Meteorology**

Data mentioned in this section 1.3 are required only if the modification of the discharges from the plant of gaseous radioactive effluents in normal conditions envisages less restrictive authorised limits or associated requirements than in the existing plan or if the potential consequences of the reference accident(s) entailing releases to atmosphere are increased.

Local climatology with frequency distributions of:

- wind directions and speeds,
- precipitation intensity and duration,
- for each wind sector, atmospheric dispersion conditions, duration of temperature inversions,
- extreme weather phenomena (for example, tornadoes, severe storms, heavy rainfall, droughts).

1.4. **Natural resources and foodstuffs**

Brief description of:

- water utilisation in the region and as appropriate in neighbouring Member States,
- principal food resources in the region and as appropriate in other Member States: crops, stock breeding, fishing, hunting and, for discharges into sea, data on fishing in territorial and extraterritorial waters,
- foodstuff distribution system and particularly the export to other Member States from the regions concerned, in so far as they are related to the risk of exposure from discharges through the significant exposure pathways.

2. **THE INSTALLATION**

- brief description of the installation,
- type, purpose and main features of the processes,
- site layout plan,
- safety provisions,
- waste treatment,
- relevant details of the modification.

3. **RELEASE FROM THE INSTALLATION OF AIRBORNE RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS**

Data mentioned in this section 3 are required only if the modification of the discharges from the plant of gaseous radioactive effluents in normal conditions envisages less restrictive authorised limits or associated requirements than in the existing plan.

3.1. **Authorisation procedure in force**

- outline of the procedure in force,
- current authorisation limits,
- discharge limits and associated requirements envisaged by the authorities, including the assumed radionuclide composition.

3.2. **Technical aspects**

- annual discharges expected,
- composition and physico-chemical forms of the radioactive effluents,
- management of these effluents, methods and paths of release.

3.3. **Monitoring of discharges**

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of the monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

3.4. Evaluation of transfer to man

If the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 μ Sv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected Member States are required if doses to the reference groups in the vicinity of the plant are provided.

3.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the installation and for other affected ⁽¹⁾ Member States:

- atmospheric dispersion of the effluents,
- ground deposition and re-suspension,
- food chains, inhalation, external exposure, etc.,
- living habits (diet, exposure time, etc.),
- other parameter values used in the calculations.

3.4.2. Evaluation of the concentration and exposure levels associated with the envisaged discharge limits cited in 3.1 above:

- annual average concentrations of activity in the atmosphere near the ground and surface contamination levels, for the most exposed areas in the vicinity of the plant and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States, corresponding annual exposure levels: effective dose to adults, children and infants, taking account of all significant exposure pathways.

3.5. Radioactive discharges to atmosphere from other installations

Procedures for coordination with radioactive discharges from other installations referred to in 1.1, third indent

4. RELEASE FROM THE INSTALLATION OF LIQUID RADIOACTIVE EFFLUENTS IN NORMAL CONDITIONS

Data mentioned in this section 4 are required only if the modification of the discharges from the plant of liquid radioactive effluents in normal conditions envisages less restrictive authorised limits or associated requirements than in the existing plan.

4.1. Authorisation procedure in force

- outline of the general procedure involved,
- current authorisation limits,
- discharge limits and associated requirements envisaged by the authorities, including the assumed radionuclide composition.

4.2. Technical aspects

- annual discharges expected,
- composition and physico-chemical forms of the radioactive effluents,
- management of the effluents, methods and paths of release.

⁽¹⁾ Affected Member States are to be selected by taking into account distance from the installation, wind direction for gaseous effluent releases and the route of water courses for liquid effluent releases.

4.3. Monitoring of discharges

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

4.4. Evaluation of transfer to man

If the assessed maximum exposure levels from releases in normal conditions to adults, children and infants in the vicinity of the plant are below 10 μ Sv per annum and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on effective doses in other affected Member States are required if doses to reference groups in the vicinity of the plant are provided.

4.4.1. Models, including where appropriate generic models, and parameter values used to calculate the consequences of the releases in the vicinity of the plant and for other affected Member States:

- aquatic dispersion of the effluents,
- their transfer by sedimentation and ion exchange,
- food chains, inhalation of sea spray, external exposure, etc.,
- living habits (diet, exposure time, etc.),
- other parameter values used in the calculations.

