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Legislation

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Price: EUR 4

⁽¹⁾ Text with EEA relevance

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 113/2010

of 9 February 2010

implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards trade coverage, definition of the data, compilation of statistics on trade by business characteristics and by invoicing currency, and specific goods or movements

(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 471/2009 of the European Parliament and of the Council of 6 May 2009 on Community statistics relating to external trade with non-member countries and repealing Council Regulation (EC) No 1172/95 ⁽¹⁾, and in particular Article 3(2), (3) and (4), Article 4(5), Article 5(2) and (4), Article 6(2) and (3) and Article 8(1) and (2) thereof,

Whereas:

- (1) Regulation (EC) No 471/2009 establishes a common framework for the systematic production of European statistics relating to the trading of goods with non-member countries.
- (2) It is necessary to align the scope of external trade statistics with specific customs procedures in order to avoid double counting of trade flows, and to specify the goods or movements exempted from external trade statistics for methodological reasons.
- (3) For the purpose of harmonised compilation of external trade statistics, the data from records on imports and exports, including the codes to be used, should be specified.
- (4) Provisions applicable to specific goods or movements should be established for methodological reasons.
- (5) In order to ensure harmonised compilation of statistics on trade by business characteristics and aggregated statistics on trade broken down by invoicing currency, the methodology for production of these statistics should be defined.
- (6) Provisions relating to the transmission of data by Member States to the Commission (Eurostat) and to

the revision of statistics should be laid down in order to ensure comparable and accurate figures.

- (7) The codes of nature of transaction should be amended in order to identify goods for processing under contract returning to the initial country of exports.
- (8) Measures should be adopted which ensure the provision of statistical data when further simplifications of customs formalities and controls would lead to non-availability of customs data, in particular simplifications pursuant to Article 116 of Regulation (EC) No 450/2008 of the European Parliament and of the Council of 23 April 2008 laying down the Community Customs Code (Modernised Customs Code) ⁽²⁾.
- (9) Commission Regulation (EC) No 1917/2000 of 7 September 2000 laying down certain provisions for the implementation of Council Regulation (EC) No 1172/95 as regards statistics on external trade ⁽³⁾ should consequently be repealed.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Committee on statistics relating to the trading of goods with non-member countries,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Excluded goods and movements

The goods and movements listed in Annex I shall be excluded from external trade statistics.

⁽¹⁾ OJ L 152, 16.6.2009, p. 23.

⁽²⁾ OJ L 145, 4.6.2008, p. 1.

⁽³⁾ OJ L 229, 9.9.2000, p. 14.

CHAPTER 2

DATA DEFINITION AND SPECIFICATION

Article 2

Trade flow codes

The following codes shall be used for data derived from customs records on the trade flow:

- 1 — when an import is recorded,
- 2 — when an export is recorded.

Article 3

Reference period

1. The reference period shall indicate the calendar year and month in which the goods are imported or exported.

When the customs declaration is the source for records on imports and exports, the reference period shall indicate the calendar year and month when the declaration is accepted by customs authorities.

2. The data on the reference period shall be a six-digit numerical code, where the first four digits indicate the year and the last two digits indicate the month.

Article 4

Statistical value

1. The statistical value shall be based on the value of the goods at the time and place the goods cross the border of the Member State of destination on import and of the Member State of actual export on export.

The statistical value shall be calculated on the basis of the value of the goods referred to in paragraph 2 and, where necessary, adjusted for the costs of transport and insurance according to paragraph 4.

2. With respect to the valuation principles laid down in the agreement on the implementation of Article VII of the General Agreement on Tariffs and Trade (WTO customs valuation agreement), the value of the goods for imports or exports shall be:

- (a) in the event of a sale or purchase, the price actually paid or payable for the imported or exported goods, excluding arbitrary or fictitious values;
- (b) in other cases, the price which would have been paid in the event of sale or purchase.

The customs value shall be used if determined according to the Customs Code for goods released for free circulation.

3. The value of goods involved in processing operations shall be determined on a gross basis as follows:

- (a) the value of the unprocessed goods shall be established for goods with a view to processing;
- (b) the value of the unprocessed goods plus the added value of the processing activity shall be established for goods following processing.

4. The value as referred to in paragraphs 2 and 3 shall be adjusted, where necessary, in such a way that the statistical value contains solely and entirely the costs of transport and insurance performed to deliver the goods from the place of their departure:

- (a) to the border of the Member State of destination on import (CIF-type value);
- (b) to the border of the Member State of actual export on export (FOB-type value).

5. The statistical value shall be expressed in the national currency of the Member State where the customs declaration is lodged. Where a conversion of currency is necessary for expressing the statistical value in the national currency, the rate of exchange to be used shall be:

- (a) the rate applicable according to the provisions on currency conversion laid down in the Customs Code at the time the customs declaration is accepted; or failing this
- (b) the reference rate applicable at the time the goods are imported or exported set by the European Central Bank for Member States belonging to the euro area or the official rate set by Member States not belonging to the euro area.

Article 5

Quantity

The data on the quantity shall be indicated as follows:

- (a) the net mass expressed in kilograms, which is the mass of the goods excluding all packaging; and
- (b) where applicable, the supplementary unit expressed in the respective measurement unit, according to the Combined Nomenclature in force.

Article 6

Importing and exporting Member States

1. The data on the importing or exporting Member States shall be coded in accordance with the nomenclature of countries and territories for the external trade statistics of the European Union and statistics of trade between Member States as laid down by the Commission, hereinafter referred to as the 'Geonomenclature'.

2. The data on the Member State where the customs declaration is lodged shall indicate the Member State with whose customs administration the customs declaration is lodged, or if a simplified procedure as defined in the Customs Code is used, to whose customs administration the supplementary declaration is submitted, including, if allowed by the customs authorities, the respective entry in the declarant's records.

3. On import, the data on the Member State of destination shall indicate the Member State to which it is known, at the time of release into the customs procedure, that the goods will be dispatched without any commercial transactions or other operations which change the legal status of the goods taking place in any intermediate Member State.

Failing that, the data shall indicate the Member State where the goods are located at the time of release into the customs procedure.

Where goods are imported with a view to processing under customs supervision, the Member State of destination shall be the Member State where the first processing activity is carried out.

4. On export, the data on the Member State of actual export shall indicate the Member State from which it is known, at the time of release into the customs procedure, the goods are dispatched without any commercial transaction or other operations which change the legal status of the goods taking place in any intermediate Member State before release into the customs procedure.

Where goods are exported following processing under customs supervision, the Member State where the last processing activity was carried out shall be the Member State of actual export.

Article 7

Partner countries

1. The data on the partner countries shall be coded in accordance with the Geonomenclature in force.

2. On import, the data on the country of origin shall indicate the country in which the goods are wholly produced or the last substantial transformation took place in accordance with the provisions of the Customs Code laying down the rules on non-preferential origin.

The data on the country of consignment/dispatch shall indicate the non-member country from which goods were dispatched to the Member State of destination without any commercial transactions or other operations which change the legal status of the goods taking place in any intermediate non-member country.

3. On export, data on the country of last known destination shall indicate the last non-member country to which it is known at the time of release into the customs procedure or customs approved treatment that the goods are to be delivered.

Article 8

Goods code

The data on the goods shall be coded:

- (a) on imports, according to the goods code of the Taric subheading;
- (b) on exports, according to the goods code of the Combined Nomenclature subheading.

Article 9

Statistical procedure

1. The statistical procedure shall identify the different characteristics used in distinguishing trade transactions, in particular according to their placement under a customs procedure.

2. The statistical procedure code shall be a code derived, if applicable, from the four digit code indicating the declared procedure pursuant to the Customs Code. The following codes shall be used:

- 1 — normal imports or exports,
- 2 — imports or exports covered by the customs inward processing procedure,
- 3 — imports or exports covered by the customs outward processing procedure,
- 9 — imports or exports not recorded from customs declarations.

Article 10

Nature of transaction

1. The nature of transaction shall identify the different characteristics which are required to determine the scope of trade in goods based on customs declarations, in order to reconcile trade statistics for Balance of Payments and National Accounts purposes and for other characteristics of statistical relevance.

2. The data on the nature of transaction shall be coded as specified in Annex II. Member States shall apply the codes in column A or a combination of the codes in column A and their subdivisions in column B indicated in that Annex.

Article 11

Preferential treatment on imports

1. The data on preferential treatment shall be the tariff treatment indicated by the preference code according to the classification laid down by the Customs Code.

2. The data shall refer to the preferential treatment applied or granted by the customs authorities.

Article 12

Mode of transport

1. The data on the mode of transport at the frontier and the internal mode of transport shall be coded as set out in Annex III.

The mode of transport at the frontier shall indicate the active means of transport by which, on export, the goods are presumed to leave the statistical territory of the European Union and, on import, the goods are presumed to have entered the statistical territory of the European Union.

The internal mode of transport shall indicate, if applicable, the active means of inland transport by which the goods reach the place of arrival, on import, or are presumed to have left the place of departure, on export.

2. The following codes shall be used for the data on the container:

- 0 — if goods are not transported in containers when crossing the border of the statistical territory of the European Union,
- 1 — if goods are transported in containers when crossing the border of the statistical territory of the European Union.