4.4.2. Evaluation of concentration and exposure levels associated with the discharge limits cited in 4.1 above:

- annual average concentrations of activity in surface waters, at the points where such concentrations are highest, in the vicinity of the plant and in other affected Member States,
- for the reference group(s) in the vicinity of the plant and in other affected Member States: effective dose to adults, children and infants, taking account of all significant exposure pathways.

4.5. Radioactive discharges into the same receiving waters from other installations

Procedures for coordination with discharges from other installations referred to in 1.1, third indent

5. DISPOSAL OF SOLID RADIOACTIVE WASTE FROM THE INSTALLATION

Data mentioned in this section 5 are required only if the modification of the disposal from the plant of solid radioactive waste in normal conditions envisages less restrictive authorised limits or associated requirements than in the existing plan.

5.1. Solid radioactive waste

- categories of solid radioactive waste and estimated amounts,
- processing and packaging,
- storage arrangements on site.

5.2. Radiological risks to the environment

- assessment of risks to the environment,
- precautions taken.

5.3. **Off-site arrangements for the transfer of waste**

5.4. **Release of materials from the requirements of the basic safety standards**

- national strategy, criteria and procedures for the release of contaminated or activated materials,
- clearance levels established by competent authorities for disposal, recycling and reuse,
- envisaged types and amounts of released materials.

6. UNPLANNED RELEASES OF RADIOACTIVE EFFLUENTS

Data mentioned in this section 6 are required only if the potential consequences of the reference accident(s) are increased.

6.1. **Review of accidents of internal and external origin which could result in unplanned releases of radioactive substances**

List of the accidents studied in the safety report

6.2. **Reference accident(s) taken into consideration by the competent national authorities for evaluating possible radiological consequences in the case of unplanned releases**

Outline of the accident(s) considered and reasons for its (their) choice

Impact of the modification on the reference accident(s)

6.3. **Evaluation of the radiological consequences of the reference accident(s)**

6.3.1. Accidents entailing releases to atmosphere

Data mentioned in this section 6.3.1 are required only if the potential consequences of the reference accident(s) entailing releases to atmosphere are increased.

If the assessed maximum exposure levels from the reference accident to adults children and infants in the vicinity of the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the releases to atmosphere,
- release paths; time patterns of the releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameter values used to calculate for the releases their atmospheric dispersion, ground deposition, re-suspension and transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways in the vicinity of the plant and for other affected Member States,
- maximum time-integrated concentrations of radioactivity in the atmosphere near the ground and maximum surface contamination levels (in dry and wet weather) for the most exposed areas in the vicinity of the plant and for relevant areas in other affected Member States,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,

- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

If not already submitted under heading 3.3:

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of the monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

6.3.2. Accidents entailing releases into an aquatic environment

Data mentioned in this section 6.3.2 are required only if the potential consequences of the reference accident(s) entailing releases into an aquatic environment are increased.

If the assessed maximum exposure levels from the reference accident to adults children and infants close to the plant are below 1 mSv and there are no exceptional pathways of exposure, e.g. involving the export of foodstuffs, no data on exposure levels in other affected Member States are required if exposure levels in the vicinity of the plant are provided.

- assumptions used to calculate the liquid release,
- release paths, time pattern of releases,
- amounts and physico-chemical forms of those radionuclides released which are significant from the point of view of health,
- models and parameters used to calculate for the releases their aquatic dispersion, their transfer by sedimentation and ion exchange, their transfer via food chains and to evaluate the maximum exposure levels via the significant exposure pathways,
- expected levels of radioactive contamination of foodstuffs which might be exported to other affected Member States,
- corresponding maximum exposure levels: effective dose to adults, children and infants living in the vicinity of the plant and in relevant areas of other affected Member States taking account of all significant exposure pathways.

If not already submitted under heading 4.3:

- sampling, measurement and analysis of discharges, whether undertaken by the operator or by competent authorities,
- principal features of the monitoring equipment,
- alarm levels, intervention actions (manual and automatic).

7. EMERGENCY PLANS; AGREEMENTS WITH OTHER MEMBER STATES

In relation to possible radiological emergencies which may affect other Member States in order to facilitate the organisation of radiological protection in these States

Brief description of:

- intervention levels established for different types of countermeasures,

- emergency planning arrangements, including the emergency planning zones adopted for the installation,
- arrangements in place for the early exchange of information with other Member States, bilateral or multilateral agreements on transfrontier information, coordination of emergency plans and their implementation and mutual assistance,
- emergency plan testing arrangements with particular reference to the involvement of other Member States.

8. ENVIRONMENTAL MONITORING

Relevant information in relation with the modification

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2010 OF THE EU-CROATIA STABILISATION AND ASSOCIATION COUNCIL

of 25 May 2010

on the participation of Croatia as an observer in the European Union Agency for Fundamental Rights' work and the respective modalities thereof

(2010/636/EU)

THE EU-CROATIA STABILISATION AND ASSOCIATION COUNCIL,

Article 2

Having regard to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Croatia, of the other part ⁽¹⁾,

1. The Agency may deal with fundamental rights issues within the scope of Article 3(1) of Regulation (EC) No 168/2007 in Croatia to the extent necessary for its gradual alignment to Community law.

Having regard to Council Regulation (EC) No 168/2007 of 15 February 2007 establishing a European Union Agency for Fundamental Rights ⁽²⁾, and in particular Article 28(2) thereof,

2. To this end the Agency shall be able to carry out in Croatia the tasks laid down in Articles 4 and 5 of Regulation (EC) No 168/2007.

Whereas:

Article 3

(1) The Luxembourg European Council of December 1997 made participation in Community agencies a way of stepping up the pre-accession strategy. The European Council's conclusions provide that 'the Community agencies in which applicant countries will be able to participate will be determined on a case-by-case basis'.

Croatia shall contribute financially to the activities of the Agency referred to Article 4 of Regulation (EC) No 168/2007 in accordance with the provisions laid down in the Annex to this Decision.

Article 4

(2) Croatia shares the aims and objectives laid down for the European Union Agency for Fundamental Rights (the Agency) and subscribes to the scope and description of the tasks of the Agency as laid down in Regulation (EC) No 168/2007.

1. Croatia shall appoint persons complying with the criteria laid down in Article 12(1) of Regulation (EC) No 168/2007 as observer and alternate observer, respectively. They may participate in the works of the Management Board on an equal footing with the members and alternate members appointed by Member States, but without a right to vote.

(3) It is appropriate to enable the participation of Croatia as an observer in the Agency's work and to lay down the modalities for such participation including provisions relating to participation in initiatives undertaken by the Agency, to the financial contribution and to staff.

2. Croatia shall nominate a government official as a National Liaison Officer, as referred to in Article 8(1) of Regulation (EC) No 168/2007.

(4) It is also appropriate that the Agency deal with fundamental rights issues within the scope set out by Regulation (EC) No 168/2007 in Croatia to the extent necessary for its gradual alignment to Community law,

3. Within 4 months of the entry into force of this Decision, Croatia shall inform the Commission of the names, qualifications and contact details of the persons referred to in paragraphs 1 and 2.

HAS DECIDED AS FOLLOWS:

Article 1

Croatia, as a candidate country, shall participate as an observer in the European Union Agency for Fundamental Rights, set up by Regulation (EC) No 168/2007.

Article 5

The data supplied to or emanating from the Agency may be published and shall be made accessible to the public, provided that confidential information is afforded the same degree of protection in Croatia as it is afforded within the Community.

⁽¹⁾ OJ L 26, 28.1.2005, p. 3.

⁽²⁾ OJ L 53, 22.2.2007, p. 1.

Article 6

The Agency shall enjoy in Croatia the same capacity as that afforded to legal entities under Croatia's law.

Article 7

To enable the Agency and its staff to perform their tasks, Croatia shall grant the privileges and immunities identical to those contained in Articles 1 to 4, 6, 7, 11 to 14, 16, 18 and 19 of the Protocol (No 36) on the privileges and immunities of the European Communities, attached to the Treaties establishing the European Community and the European Atomic Energy Community.

Article 8

By way of derogation from Article 12(2)(a) of the Conditions of Employment of Other Servants of the European Communities provided for in Council Regulation (EEC, Euratom, ECSC) No 259/68 ⁽¹⁾, nationals of Croatia enjoying their full rights as citizens may be engaged under contract by the Director of the Agency.

Article 9

The Parties shall each take any general or specific measures required to fulfil their obligations under this Decision and shall notify them to the Stabilisation and Association Council.

Article 10

This Decision shall enter into force on the first day of the second month following the date of its adoption.

Done at Brussels, 25 May 2010.