Article 13

Trader identification

The data on the trader shall be an appropriate identification number assigned to the importer/consignee, on import, and to the exporter/consignor, on export.

Article 14

Invoicing currency

The data on the invoicing currency shall be derived, if applicable, from the customs declaration and coded as follows:

- 0 — where the currency is indicated in the national currency of Member States not belonging to the euro area,
- 1 — where the currency is indicated in euro,
- 2 — where the currency is indicated in US dollars,
- 3 — where the currency is indicated in a currency other than the national currency of Member States not belonging to the euro area, euro or US dollars.

CHAPTER 3

COMPILATION OF STATISTICS ON TRADE BY BUSINESS CHARACTERISTICS AND STATISTICS ON TRADE BROKEN DOWN BY INVOICING CURRENCY

Article 15

Compilation of statistics on trade by business characteristics

1. National statistical authorities shall compile annual statistics on trade by business characteristics.
2. The statistical units shall be enterprises as defined in the Annex to Council Regulation (EEC) No 696/93 ⁽¹⁾.
3. Statistical units are constructed by linking the trader identification number according to Article 13 with the legal unit of the Business Register according to the variable 1.7a referred to in the Annex to Regulation (EC) No 177/2008 of the European Parliament and of the Council ⁽²⁾.
4. In order to ensure the identification of the trader and to manage the link with the Business Register, national statistical

authorities shall have access to the registration and identification data of economic operators provided for under customs provisions of the European Union. The authorities responsible for assigning the Economic Operator Registration Identification number shall, at the request of the national statistical authorities, provide access to data listed in Annex 38d to Commission Regulation (EEC) No 2454/93 ⁽³⁾.

5. The following characteristics shall be compiled:

- (a) trade flow;
- (b) statistical value;
- (c) partner country;
- (d) goods code, according to the section or two-digit level as defined in the Annex to Regulation (EC) No 451/2008 of the European Parliament and of the Council ⁽⁴⁾;
- (e) number of enterprises;
- (f) activity carried out by the enterprise according to the section or two-digit level of the statistical classification of economic activity (NACE) as laid down in Annex I to Regulation (EC) No 1893/2006 of the European Parliament and of the Council ⁽⁵⁾;
- (g) size class, measured in terms of number of employees according to the definitions of characteristics for structural business statistics as laid down in Annex I to Commission Regulation (EC) No 250/2009 ⁽⁶⁾.

6. The following datasets shall be compiled:

- (a) matching rates between trade and business registers;
- (b) trade by activity and enterprise size class;
- (c) share of largest enterprises in terms of value of trade by activity;
- (d) trade by partner country and activity;
- (e) trade by number of partner countries and activity;
- (f) trade by goods and activity.

7. The first reference year for which annual statistics are to be compiled shall be 2010. Member States shall provide data for every calendar year thereafter.

8. The statistics shall be transmitted within 18 months of the end of the reference year.

⁽¹⁾ OJ L 76, 30.3.1993, p. 1.

⁽²⁾ OJ L 61, 5.3.2008, p. 6.

⁽³⁾ OJ L 253, 11.10.1993, p. 1.

⁽⁴⁾ OJ L 145, 4.6.2008, p. 65.

⁽⁵⁾ OJ L 393, 30.12.2006, p. 1.

⁽⁶⁾ OJ L 86, 31.3.2009, p. 1.

9. Member States shall ensure that statistics are provided in such a way that dissemination by the Commission (Eurostat) does not make it possible to identify an enterprise or trader. National statistical authorities shall specify what data are affected by confidentiality provisions.

Article 16

Compilation of statistics on trade broken down by invoicing currency

1. National statistical authorities shall compile annual statistics on trade broken down by invoicing currency.

2. The statistics shall contain the following characteristics:

- (a) trade flow;
- (b) statistical value;
- (c) invoicing currency according to the coding in Article 14;
- (d) total and a product breakdown according to sections and divisions of the Standard International Trade Classification (SITC) in force, indicating the following codes:
 - 1 — raw materials without oil according to SITC section 0-4 excluding division 33,
 - 2 — oil according to SITC division 33,
 - 3 — manufactured products according to SITC sections 5-8.

3. The first reference year for which annual statistics shall be compiled is 2010. Member States shall compile the data for every second calendar year thereafter.

4. The statistics shall be transmitted to the Commission (Eurostat) within three months of the end of the reference year.

5. The data source shall be the information recorded from customs declarations according to Article 4(1) of Regulation (EC) No 471/2009. However, if the invoicing currency for exports is not available on the customs declaration, Member States shall carry out a survey for compiling exports broken down by invoicing currency which provides statistics with accurate results.

CHAPTER 4

SPECIFIC GOODS OR MOVEMENTS

Article 17

Industrial plants

1. For the purposes of this Article:

- (a) 'industrial plant' means a combination of machines, apparatus, appliances, equipment, instruments and materials which together make up large-scale, stationary units producing goods or providing services;
- (b) 'component part' means a delivery for an industrial plant which is made up of goods which all belong to the same chapter of the CN;

(c) goods code of a component part shall be composed as follows:

- (i) the first four digits shall be 9880;
- (ii) the fifth and the sixth digits shall correspond to the CN chapter to which the goods of the component part belong;
- (iii) the seventh and the eighth digits shall be 0.

2. Member States may compile export statistics at the level of component parts on condition that the overall statistical value of a given industrial plant exceeds 3 million EUR, unless it is a complete industrial plant for re-use. The compilation of the quantity shall be optional.

Article 18

Staggered consignments

1. For the purposes of this Article 'staggered consignments' means the delivery of components of a complete item in an unassembled or disassembled state which is shipped during more than one reference period for commercial or transport-related reasons.

2. The reference period for imports or exports of staggered consignments may be adjusted so that data are reported only once, in the month when the last consignment is imported or exported.

Article 19

Vessels and aircraft

1. For the purposes of this Article:

- (a) 'vessel' means vessels considered as sea-going according to CN Chapter 89, tugs, warships and floating structures;
- (b) 'aircraft' means aeroplanes falling within CN code 8802 30 and 8802 40;
- (c) 'economic ownership' means the right of a natural or legal person to claim the benefits associated with the use of a vessel or aircraft in the course of an economic activity by virtue of accepting the associated risks.

2. External trade statistics shall cover only the following imports and exports of vessels and aircraft:

- (a) the transfer of economic ownership of a vessel or aircraft from a natural or legal person established in a non-member country to a natural or legal person established in the importing Member State; this transaction shall be treated as an import;
- (b) the transfer of economic ownership of a vessel or aircraft from a natural or legal person established in the exporting Member State to a natural or legal person established in a non-member country; this transaction shall be treated as an export. If the vessel or aircraft is new, the export is recorded in the Member State of construction;
- (c) the import and export of vessels or aircraft before or following processing under contract as defined in Annex II, note 2.

3. External trade statistics relating to trade in vessels and aircraft shall be compiled as follows:

- (a) the quantity shall be expressed in number of items and any other supplementary units laid down in the CN, for vessels, and in net mass and supplementary units, for aircraft;
- (b) transport and insurance costs shall be excluded from the statistical value;
- (c) the partner country shall be:
 - (i) the non-member country where the natural or legal person transferring the economic ownership of the vessel or aircraft is established, on import, or the natural or legal person to whom the economic ownership of the vessel or aircraft is transferred, on export, for movements referred to in paragraph 2(a) and (b);
 - (ii) the non-member country of construction, on import, in the case of new vessels or aircraft constructed outside the European Union;
 - (iii) the non-member country where the natural or legal person who exercises the economic ownership of the vessel or aircraft is established, on import, or the non-member country undertaking the processing under contract, on export, for movements referred to in paragraph 2(c);
- (d) the reference period for imports and exports referred to in paragraph 2(a) and (b) shall be the month when the transfer of economic ownership takes place.

4. At the request of the national statistical authorities, the authorities responsible for managing the ships and aircraft registers shall provide all information available in order to identify a change of economic ownership of a vessel or aircraft between a natural or legal person established in a Member State and a natural or legal person established in a non-member country.

Article 20

Goods delivered to vessels and aircraft

1. For the purposes of this Article:
 - (a) 'delivery of goods to vessels and aircraft' means the delivery of products for the crew and passengers, and for the operation of the engines, machines and other equipment of vessels or aircraft;
 - (b) vessels or aircraft shall be deemed to belong to the country where the natural or legal person who exercises the economic ownership of the vessel or aircraft as defined in Article 19(1)(c) is established.
2. External trade statistics shall cover exports of goods delivered from the territory of the exporting Member State to vessels and aircraft belonging to a non-member country.

3. Member States may use the following goods codes for goods delivered to vessels and aircraft:

- 9930 24 00: goods from CN Chapters 1 to 24,
- 9930 27 00: goods from CN Chapter 27,
- 9930 99 00: goods classified elsewhere.

The transmission of data on the quantity is optional, except for goods belonging to CN Chapter 27.

In addition, the simplified partner country code 'QS' may be used.