*For the EU-Croatia Stabilisation and
Association Council*

The President

G. JANDROKOVIĆ

⁽¹⁾ OJ L 56, 4.3.1968, p. 1.

ANNEX

FINANCIAL CONTRIBUTION OF CROATIA TO THE EUROPEAN UNION AGENCY FOR FUNDAMENTAL RIGHTS

1. The financial contribution to be paid by Croatia to the general budget of the European Union to participate in the European Union Agency for Fundamental Rights (the Agency), as laid down in point 2, represents the full cost of its participation therein.
2. The financial contribution to be paid by Croatia to the general budget of the European Union shall be as follows:

Year 1:	EUR 180 020
Year 2:	EUR 180 020
Year 3:	EUR 180 020
Year 4:	EUR 205 020
Year 5:	EUR 205 020

3. The possible financial support from Community assistance programmes will be agreed separately in accordance with the relevant Community programme.
4. The contribution of Croatia will be managed in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽¹⁾.
5. Travel costs and subsistence costs incurred by representatives and experts of Croatia for the purposes of taking part in the Agency or meetings related to the implementation of the Agency's work programme shall be reimbursed by the Agency on the same basis as, and in accordance with the procedures currently in force for, the Member States of the European Union.
6. After the entry into force of this Decision and at the beginning of each following year, the Commission will send Croatia a call for funds corresponding to its contribution to the Agency under this Decision. For the first calendar year of its participation, Croatia will pay a contribution calculated from the date of participation to the end of the year on a pro rata basis. For the following years, the contribution will be in accordance with this Decision.
7. This contribution shall be expressed in EUR and paid into a EUR bank account of the Commission.
8. Croatia will pay its contribution according to the call for funds for its own part at the latest within 30 days after the call for funds is sent by the Commission.
9. Any delay in the payment of the contribution shall give rise to the payment of interest by Croatia on the outstanding amount from the due date. The interest rate corresponds to the rate applied by the European Central Bank, on the due date, for its operations in EUR, increased by 1,5 percentage points.

⁽¹⁾ OJ L 248, 16.9.2002, p. 1.

**DECISION No 1/2010 OF THE JOINT CUSTOMS COOPERATION COMMITTEE
of 24 June 2010**

**pursuant to Article 21 of the Agreement between the European Community and the Government
of Japan on Cooperation and Mutual Administrative Assistance in Customs Matters**

**regarding mutual recognition of Authorised Economic Operators programmes in the European
Union and in Japan**

(2010/637/EU)

THE JOINT CUSTOMS COOPERATION COMMITTEE (hereinafter referred to as 'the JCCC'),

Having regard to the Agreement between the European Community and the Government of Japan on Cooperation and Mutual Administrative Assistance in Customs Matters, signed on 30 January 2008 (hereinafter referred to as 'the CCMAAA'), and in particular Article 21 thereof,

Considering that a joint evaluation has confirmed that Authorised Economic Operators (hereinafter referred to as 'AEO') programmes in the European Union (hereinafter referred to as 'the Union') and in Japan are security and compliance initiatives and has revealed that their qualification standards for membership are compatible and lead to equivalent results,

Considering that the programmes apply internationally recognised security standards advocated by the SAFE Framework of Standards adopted by the World Customs Organisation (hereinafter referred to as 'the SAFE Framework'),

Acknowledging the special nature of the legislation and management of each programme,

Considering that, in accordance with the CCMAAA, the Union and Japan are to develop customs cooperation to facilitate trade and that customs security and safety, and facilitation of the international trade supply chain, can be significantly enhanced by mutual recognition of their AEO programmes, and

Considering that mutual recognition allows the Union and Japan to provide facilitative benefits to operators who have invested in supply chain security and have been certified by their AEO programmes,

HAS DECIDED AS FOLLOWS:

I

Mutual Recognition and Responsibility for Implementation

1. The AEO programmes of the Union and Japan are hereby mutually recognised to be compatible and equivalent and the corresponding AEO statuses granted are mutually accepted.
2. The customs authorities defined in Article 1(c) of the CCMAAA (hereinafter referred to as 'customs authorities') are responsible for implementation of this Decision.