Article 21

Goods delivered to and from offshore installations

1. For the purposes of this Article:
 - (a) 'offshore installation' means the equipment and devices installed and stationary in the sea outside the statistical territory of any given country;
 - (b) 'goods delivered to offshore installations' means the delivery of products for the crew and for the operation of the engines, machines and other equipment of the offshore installation;
 - (c) 'goods obtained from or produced by offshore installations' means products extracted from the seabed or subsoil, or manufactured by the offshore installation.
2. External trade statistics shall record:
 - (a) an import, where goods are delivered from:
 - (i) a non-member country to an offshore installation established in an area where the importing Member State has exclusive rights to exploit that seabed or subsoil;
 - (ii) an offshore installation established in an area where a non-member country has exclusive rights to exploit that seabed or subsoil to the importing Member State;
 - (iii) an offshore installation established in an area where a non-member country has exclusive rights to exploit that seabed or subsoil to an offshore installation in an area where the importing Member State has exclusive rights to exploit that seabed or subsoil;
 - (b) an export, where goods are delivered to:
 - (i) a non-member country from an offshore installation established in an area where the exporting Member State has exclusive rights to exploit that seabed or subsoil;

- (ii) an offshore installation established in an area where a non-member country has exclusive rights to exploit that seabed or subsoil from the exporting Member State;
- (iii) an offshore installation established in an area where a non-member country has exclusive rights to exploit that seabed or subsoil from an offshore installation established in an area where the exporting Member State has exclusive rights to exploit that seabed or subsoil.

3. Member States may use the following goods codes for goods delivered to offshore installations:

- 9931 24 00: goods from CN Chapters 1 to 24,
- 9931 27 00: goods from CN Chapter 27,
- 9931 99 00: goods classified elsewhere.

The transmission of data on the quantity is optional, except for goods belonging to CN Chapter 27.

In addition, the simplified partner country code 'QW' may be used.

Article 22

Sea products

1. For the purposes of this Article:
 - (a) 'sea products' means fishery products, minerals, salvage and all other products which have not yet been landed by sea-going vessels;
 - (b) vessels shall be deemed to belong to the country where the natural or legal person who exercises the economic ownership of the vessel as defined in Article 19(1)(c) is established.
2. External trade statistics shall cover the following imports and exports of sea products:
 - (a) the landing of sea products in the ports of the importing Member State, or their acquisition by vessels belonging to the importing Member State from vessels belonging to a non-member country; these transactions being treated as imports;
 - (b) the landing of sea products in the ports of a non-member country from a vessel belonging to the exporting Member State, or their acquisition by vessels belonging to a non-member country from vessels belonging to the exporting Member State; these transactions being treated as exports.
3. The partner country shall be, on import, the non-member country where the natural or legal person who exercises the economic ownership of the vessel which is carrying out the capturing is established and, on export, the non-member

country where the sea products are landed or where the natural or legal person who exercises the economic ownership of the vessel acquiring the sea products is established.

4. Provided that there is no conflict with other acts of Union law, national statistical authorities shall have access to data sources in addition to customs declarations, such as information on declarations of national registered vessels on sea products landed in non-member countries.

Article 23

Spacecraft

1. For the purposes of this Article:
 - (a) 'spacecraft' means vehicles which are able to travel outside the earth's atmosphere;
 - (b) 'economic ownership' means the right of a natural or legal person to claim the benefits associated with the use of a spacecraft in the course of an economic activity by virtue of accepting the associated risks.
2. The launching of a spacecraft for which economic ownership has been transferred between a natural or legal person established in a non-member country and a natural or legal person established in a Member State shall be recorded:
 - (a) as an import in the Member State where the new owner is established;
 - (b) as an export in the Member State of construction of the finished spacecraft.
3. The following specific provisions shall apply to the statistics referred to in paragraph 2:
 - (a) the data on the statistical value shall be defined as the value of the spacecraft, excluding transport and insurance costs;
 - (b) the data on the partner country shall be the non-member country of construction of the finished spacecraft, on import, and the non-member country where the new owner is established, on export.
4. Provided that there is no conflict with other acts of Union law, national statistical authorities shall have access to all available data sources, necessary for the compliance with this Article, in addition to customs declarations.

Article 24

Electricity and gas

1. In addition to customs declarations, national statistical authorities may require that relevant information for recording imports and exports of electricity and gas between the statistical territory of the Member State and non-member countries be provided directly by operators who own or operate a transmission network for electricity or gas.

2. The statistical value transmitted to the Commission (Eurostat) may be based on estimates. Member States shall inform the Commission (Eurostat) of the methodology used for the estimation before application.

Article 25

Military goods

1. External trade statistics shall cover imports and exports of goods intended for military use.

2. Member States may transmit less detailed information than indicated in Article 6(1) of Regulation (EC) No 471/2009 when the information falls under military secrecy in compliance with the definitions in force in the Member State. However, as a minimum, data on the total monthly statistical value of the imports and exports shall be transmitted to the Commission (Eurostat).

CHAPTER 5

FINAL PROVISIONS

Article 26

Transmission of European statistics on imports and exports of goods

1. Member States shall take all necessary measures to ensure that the data transmitted to the Commission (Eurostat) are

exhaustive and comply with the quality criteria as specified in Article 9(1) of Regulation (EC) No 471/2009.

2. The statistics transmitted to the Commission (Eurostat) shall be expressed in national currency of compiling Member State.

3. Where monthly results already transmitted to the Commission (Eurostat) are subject to revisions, Member States shall transmit the revised results no later than in the month following the availability of the revised data.

Article 27

Repeal

Regulation (EC) No 1917/2000 is hereby repealed with effect from 1 January 2010.

It shall continue to apply to data pertaining to reference periods before 1 January 2010.

Article 28

Entry into force

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 2010.

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

Done at Brussels, 9 February 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

LIST OF GOODS AND MOVEMENTS EXCLUDED FROM EXTERNAL TRADE STATISTICS

- (a) monetary gold;
 - (b) means of payment which are legal tender and securities, including means which are payments for services such as postage, taxes, user fees;
 - (c) goods for or following temporary use (e.g. hire, loan, operational leasing), provided all the following conditions are met:
 - no processing is or was planned or carried out,
 - the expected duration of the temporary use was or is not intended to be longer than 24 months,
 - no change of ownership took place or is intended to take place;
 - (d) goods moving between:
 - the Member State and its territorial enclaves in non-member countries, and
 - the host Member State and territorial enclaves of non-member countries or international organisations.

Territorial enclaves include embassies and national armed forces stationed outside the territory of the mother country;
 - (e) goods used as carriers of customised information including software;
 - (f) software downloaded from the Internet;
 - (g) goods supplied free of charge which are themselves not the subject of a commercial transaction, provided that their movement is with the sole intention of preparing or supporting an intended subsequent trade transaction by demonstrating the characteristics of goods or services such as:
 - advertising material,
 - commercial samples;
 - (h) goods for and after repair and replacement parts that are incorporated in the framework of the repair and the replaced defective parts;
 - (i) means of transport travelling in the course of their work, including spacecraft launchers at the time of launching;
 - (j) goods declared orally to Customs authorities which are either of a commercial nature provided that their value does not exceed the statistical threshold of 1 000 EUR or 1 000 kilograms or of a non-commercial nature;
 - (k) goods released for free circulation after being subject to the customs procedures of inward processing or processing under customs control.
-

ANNEX II

LIST OF NATURE OF TRANSACTIONS CODES

A	B
1. Transactions involving actual or intended transfer of ownership from residents to non-residents against financial or other compensation (except the transactions listed under 2, 7, 8)	1. Outright purchase/sale 2. Supply for sale on approval or after trial, for consignment or with the intermediation of a commission agent 3. Barter trade (compensation in kind) 4. Financial leasing (hire-purchase) ⁽¹⁾ 9. Other
2. Return and replacement of goods free of charge after registration of the original transaction	1. Return of goods 2. Replacement for returned goods 3. Replacement (e.g. under warranty) for goods not being returned 9. Other
3. Transactions involving transfer of ownership without financial or in kind compensation (e.g. aid shipments)	
4. Operations with a view to processing ⁽²⁾ under contract (no transfer of ownership to the processor)	1. Goods expected to return to the initial country of export 2. Goods not expected to return to the initial country of export
5. Operations following processing under contract (no transfer of ownership to the processor)	1. Goods returning to the initial country of export 2. Goods not returning to the initial country of export
6. Particular transactions recorded for national purposes	
7. Operations under joint defence projects or other joint intergovernmental production programmes	
8. Transactions involving the supply of building materials and technical equipment under a general construction or civil engineering contract for which no separate invoicing of the goods is required and an invoice for the total contract is issued	
9. Other transactions which cannot be classified under other codes	1. Hire, loan, and operational leasing longer than 24 months 9. Other

⁽¹⁾ Financial leasing covers operations where the lease instalments are calculated in such a way as to cover all or virtually all of the value of the goods. The risks and rewards of ownership are transferred to the lessee. At the end of the contract the lessee becomes the legal owner of the goods.

⁽²⁾ Processing covers operations (transformation, construction, assembling, enhancement, renovation ...) with the objective of producing a new or really improved item. This does not necessarily involve a change in the product classification. Processing activities on a processor's own account are not covered by this item and should be registered under item 1 of column A.