3. The AEO programmes concerned are:

- (a) the European Union Authorised Economic Operator programme (covering the 'security and safety' AEO certificate and the 'customs simplifications, security and safety' AEO certificates)

(Council Regulation (EEC) No 2913/92 ⁽¹⁾ and Commission Regulation (EEC) No 2454/93 ⁽²⁾, as amended by Regulation (EC) No 648/2005 of the European Parliament and of the Council ⁽³⁾ and Title IIA of Regulation (EC) No 1875/2006 ⁽⁴⁾); and

- (b) the Japanese Authorised Economic Operators programme (Customs Law).

II

Compatibility

1. The customs authorities maintain the consistency between the programmes and ensure that standards applied to each programme remain compatible with respect to the following matters:
 - (a) application process for granting AEO status;
 - (b) assessment of applications; and
 - (c) granting and monitoring AEO status.
2. The customs authorities ensure that the programmes operate within the SAFE Framework.

III

Benefits

1. Each customs authority provides comparable benefits to economic operators holding AEO status under the other customs authority's programme.

These include, in particular:

- (a) taking the AEO status of an operator authorised by the other customs authority into account favourably in its risk assessment to reduce inspections or controls and in other security-related measures; and

⁽¹⁾ OJ L 302, 19.10.1992, p. 1.

⁽²⁾ OJ L 253, 11.10.1993, p. 1.

⁽³⁾ OJ L 117, 4.5.2005, p. 13.

⁽⁴⁾ OJ L 360, 19.12.2006, p. 64.

- (b) endeavouring to establish a joint business continuity mechanism to respond to disruptions in trade flows due to increases in security alert levels, border closures and/or natural disasters, hazardous emergencies or other major incidents, where priority cargos shipped by AEO could be facilitated and expedited to the extent possible by the customs authorities.
2. Each customs authority may also provide further benefits with a view to facilitating trade following the review process referred to in paragraph 2 of Part V of this Decision.
 3. Each customs authority retains the authority to suspend the benefits provided to members of the other customs authority's programme under this Decision. Such suspension of benefits by one customs authority is promptly communicated and reasoned to the other customs authority for consultation.
 4. Each customs authority reports irregularities involving economic operators holding AEO status under the other customs authority's programme to the other customs authority in order to ensure immediate analysis of the appropriateness of the benefits and status granted by the other customs authority.

IV

Information Exchange and Communication

1. The customs authorities enhance communication in order to implement this Decision effectively. They exchange information and foster communication on their programmes in particular by:
 - (a) providing updates on operation and development of their programmes in a timely manner;
 - (b) engaging in mutually beneficial exchanges of information regarding supply chain security; and
 - (c) ensuring effective inter-agency communication between the European Commission Directorate-General for Taxation and Customs Union and the International Intelligence Office of the Customs Administration of Japan to enhance risk management practices with respect to supply chain security on the part of the members of the programmes.
2. Exchanges of information are conducted in accordance with the CCMAAA in electronic format.
3. Information and related data, notably on members of the programmes, are exchanged in a systematic manner by electronic means.
4. Details to be exchanged on economic operators authorised by the AEO programmes include:
 - (a) the name of the economic operator holding AEO status;
 - (b) the address of the economic operator concerned;
 - (c) the status of the economic operator concerned;
 - (d) the validation or authorisation date;
 - (e) suspensions and revocations;
 - (f) the unique authorisation number (e.g. EORI or AEO numbers); and
 - (g) other details that may be established between the customs authorities.
5. The customs authorities guarantee data protection in accordance with the CCMAAA, in particular Article 16 thereof.
6. The data exchanged are used strictly for the purposes of implementing this Decision.

V

Consultation and Review

1. All issues related to implementation of this Decision are to be settled by consultations between the customs authorities in the framework of the JCCC.
2. The JCCC reviews implementation of this Decision regularly. This review process may include, in particular:
 - (a) joint verifications to identify strengths and weaknesses in implementing mutual recognition;
 - (b) exchanges of views on details to be exchanged and benefits, including any future benefit, to be granted to operators in accordance with paragraph 2 of Part III of this Decision;
 - (c) exchanges of views on security provisions such as protocols to be followed during and after a serious security incident (business resumption) or when conditions merit suspension of mutual recognition;
 - (d) reviews of conditions for suspension of the benefits referred to in paragraph 3 of Part III of this Decision; and
 - (e) comprehensive reviews of this Decision.
3. This Decision may be modified by a decision of the JCCC.

VI

General Acknowledgments

1. This Decision implements the existing provisions of the CCMAAA and does not constitute a new international agreement.

2. All activities of each customs authority pursuant to this Decision are carried out in accordance with the respective laws and regulations of the Union and Japan and the applicable international agreements to which they are a party.
3. The contents of this Decision are without prejudice to customs authorities granting assistance to each other.

3. The cooperation under this Decision may be terminated by a decision of the JCCC.

Done at Brussels, 24 June 2010.

VII

Commencement, Suspension and Termination

1. The cooperation under this Decision commences on 24 June 2010.
2. Either customs authority may suspend cooperation under this Decision at any time but provides at least thirty (30) days written notice thereof.

For the EU-Japan Joint Customs Cooperation Committee

*Director-General Taxation and
Customs Union of the European
Commission*

Walter DEFFAA

*Director-General Customs and
Tariff Bureau of Ministry of
Finance, Japan*

Toshiyuki OHTO

CORRIGENDA

Corrigendum to Commission Regulation (EU) No 950/2010 of 21 October 2010 fixing the export refunds on eggs*(Official Journal of the European Union L 278 of 22 October 2010)*

On page 18, the text of the Regulation shall read as follows:

**‘COMMISSION REGULATION (EU) No 950/2010
of 21 October 2010
fixing the export refunds on eggs**

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⁽¹⁾, and in particular Article 164(2), and Article 170, in conjunction with Article 4 thereof,

Whereas:

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

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

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

(4) Refunds should be granted only on products which are authorised to move freely within the Union and comply with requirements under Regulation (EC) No 852/2004

of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁽²⁾ and of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁽³⁾, as well as marking requirements under point A of Annex XIV to Regulation (EC) No 1234/2007.

(5) The currently applicable refunds have been fixed by Commission Regulation (EU) No 653/2010⁽⁴⁾. Since new refunds should be fixed, that Regulation should therefore be repealed.

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

HAS ADOPTED THIS REGULATION:

Article 1

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

2. The products eligible for a refund under paragraph 1 shall meet the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and, in particular, shall be prepared in an approved establishment and comply with the marking conditions laid down in Section I of Annex II to Regulation (EC) No 853/2004 and those defined in point A of Annex XIV to Regulation (EC) No 1234/2007.

Article 2

Regulation (EU) No 653/2010 is hereby repealed.

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 139, 30.4.2004, p. 1.

⁽³⁾ OJ L 139, 30.4.2004, p. 55.

⁽⁴⁾ OJ L 191, 23.7.2010, p. 13.

Article 3

This Regulation shall enter into force on 22 October 2010.

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

Done at Brussels, 21 October 2010.

*For the Commission,
On behalf of the President,
Jean-Luc DEMARTY
Director-General for Agriculture and
Rural Development*

ANNEX

Export refunds on eggs applicable from

Product code	Destination	Unit of measurement	Amount of refund
0407 00 11 9000	A02	EUR/100 pcs	0,39
0407 00 19 9000	A02	EUR/100 pcs	0,20
0407 00 30 9000	E09	EUR/100 kg	0,00
	E10	EUR/100 kg	22,00
	E19	EUR/100 kg	0,00
0408 11 80 9100	A03	EUR/100 kg	84,72
0408 19 81 9100	A03	EUR/100 kg	42,53
0408 19 89 9100	A03	EUR/100 kg	42,53
0408 91 80 9100	A03	EUR/100 kg	53,67
0408 99 80 9100	A03	EUR/100 kg	9,00

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

The other destinations are defined as follows:

E09: Kuwait, Bahrain, Oman, Qatar, the United Arab Emirates, Yemen, Hong Kong SAR, Russia and Turkey.

E10: South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines.

E19: all destinations except Switzerland and those of E09 and E10.

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

2010/636/EU:

- ★ **Decision No 1/2010 of the EU-Croatia Stabilisation and Association Council of 25 May 2010 on the participation of Croatia as an observer in the European Union Agency for Fundamental Rights' work and the respective modalities thereof** 68

2010/637/EU:

- ★ **Decision No 1/2010 of the Joint Customs Cooperation Committee of 24 June 2010 pursuant to Article 21 of the Agreement between the European Community and the Government of Japan on Cooperation and Mutual Administrative Assistance in Customs Matters regarding mutual recognition of Authorised Economic Operators programmes in the European Union and in Japan** 71

Corrigenda

- Corrigendum to Commission Regulation (EU) No 950/2010 of 21 October 2010 fixing the export refunds on eggs (OJ L 278, 22.10.2010) 74

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