ANNEX III

CODING OF MODE OF TRANSPORT

Code	Title
1	Sea transport
2	Rail transport
3	Road transport
4	Air transport
5	Postal consignment
7	Fixed transport installations
8	Inland waterway transport
9	Own propulsion

COMMISSION REGULATION (EU) No 114/2010

of 9 February 2010

amending Regulation (EC) No 2229/2004 as regards the time period granted to EFSA for the delivery of its view on the draft review reports concerning the active substances for which there are clear indications that they do not have any harmful effects

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽¹⁾, and in particular the second subparagraph of Article 8(2) thereof,

Whereas:

- (1) In accordance with Article 24b of Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC⁽²⁾, where there are clear indications that it might be expected that an active substance does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, that substance is to be included in Annex I to Directive 91/414/EEC without EFSA having been consulted previously.
- (2) Where an active substance was included in accordance with Article 24b of Regulation (EC) No 2229/2004 without EFSA having been consulted, Article 25a thereof provides that EFSA is to deliver its view on the draft review report by 31 December 2010 at the latest.

- (3) Given the number of active substances which were included in accordance with Article 24b of Regulation (EC) No 2229/2004, it is necessary to allow more time for EFSA to deliver its view. For the substances concerned there are clear indications that they do not have any harmful effects. Taking into account these facts, it is appropriate to extend the time period within which EFSA is to deliver its view until 31 December 2012.

- (4) Regulation (EC) No 2229/2004 should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

In Article 25a of Regulation (EC) No 2229/2004, the words '31 December 2010' are replaced by '31 December 2012'.

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, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 379, 24.12.2004, p. 13.

COMMISSION REGULATION (EU) No 115/2010**of 9 February 2010****laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

neither the European Parliament nor the Council has opposed them,

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

HAS ADOPTED THIS REGULATION:

Having regard to Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 ⁽¹⁾, on the exploitation and marketing of natural mineral waters, and in particular Article 4(1)(c) and Article 12 (d) thereof,

Article 1

1. The treatment of natural mineral waters and spring waters with activated alumina in order to remove fluoride, hereinafter 'the fluoride removal treatment', shall be allowed.

Having regard to the opinion of the European Food Safety Authority,

Natural mineral waters and spring waters together are referred to hereinafter as 'water'.

Whereas:

(1) Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters ⁽²⁾ sets a maximum limit for fluoride in natural mineral waters. As regards spring water, such a limit is fixed by Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽³⁾.

2. The fluoride removal treatment shall be performed in accordance with the technical requirements as set out in the Annex.

Article 2

The release of residues into the water as a result of the fluoride removal treatment shall be as low as technically feasible according to the best practices and shall not pose a risk to public health. To ensure this, the operator shall implement and monitor the critical processing steps set in the Annex.

(2) To allow operators to comply with those Directives, a treatment to remove fluoride from natural mineral waters and spring waters by using activated alumina (hereinafter 'the fluoride removal treatment') should be authorised.

Article 3

1. The application of a fluoride removal treatment shall be notified to the competent authorities at least three months prior to use.

(3) The fluoride removal treatment should not add residues to the treated water at concentrations which may pose a risk to public health.

2. With the notification the operator shall communicate to the competent authorities relevant information, documentation and analytical results on the treatment which show that it complies with the Annex.

(4) The fluoride removal treatment should be notified to the competent authorities to allow those authorities to exercise the controls necessary to ensure correct application of the treatment.

Article 4

The label on water which has been the subject of a fluoride removal treatment shall include, in proximity to the statement of the analytical composition, the indication 'water subjected to an authorised adsorption technique'.

(5) The use of a fluoride removal treatment should be indicated on the label of treated water.

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

Article 5

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

⁽¹⁾ OJ L 164, 26.6.2009, p. 45.

⁽²⁾ OJ L 126, 22.5.2003, p. 34.

⁽³⁾ OJ L 330, 5.12.1998, p. 32.

Products which were placed on the market by 10 August 2010 and which do not comply with Article 4, may continue to be marketed until 10 August 2011.

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

Done at Brussels, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

Technical requirements for the use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

The following critical processing steps shall be implemented and monitored appropriately:

1. Before the activated alumina is used for the treatment of water it shall be subjected to an initialisation procedure which includes the use of acidic or alkaline chemicals to remove any residues and a backwash treatment to remove fine particles.
2. A regeneration procedure shall be applied at intervals ranging from one to four weeks depending on the water quality and throughput. It shall include the use of appropriate chemicals to remove the adsorbed ions in order to restore the adsorption capacity of the activated alumina, and to remove any possibly formed biofilms. This procedure shall be done in the following three stages:
 - Treatment with sodium hydroxide to remove fluoride ions and replace them with hydroxide ions.
 - Treatment with an acid to remove residual sodium hydroxide and activate the medium.
 - Rinsing with drinking or demineralised water and conditioning with the water as the final step in order to ensure that the filter has no impact on the overall mineral content of the treated water.
3. The chemicals and reagents used for the initialisation and regeneration procedures shall comply with the relevant European standards ⁽¹⁾ or applicable national standards relating to the purity of the chemical reagents used for treatment of water intended for human consumption.
4. The activated alumina shall comply with the European standard for leaching tests (EN 12902) ⁽²⁾ to ensure that no residues are released into the water resulting in concentrations exceeding the limits set in Directive 2003/40/EC or in the absence of limits in that Directive, the limits set in Directive 98/83/EC or in applicable national legislation. The total amount of aluminium ions in the treated water as it results after the release of aluminium, the main component of activated alumina, shall not exceed 200microg/L, as established in Directive 98/83/EC. This amount shall be checked regularly in accordance with the Council Directive.
5. The processing steps shall be subject to good manufacturing practices and HACCP principles set out in Regulation (EC) No 852/2004 of the European Parliament and of the Council on food hygiene ⁽³⁾.
6. The operator shall establish a monitoring programme in order to ensure the proper functioning of the processing steps in particular as regards the maintenance of the essential characteristics of the water and its fluoride content.

⁽¹⁾ European Standards developed by the European Committee for Standardisation (CEN).

⁽²⁾ European Standard EN 12902 (2004): Products used for treatment of water intended for human consumption. Inorganic supporting and filtering materials.

⁽³⁾ OJ L 139, 30.4.2004, p. 1.

COMMISSION REGULATION (EU) No 116/2010**of 9 February 2010****amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims****(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 8(2) thereof,

Whereas:

- (1) Article 8(1) of Regulation (EC) No 1924/2006 states that nutrition claims made on foods shall be only permitted if they are listed in its Annex, which sets out also their conditions of use.
- (2) Regulation (EC) No 1924/2006 also provides that amendments to that Annex shall be adopted where appropriate, after consulting the European Food Safety Authority (EFSA), hereinafter referred to as the Authority.
- (3) Prior to the adoption of Regulation (EC) No 1924/2006, the Commission asked the opinion of the Authority on nutrition claims and their conditions of use concerning omega-3 fatty acids, monounsaturated fat, polyunsaturated fat and unsaturated fat.
- (4) In its opinion adopted on 6 July 2005 ⁽²⁾, the Authority concludes that omega-3 fatty acids, monounsaturated fat, polyunsaturated fat and unsaturated fat have important roles in the diet. Some unsaturated fats such as omega-3 fatty acids are sometimes consumed at a level lower than recommended. Therefore, nutrition claims identifying foods being source of these nutrients, or being rich in these nutrients could help consumers to make healthier choices. However, those nutrition claims were not

included in the list established in the Annex to Regulation (EC) No 1924/2006, as adopted by the European Parliament and the Council, as their conditions of use could not yet be clearly defined.

- (5) Those conditions of use having been clarified, taking also into account an opinion of the Authority on labelling reference intake values for omega-3 and omega-6 fatty acids adopted on 30 June 2009 ⁽³⁾, it is, therefore, advisable to include the claims concerned in the list.
- (6) Concerning the claims 'Source of omega-3 fatty acids' and 'High in omega-3 fatty acids', the conditions of use should distinguish between the two types of omega-3 fatty acids, which have different physiological roles and for which different levels of consumption are recommended. Furthermore, those conditions of use should establish a minimum quantity requested per 100 g and 100 kcal of product in order to ensure that only foods providing a significant amount of omega-3 fatty acids at their level of consumption can bear those claims.
- (7) Concerning the claims 'High in monounsaturated fat', 'High in polyunsaturated fat' and 'High in unsaturated fat', the conditions of use should require a minimum unsaturated fat content in the food, and, consequently, ensure that the claimed amount always corresponds to a significant amount at the level of consumption attainable through a balanced diet.
- (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

The Annex to Regulation (EC) No 1924/2006 is amended as set out in the Annex to this Regulation.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ *The EFSA Journal* (2005) 253, 1-29.

⁽³⁾ *The EFSA Journal* (2009) 1176, 1-11.

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, 9 February 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

In the Annex to Regulation (EC) No 1924/2006, the following text is added:

'SOURCE OF OMEGA-3 FATTY ACIDS

A claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,3 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.

HIGH OMEGA-3 FATTY ACIDS

A claim that a food is high in omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,6 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.

HIGH MONOUNSATURATED FAT

A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20 % of energy of the product.

HIGH POLYUNSATURATED FAT

A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45 % of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20 % of energy of the product.

HIGH UNSATURATED FAT

A claim that a food is high in unsaturated fat, and any claim likely to have the same meaning for the consumer may only be made where at least 70 % of the fatty acids present in the product derive from unsaturated fat under the condition that unsaturated fat provides more than 20 % of energy of the product.'

COMMISSION REGULATION (EU) No 117/2010

of 9 February 2010

amending Regulation (EC) No 904/2008 laying down the methods of analysis and other technical provisions necessary for the application of the export procedure for goods not covered by Annex I to the Treaty

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽¹⁾, and in particular Article 9 thereof,

Whereas:

- (1) Commission Regulation (EC) No 904/2008 ⁽²⁾ lays down the methods, procedures and formulae to be used for the calculation of the data obtained from the analysis of goods as set out in Annex IV to Commission Regulation (EC) No 1043/2005 of 30 June 2005 implementing Council Regulation (EC) No 3448/93 as regards the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds ⁽³⁾.
- (2) Regulation (EC) No 904/2008 has been examined by a group of experts, with a view to assessing whether that Regulation takes account of the scientific and technological evolution of the methods laid down in that Regulation. Studies and tests carried out in the framework of that examination indicate that the determination of the starch (or dextrin) content by hydrolysis by means of sodium hydroxide and the determination of the glucose content using the enzymatic method with spectrophotometry as prescribed for most goods now, do not meet any longer the current technical requirements and are therefore to be updated.
- (3) It is therefore appropriate to provide that the determination of starch (or dextrin) content is to be carried out in an enzymatic way by amylase and amyloglucosidase and that the glucose content is to be determined using high performance liquid chromatography (HPLC), as set out in Annex I to Commission Regulation (EC) No 900/2008 of 16 September 2008 laying down the methods of analysis and other technical provisions necessary for the application of the arrangements for

imports of certain goods resulting from the processing of agricultural products ⁽⁴⁾ as amended by Commission Regulation (EU) No 118/2010 ⁽⁵⁾.

- (4) Regulation (EC) No 904/2008 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 2 of Regulation (EC) No 904/2008, point 2 is replaced by the following:

‘2. Starch (or dextrin)

(dextrin shall be expressed as starch)

1. For all CN codes other than CN codes 3505 10 10, 3505 10 90, 3505 20 10 to 3505 20 90 and 3809 10 10 to 3809 10 90, the starch (or dextrin) content referred to in column 3 of Annex IV to Regulation (EC) No 1043/2005 shall be calculated using the formula:

$$(Z - G) \times 0,9,$$

where

Z = is the glucose content determined by the method described in Annex I to Commission Regulation (EC) No 900/2008 ^(*);

G = is the glucose content before enzymatic treatment, determined by high performance liquid chromatography (HPLC).

2. For CN codes 3505 10 10, 3505 10 90, 3505 20 10 to 3505 20 90 and 3809 10 10 to 3809 10 90, the starch (or dextrin) content shall be determined by the method set out in Annex II to Regulation (EC) No 900/2008.

^(*) OJ L 248, 17.9.2008, p. 8.’

⁽¹⁾ OJ L 256, 7.9.1987, p. 1.

⁽²⁾ OJ L 249, 18.9.2008, p. 9.

⁽³⁾ OJ L 172, 5.7.2005, p. 24.

⁽⁴⁾ OJ L 248, 17.9.2008, p. 8.

⁽⁵⁾ See page 21 of this Official Journal.

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, 9 February 2010.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 118/2010

of 9 February 2010

amending Regulation (EC) No 900/2008 laying down the methods of analysis and other technical provisions necessary for the application of the arrangements for imports of certain goods resulting from the processing of agricultural products

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽¹⁾, and in particular Article 9 thereof,

Whereas:

(1) Commission Regulation (EC) No 900/2008 ⁽²⁾ lays down the formulas, procedures and methods to be used for the determination of starch/glucose for applying Annexes II and III of Commission Regulation (EC) No 1460/96 of 25 July 1996 establishing the detailed rules for implementing the preferential trade arrangements applicable to certain goods resulting from the processing of agricultural products, as provided for in Article 7 of Council Regulation (EC) No 3448/93 ⁽³⁾.

(2) Regulation (EC) No 900/2008 has been examined by a group of experts, with a view to assessing whether that Regulation takes account of the scientific and technological evolution of the methods laid down in that Regulation. Studies and tests carried out in the framework of that examination indicate that the determination of the starch/glucose content by solubilisation by means of sodium hydroxide (prior to enzymatic degradation to glucose) and the measurement of the

total glucose content using the enzymatic method with spectrophotometry as prescribed for most goods now, do not meet any longer the current technical requirements and are therefore to be updated.

(3) It is therefore appropriate to provide that the degradation of starch/glucose is to be carried out in an enzymatic way by amylase and amyloglucosidase and that the total glucose content is to be determined using high performance liquid chromatography (HPLC) and to specify how the enzymatic method is to be carried out.

(4) Regulation (EC) No 900/2008 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 900/2008 is replaced by the text set out in 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*.

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

Done at Brussels, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 256, 7.9.1987, p. 1.

⁽²⁾ OJ L 248, 17.9.2008, p. 8.

⁽³⁾ OJ L 187, 26.7.1996, p. 18.

ANNEX

‘ANNEX I

Enzymatic determination of starch and its degradation products including glucose in food products using high performance liquid chromatography (HPLC)**1. Scope**

This method describes the determination of the content of starch and its degradation products including glucose in food products for human consumption hereafter referred to as “starch”. The starch content is determined from the quantitative analysis of glucose by high-performance liquid chromatography (HPLC) after enzymatic conversion of starch and its degradation products into glucose.

2. Definition of the total glucose content and of the total glucose content expressed as starch

The total glucose content means the value Z as calculated in point 7.2.1 of this Annex. It represents the content of starch and all its degradation products, glucose included.

The starch/glucose content as defined in Annex III to Regulation (EC) No 1460/96 shall be calculated on the basis of the total glucose content Z and as set out in Article 2 point 1 of this Regulation.

The starch (or dextrin) content as referred to in column 3 of Annex IV to Commission Regulation (EC) No 1043/2005 ⁽¹⁾ shall be calculated on the basis of the total glucose content Z as set out in Article 2 point 2.1 of Commission Regulation (EC) No 904/2008 ⁽²⁾.

The Starch content referred to in point 1 of this Annex means the value E, as calculated in point 7.2.2 of this Annex. It is expressed in % (m/m). It is equivalent to the total glucose content Z, expressed as starch. This value E does not interfere in the above mentioned calculations.

3. Principle

The samples are homogenised and suspended in water. The starch and its degradation products, present in the samples, are enzymatically converted into glucose in two steps:

1. Starch and its degradation products are partially converted into soluble glucose chains using thermostable alpha-amylase at 90 °C. For effective conversion it is necessary that the samples should be completely solved or should be present in the form of a suspension containing very small solid parts
2. The soluble glucose chains are converted into glucose using amyloglucosidase at 60 °C.

Products containing a high content of proteins or fat are clarified and filtrated.

The determination of sugars is performed by HPLC analysis.

Because a partial inversion of sucrose may occur during the enzymatic treatment, the determination of free sugars is also performed by HPLC analysis to calculate the corrected glucose content.

4. Reagents and other materials

Use reagents of recognised analytical grade and demineralised water.

- 4.1. Glucose, min 99 %.
- 4.2. Fructose, min 99 %.
- 4.3. Sucrose, min 99 %.
- 4.4. Maltose-monohydrate, min 99 %.
- 4.5. Lactose-monohydrate, min 99 %.
- 4.6. Solution of thermostable alpha-amylase (1,4-alpha-D-Glucan-glucanohydrolase), with activity about 31 000 U/ml (1U will liberate 1,0 mg of maltose from starch in 3 minutes at pH 6,9 and 20 °C). This enzyme can contain a low amount of impurities (e.g. glucose or sucrose) and other interfering enzymes. Storage at ca. 4 °C. Alternatively, other sources of alpha-amylase may be used yielding a final solution with comparable enzyme activity.

⁽¹⁾ OJ L 172, 5.7.2005, p. 24.

⁽²⁾ OJ L 249, 18.9.2008, p. 9.

- 4.7. Amyloglucosidase (1,4- α -D-Glucan glucohydrolase) from *Aspergillus niger*, powder with activity about 120 U/mg or about 70 U/mg (1U will liberate 1 micromol glucose from starch per minute at pH 4,8 and 60 °C). This enzyme can contain a low amount of impurities (e.g. glucose or sucrose) and other interfering enzymes (e.g., Invertase). Storage at ca. 4 °C. Alternatively, other sources of amyloglucosidase may be used yielding a final solution with comparable enzyme activity.
- 4.8. Zinc acetate dihydrate, p.a..
- 4.9. Potassium hexacyanoferrate (II) ($K_4[Fe(CN)_6 \cdot 3H_2O]$), extra pure.
- 4.10. Sodium acetate anhydrous, p.a..
- 4.11. Glacial acetic acid, 96 % (v/v) (minimum).
- 4.12. Sodium acetate buffer (0,2 mol/l). Weigh 16,4 gram sodium acetate (point 4.10) into a beaker glass. Dissolve in water and rinse into a volumetric flask of 1 000 ml. Dilute to the mark with water and adjust the pH to 4,7 with acetic acid (by use of a pH-meter (point 5.7)). This solution may be used for max 6 months with storage at 4 °C.
- 4.13. Amyloglucosidase solution. Prepare a solution of amyloglucosidase powder (point 4.7) by using sodium acetate buffer (point 4.12). The enzyme activity must be sufficient and in accordance with the starch content in the amount of sample (for example, activity about 600 U/ml is obtained from 0,5 g amyloglucosidase powder 120 U/mg (point 4.7) in a final volume of 100 ml for 1 g starch in the amount of sample). Prepare immediately before use.
- 4.14. Reference solutions. Prepare solutions of glucose, fructose, sucrose, maltose and lactose in water, as conventionally used in the HPLC analysis of sugars.
- 4.15. Reagent for clarification (Carrez I). Dissolve 219,5 gram zinc acetate (point 4.8) in water in a beaker glass. Rinse into a volumetric flask of 1 000 ml and add 30 ml acetic acid (point 4.11). Mix thoroughly and dilute to the mark with water. This solution may be used for max 6 months while stored at ambient temperature. Other clarification reagents, equivalent to Carrez solution, may be used.
- 4.16. Reagent for clarification (Carrez II). Dissolve 106,0 gram potassium hexacyanoferrate (II) (point 4.9) in water in a beaker glass. Rinse into a volumetric flask of 1 000 ml. Mix thoroughly and dilute to the mark with water. This solution may be used for max. 6 months while stored at ambient temperature. Other clarification reagents, equivalent to Carrez solution, may be used.
- 4.17. HPLC Mobile phase. Prepare a mobile phase which is conventionally used in the HPLC analysis of sugars. In case of using an aminopropyl silicagel column, e.g., a common mobile phase is a mixture of HPLC grade water and acetonitrile.

5. Apparatus

- 5.1. Standard laboratory glass ware.
- 5.2. Fluted filters, e.g., 185 mm.
- 5.3. Syringe filters, 0,45 μ m, suitable for aqueous solutions.
- 5.4. Sample vials suitable for the HPLC autosampler.
- 5.5. 100 ml volumetric flasks.
- 5.6. Plastic syringes, 10 ml.
- 5.7. pH-meter.
- 5.8. Analytical balance.
- 5.9. Water bath with thermostat, adjustable to 60 °C and 90 °C.
- 5.10. HPLC Apparatus suitable for analysis of sugars.

6. Procedure

6.1. Preparation of the sample for several types of products

The product is homogenised.

6.2. Sample portion

The amount of sample is estimated from the ingredient declaration and the conditions of the HPLC analysis (concentration of the glucose reference solution), and shall not exceed:

$$\text{amount of sample (g)} = \frac{\text{volume of volumetric flask (e.g., 100ml)}}{\text{estimated starch content (\%)}}$$

Weigh the sample to 0,1 mg accuracy.

6.3. Blank determination

The blank is determined by performing a complete analysis (as described in point 6.4), without adding sample. The result of the blank determination is used in the calculation of the starch content (point 7.2).

6.4. Analysis

6.4.1. Preparation of the samples

Homogenise the sample by shaking or stirring. The chosen test portion (point 6.2) is weighed into a volumetric flask (point 5.5) and about 70 ml warm water is added.

After dissolving or suspending, add 50 microliter of thermostable alpha-amylase (point 4.6) and heat at 90 °C for 30 min in a water bath (point 5.9). Cool as quick as possible to 60 °C in a water bath, and add 5 ml of a solution of amyloglucosidase (point 4.13). For samples which could influence the pH of the reaction solution, control the pH and adjust it to 4,6 to 4,8, if necessary. Allow to react for 60 min at 60 °C. Cool the samples to ambient temperature.

6.4.2. Clarification

For samples with a high content of proteins or fat, clarification is necessary by adding 1 ml Carrez I (point 4.15) to the sample solution. After shaking, 1 ml Carrez II (point 4.16) is added. Shake the sample again.

6.4.3. Processing for HPLC analysis

The sample in the volumetric flask is diluted to the mark with water, homogenised and filtered through a fluted filter (point 5.2). Collect the sample extract.

Filter the extracts through a syringe filter (point 5.3) with a syringe (point 5.6) that has been preflushed with the extract. Collect the filtrates in vials (point 5.4).

6.5. Chromatography

HPLC is performed as conventionally for analysis of sugars. If the HPLC analysis shows traces of maltose, then the starch is incompletely converted, which results in a too low recovery for glucose.

7. Calculation and expression of results

7.1. Calculation of the HPLC results

For the calculation of the starch content, the results of two HPLC analysis are necessary, namely sugars present in the sample before ('free sugars') and after enzymatic treatment (as described in this method). Also a blank determination has to be performed to be able to correct for sugars present in the enzymes.

In the HPLC analysis, the peak area is determined after integration and the concentration is calculated after calibration with reference solutions (point 4.14). From the glucose concentration (g/100 ml) after enzymatic treatment, the concentration of glucose (g/100 ml) in the blank is subtracted. Eventually the content (g sugar/100 g sample) of sugars is calculated using the weighted amount of sample, which results in:

1. HPLC analysis before enzymatic treatment, giving the content (g/100 g) of free sugars:

- glucose G
- fructose F
- sucrose S

2. HPLC analysis after enzymatic treatment, giving the content (g/100 g) of sugars:

- glucose after correction for the blank ($G_{e\text{ cor}}$)
- fructose F_e
- sucrose S_e

7.2. Calculation of the starch content

7.2.1. Calculation of total glucose "Z"

If the amount of fructose after enzymatic treatment (F_e) is higher than the amount of fructose before enzymatic treatment (F), then the sucrose, present in the sample, is partly converted into fructose and glucose. This means that a correction shall be made for the liberated glucose ($F_e - F$).

Z, final glucose content after correction in g/100g:

$$Z = (G_{e\text{ cor}}) - (F_e - F)$$

7.2.2. Calculation of the total glucose content expressed as starch

E, "starch" content in g/100g:

$$E = [(G_{e\text{ cor}}) - (F_e - F)] \times 0,9$$

8. Precision

Details of an inter laboratory test relating to precision data of the method performed on 2 samples are given in this point. They reflect the performance requirements for the method described in this annex.

Results of an interlaboratory test (Informative)

An inter laboratory test was carried out in 2008 with the participation of the European Customs laboratories.

The evaluation of precision data was performed according to the "Protocol for the design, conduct and interpretation of method-performance studies", W. Horwitz, (IUPAC technical report), Pure & Appl. Chem., Vol. 67, N° 2, PP.331-343, 1995.

The precision data are given in the table below.

Samples 1 : chocolate and biscuit bar 2 : biscuit	Z sample 1	Z sample 2
Number of laboratories	41	42
Number of laboratories after eliminating outliers	38	39
Mean (% m/m)	29,8	55,0
Repeatability standard deviation sr (% m/m)	0,5	0,5
Reproducibility standard deviation sR (% m/m)	1,5	2,3
Repeatability limit r (% m/m)	1,4	1,4
Reproducibility limit R (% m/m)	4,2	6,6'

COMMISSION REGULATION (EU) No 119/2010**of 9 February 2010****amending Regulation (EU) No 1233/2009 laying down a specific market support measure in the dairy sector**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 2799/98 of 15 December 1998 establishing agrimonetary arrangements for the euro ⁽¹⁾, and in particular Article 9 thereof,

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) ⁽²⁾, and in particular Articles 186 and 188(2), in conjunction with Article 4 thereof,

Whereas:

(1) In the Annex to Commission Regulation (EU) No 1233/2009 ⁽³⁾ amounts are set out to provide support to dairy farmers severely affected by the dairy crisis. As those amounts are fixed in euro, it is necessary, in order to ensure a uniform and simultaneous application throughout the Union, to fix a common date for the conversion of those amounts into national currency for the Member States which have not adopted the single currency. It is therefore appropriate to determine the operative event for the exchange rate in accordance with Article 3 of Regulation (EC) No 2799/98.

(2) In view of the principle referred to in Article 3(1), second indent, and the criteria mentioned in Article 3(2) of Regulation (EC) No 2799/98, the operative event

should be the date of the entry into force of Regulation (EU) No 1233/2009.

(3) Regulation (EU) No 1233/2009 should therefore be amended accordingly.

(4) In order to ensure, as quickly as possible, a uniform and simultaneous application throughout the Union, this Regulation should enter into force without delay and should apply as from the date of the entry into force of Regulation (EU) No 1233/2009.

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

HAS ADOPTED THIS REGULATION:

Article 1

The following Article 3a is inserted in Regulation (EU) No 1233/2009 after Article 3:

'Article 3a

The operative event for the exchange rate as regards the amounts set out in the Annex shall be 17 December 2009.'

Article 2

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*. It shall apply as from 17 December 2009.

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

Done at Brussels, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 349, 24.12.1998, p. 1.

⁽²⁾ OJ L 299, 16.11.2007, p. 1.

⁽³⁾ OJ L 330, 16.12.2009, p. 70.

COMMISSION REGULATION (EU) No 120/2010**of 9 February 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 10 February 2010.

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

Done at Brussels, 9 February 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	JO	94,7
	MA	69,2
	TN	112,8
	TR	107,2
	ZZ	96,0
0707 00 05	JO	158,2
	MA	75,9
	TR	146,1
	ZZ	126,7
0709 90 70	MA	128,2
	TR	153,7
	ZZ	141,0
0709 90 80	EG	69,8
	MA	131,9
	ZZ	100,9
0805 10 20	EG	49,8
	IL	53,6
	MA	50,5
	TN	46,3
	TR	48,6
	ZZ	49,8
0805 20 10	IL	162,6
	MA	87,1
	ZZ	124,9
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	57,9
	EG	61,9
	IL	82,3
	JM	97,3
	MA	72,9
	PK	46,5
	TR	68,3
	ZZ	69,6
0805 50 10	EG	88,6
	IL	88,6
	TR	66,7
	ZZ	81,3
0808 10 80	CA	95,3
	CL	60,1
	CN	90,6
	MK	24,7
	US	125,8
	ZZ	79,3
0808 20 50	CN	28,7
	TR	84,8
	US	96,4
	ZA	109,0
	ZZ	79,7

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

DIRECTIVES

COMMISSION DIRECTIVE 2010/6/EU

of 9 February 2010

amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards mercury, free gossypol, nitrites and *Mowrah*, *Bassia*, *Madhuca*

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed⁽¹⁾, and in particular Article 8(1) thereof,

Whereas:

(1) Directive 2002/32/EC provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I to that Directive is prohibited.

(2) As regards mercury, the European Food Safety Authority (EFSA) concluded in its opinion of 20 February 2008⁽²⁾ that the current maximum level for complete feedingstuffs for fish (0,1 mg/kg) and the maximum level for feedingstuffs produced by the processing of fish and other marine animals (0,5 mg/kg) are not harmonised. Following recent developments in feed formulation, fish feed contains more fish oil and fish meal, but with the current legal provisions the availability of these valuable feed materials for the production of fish feed is endangered. In order to address this, a slight increase of the maximum level for fish feed is appropriate and this increase would not endanger the

compliance of farmed fish with the established maximum levels for mercury. Furthermore it results from that opinion that the current maximum level for complete feedingstuffs for dogs and cats are not sufficiently protective. That maximum level should therefore be lowered. Since the degree of sensitivity of fur animals is similar to that of cats, that maximum level should also apply to fur animals.

(3) As regards nitrites, EFSA concluded in its opinion of 25 March 2009⁽³⁾ that for pigs and cattle, as representative sensitive food producing species the margins of safety with respect to the respective No Observed Adverse Effect Level (NOAEL) are sufficient. It considered furthermore that the presence of nitrite in animal products does not raise any concern for human health. Nitrite is already authorised with a maximum content of 100 mg/kg for use as a preservative in complete feedingstuffs for dogs and cats, with a moisture content exceeding 20 %, and as an additive in silage⁽⁴⁾. Nitrite is therefore not to be considered as an undesirable substance in such complete feedingstuffs and in silage. Consequently, no maximum level should apply in these cases.

(4) As regards gossypol, EFSA concluded in its opinion of 4 December 2008 that the current maximum levels for sheep, including lambs, and goats, including kids, are not sufficiently protective against adverse animal health effects. EFSA further concluded that the human exposure to gossypol through the consumption of food products from animals fed cottonseed derived products is probably low and would not result in adverse effects. Based on that opinion the maximum levels for sheep, including lambs, and goats, including kids, should be lowered.

⁽¹⁾ OJ L 140, 30.5.2002, p. 10.

⁽²⁾ Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on mercury as undesirable substance in feed, *The EFSA Journal* (2008) 654, 1-76.

⁽³⁾ Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on nitrite as undesirable substances in animal feed. *The EFSA Journal* (2009) 1017, 1-47.

⁽⁴⁾ Community Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 of the European Parliament and of the Council, entry on sodium nitrite (Dogs, Cats) and sodium nitrite in silage, http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm

- (5) As regard saponins in *Madhuca longifolia* L., EFSA concluded in its opinion of 29 January 2009 ⁽¹⁾ that no adverse animal health effects are expected because of the negligible exposure of target animals in the Union. EFSA considers that human dietary exposure to *Madhuca* saponins is negligible, since *Madhuca* products are not consumed by humans and *Madhuca* meal is not used in the Union as a feed material. Therefore it is appropriate to delete the row concerning *Mowrah*, *Bassia*, *Madhuca*.
- (6) Directive 2002/32/EC should therefore be amended accordingly.
- (7) 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

Annex I to Directive 2002/32/EC is amended in accordance with the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive by 1 November 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Saponins in *Madhuca Longifolia* L. as undesirable substances in animal feed. *The EFSA Journal* (2009) 979, 1-36.

ANNEX

Annex I to Directive 2002/32/EC is amended as follows:

1. Row 4, Mercury, is replaced by the following:

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
'4. Mercury (*) (**)	Feed materials	0,1
	with the exception of:	
	— feedingstuffs produced from fish or by the processing of fish or other aquatic animals,	0,5
	— calcium carbonate.	0,3
	Compound (complementary and complete) feedingstuffs	0,1
	with the exception of:	
	— mineral feed,	0,2
	— compound feedingstuffs for fish,	0,2
	— compound feedingstuffs for dogs, cats and fur animals.	0,3

(*) The maximum levels refer to total mercury.

(**) Maximum levels refer to an analytical determination of mercury, whereby extraction is performed in nitric acid (5 % w/w) for 30 minutes at boiling temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.'

2. Row 5, Nitrites, is replaced by the following:

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
'5. Nitrites	Feed materials	15 (expressed as sodium nitrite)
	with the exception of:	
	— fishmeal,	30 (expressed as sodium nitrite)
	— silage.	—
	Complete feedingstuffs	15 (expressed as sodium nitrite)
	with the exception of:	
	— complete feedingstuffs for dogs and cats with a moisture content exceeding 20 %.	—'

3. Row 9, Free gossypol is replaced by the following:

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
9. Free gossypol	Feed materials	20
	with the exception of:	
	— cottonseed,	5 000
	— cottonseed cakes and cottonseed meal.	1 200
	Complete feedingstuffs	20
	with the exception of:	
	— complete feedingstuffs for adult cattle,	500
	— complete feedingstuffs for sheep (except lambs and goats (except kids),	300
	— complete feedingstuffs for poultry (except laying hens) and calves,	100
	— complete feedingstuffs for rabbits, lambs, kids and pigs (except piglets).	60'

4. Row 32, 'Mowrah, *Bassia*, *Madhuca* – *Madhuca longifolia* (L.) Macbr. (= *Bassia longifolia* L. = *Illiped malabrurum* Engl.) *Madhuca indica* Gmelin (= *Bassia latifolia* Roxb.) = *Illipe latifolia* (Roscb.) F. Mueller' is deleted.

COMMISSION DIRECTIVE 2010/7/EU**of 9 February 2010****amending Directive 98/8/EC of the European Parliament and of the Council to include magnesium phosphide releasing phosphine as an active substance in Annex I thereto****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽¹⁾, and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes magnesium phosphide.
- (2) Pursuant to Regulation (EC) No 1451/2007, magnesium phosphide has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, as defined in Annex V to that Directive.
- (3) Germany was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 26 October 2007 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 17 September 2009, in an assessment report.
- (5) It appears from the examinations made that biocidal products used as insecticides and containing

magnesium phosphide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include magnesium phosphide in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as insecticides and containing magnesium phosphide can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

- (6) Not all potential uses have been evaluated at the Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to the compartments and populations that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels. In particular, where relevant, Member States should assess outdoor use, which has not been addressed in the Union level risk assessment.
- (7) In the light of the conclusions of the assessment report, it is appropriate to require that products containing magnesium phosphide and used as insecticides be authorised only for use by trained professionals in accordance with Article 10(2)(i)(e) of Directive 98/8/EC, and that specific risk mitigation measures are applied at product authorisation level to such products. Such measures should be aimed at limiting the risk of exposure of users to magnesium phosphide to an acceptable level.
- (8) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ⁽³⁾ establishes maximum limits for magnesium phosphide residues which are present in or on food and feed. Pursuant to Article 3(2)(c) of Regulation (EC) No 396/2005, the maximum residue limits apply to any pesticide residues, including those which may arise as a result of use as a biocide. Member States should ensure that adequate residue trials are provided at product authorisation to allow consumer risk assessment. Furthermore, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 2.

⁽³⁾ OJ L 70, 16.3.2005, p. 1.

- (9) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance magnesium phosphide and also to facilitate the proper operation of the biocidal products market in general.
- (10) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.
- (11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 18 containing magnesium phosphide to ensure that they comply with Directive 98/8/EC.
- (12) Directive 98/8/EC should therefore be amended accordingly.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 January 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2012.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following entry for the substance magnesium phosphide releasing phosphine is inserted in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
'26	Magnesium phosphide releasing phosphine	Trimagnesium diphosphide EC No: 235-023-7 CAS No: 12057-74-8	880 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorisations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas.

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
								3. For products containing magnesium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm>

COMMISSION DIRECTIVE 2010/8/EU**of 9 February 2010****amending Directive 98/8/EC of the European Parliament and of the Council to include warfarin sodium as an active substance in Annex I thereto****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽¹⁾, and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes warfarin sodium.

(2) Pursuant to Regulation (EC) No 1451/2007, warfarin sodium has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.

(3) Ireland was designated as Rapporteur Member State and submitted its report, together with a recommendation, to the Commission on 3 October 2005 in accordance with Article 14(4) and 14(6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 17 September 2009, in an assessment report.

(5) It appears from the examinations made that biocidal products used as rodenticides and containing warfarin sodium may be expected not to present a risk to humans except for accidental incidents with children. A risk has been identified regarding non-target animals. However, warfarin sodium is for the time being considered essential for reasons of public health and hygiene. It is therefore appropriate to include warfarin sodium in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing warfarin sodium can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) In the light of the findings of the assessment report, it is appropriate to require that specific risk mitigation measures are applied at product authorisation level to products containing warfarin sodium and used as rodenticides. Such measures should be aimed at limiting the risk of primary and secondary exposure of humans and non-target animals. To this end, certain constraints such as the maximum concentration, the prohibition on marketing the active substance in products which are not ready to use and the use of aversive agents should be imposed for all rodenticides containing warfarin sodium, while other conditions should be imposed by the Member States on a case by case basis.

(7) In view of the identified risks, warfarin sodium should be included in Annex I for five years only and should be made subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in Annex I is renewed.

(8) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance warfarin sodium and to facilitate the proper operation of the biocidal products market in general.

(9) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

- (10) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.
- (11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 14 containing warfarin sodium to ensure that they comply with Directive 98/8/EC.
- (12) Directive 98/8/EC should therefore be amended accordingly.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 January 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2012.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following entry for the substance warfarin sodium is added in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
'33	Warfarin sodium	Sodium 2-oxo-3-(3-oxo-1- phenylbutyl)chromen- 4-olate EC No: 204-929-4 CAS No: 129-06-6	910 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm>

COMMISSION DIRECTIVE 2010/9/EU**of 9 February 2010****amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance aluminium phosphide releasing phosphine to product type 18 as defined in Annex V thereto****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽¹⁾, and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes aluminium phosphide.
- (2) Commission Directive 2009/95/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include aluminium phosphide releasing phosphine as an active substance in Annex I thereto ⁽³⁾ included aluminium phosphide as an active substance in Annex I to Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.
- (3) Pursuant to Regulation (EC) No 1451/2007, aluminium phosphide has now been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, as defined in Annex V to that Directive.
- (4) Germany was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 26 October 2007 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (5) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007,

the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 17 September 2009, in an assessment report.

- (6) It appears from the examinations made that biocidal products used as insecticides and containing aluminium phosphide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include aluminium phosphide in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as insecticides and containing aluminium phosphide can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.
- (7) Not all potential uses have been evaluated at the Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to the compartments and populations that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels. In particular, where relevant, Member States should assess outdoor use, which has not been addressed in the Union level risk assessment.
- (8) In the light of the conclusions of the assessment report, it is appropriate to require that products containing aluminium phosphide and used as insecticides be authorised only for use by trained professionals in accordance with Article 10(2)(i)(e) of Directive 98/8/EC, and that specific risk mitigation measures are applied at product authorisation level to such products. Such measures should be aimed at limiting the risk of exposure of users to aluminium phosphide to an acceptable level.
- (9) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ⁽⁴⁾ establishes maximum limits for aluminium phosphide residues which are present in or on food and feed. Pursuant to Article 3(2)(c) of Regulation (EC) No 396/2005, the maximum residue limits apply to any pesticide residues, including those which may arise as a result of use as a biocide. Member

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

⁽³⁾ OJ L 201, 1.8.2009, p. 54.

⁽⁴⁾ OJ L 70, 16.3.2005, p. 1.

States should ensure that adequate residue trials are provided at product authorisation to allow consumer risk assessment. Furthermore, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005.

- (10) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance aluminium phosphide and also to facilitate the proper operation of the biocidal products market in general.
- (11) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.
- (12) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 18 containing aluminium phosphide to ensure that they comply with Directive 98/8/EC.
- (13) Directive 98/8/EC should therefore be amended accordingly.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 January 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2012.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 9 February 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following is added to entry 'No 20' in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
			'830 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorisations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas.

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
								3. For products containing aluminium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm>

COMMISSION DIRECTIVE 2010/10/EU
of 9 February 2010
amending Directive 98/8/EC of the European Parliament and of the Council to include brodifacoum
as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽¹⁾, and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes brodifacoum.
- (2) Pursuant to Regulation (EC) No 1451/2007, brodifacoum has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.
- (3) Italy was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 5 June 2005 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 17 September 2009, in an assessment report.

(5) It appears from the examinations made that biocidal products used as rodenticides and containing brodifacoum may be expected not to present a risk to humans except for accidental incidents with children. A risk has been identified regarding non-target animals and the environment. However, the target rodents are vermin and thus constitute a danger to public health. Moreover, it has not yet been established that adequate alternatives to brodifacoum exist, which are both equally effective and less damaging to the environment. It is therefore justified to include brodifacoum in Annex I for a limited period, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing brodifacoum can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) In the light of the findings of the assessment report, it is appropriate to require that specific risk mitigation measures are applied at product authorisation level to products containing brodifacoum and used as rodenticides. Such measures should be aimed at limiting the risk of primary and secondary exposure of humans and non-target animals as well as the long term effects of the substance on the environment. To this end, certain constraints such as the maximum concentration, the prohibition on marketing the active substance in products used as tracking powder or in products which are not ready for use, and the use of aversive agents should be imposed across the board, while other conditions should be imposed by the Member States on a case by case basis.

(7) Because of the identified risks and its characteristics, which render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, brodifacoum should be included in Annex I for five years only and should be made subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in Annex I is renewed.

(8) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance brodifacoum and also to facilitate the proper operation of the biocidal products market in general.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

- (9) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.
- (10) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 14 containing brodifacoum to ensure that they comply with Directive 98/8/EC.
- (11) Directive 98/8/EC should therefore be amended accordingly.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 January 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2012.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 9 February 2010.

For the Commission
The President

José Manuel BARROSO

ANNEX

The following entry for the substance brodifacoum is inserted in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
16	brodifacoum	3-[3-(4'-bromo- biphenyl-4-yl)-1,2,3,4- tetrahydro-1-naphthyl]- 4-hydroxycoumarin EC No: 259-980-5 CAS No: 56073-10-0	950 g/kg	1 February 2012	31 January 2014	31 January 2017	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm>

COMMISSION DIRECTIVE 2010/11/EU**of 9 February 2010****amending Directive 98/8/EC of the European Parliament and of the Council to include warfarin as an active substance in Annex I thereto****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market⁽¹⁾, and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes warfarin.

(2) Pursuant to Regulation (EC) No 1451/2007, warfarin has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.

(3) Ireland was designated as Rapporteur Member State and submitted its report, together with a recommendation, to the Commission on 3 October 2005 in accordance with Article 14(4) and 14(6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 17 September 2009, in an assessment report.

(5) It appears from the examinations made that biocidal products used as rodenticides and containing warfarin may be expected not to present a risk to humans except for accidental incidents with children. A risk has been identified regarding non-target animals. However, warfarin is for the time being considered essential for reasons of public health and hygiene. It is therefore appropriate to include warfarin in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing warfarin can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) In the light of the findings of the assessment report, it is appropriate to require that specific risk mitigation measures are applied at product authorisation level to products containing warfarin and used as rodenticides. Such measures should be aimed at limiting the risk of primary and secondary exposure of humans and non-target animals. To this end, certain constraints such as the maximum concentration, the prohibition on marketing the active substance in products which are not ready to use and the use of aversive agents should be imposed for all rodenticides containing warfarin, while other conditions should be imposed by the Member States on a case by case basis.

(7) In view of the identified risks, warfarin should be included in Annex I for five years only and should be made subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in Annex I is renewed.

(8) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance warfarin and to facilitate the proper operation of the biocidal products market in general.

(9) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

- (10) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.
- (11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 14 containing warfarin to ensure that they comply with Directive 98/8/EC.
- (12) Directive 98/8/EC should therefore be amended accordingly.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 January 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2012.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 9 February 2010.

For the Commission
The President

José Manuel BARROSO

ANNEX

The following entry for the substance warfarin is added in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
'32	Warfarin	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl) coumarin EC No: 201-377-6 CAS No: 81-81-2	990 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm>

DECISIONS

COUNCIL DECISION

of 25 January 2010

repealing Decision 2009/472/EC and concerning the follow-up to the consultation procedure with the Islamic Republic of Mauritania under Article 96 of the ACP-EC Partnership Agreement

(2010/73/EU)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States, of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 ⁽¹⁾, as revised in Luxembourg on 25 June 2005 ⁽²⁾ (hereinafter referred to as 'the ACP-EC Partnership Agreement'), and in particular Article 96 thereof,

Having regard to the Internal Agreement between the representatives of the governments of the Member States, meeting within the Council, on measures to be taken and procedures to be followed for the implementation of the ACP-EC Partnership Agreement ⁽³⁾, and in particular Article 3 thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Islamic Republic of Mauritania has implemented the consensual solution for ending the crisis as defined by the appropriate measures put in place by Council Decision 2009/472/EC of 6 April 2009 concerning the conclusion of consultations with the Islamic Republic of Mauritania under Article 96 of the ACP-EC Partnership Agreement ⁽⁴⁾.
- (2) The Islamic Republic of Mauritania has returned to constitutional rule.
- (3) In order to contribute to the stability of the country and to prevent new violations of the essential elements referred to in Article 9 of the ACP-EC Partnership Agreement, it is necessary to promote an inclusive national dialogue integrating all relevant and interested political and social actors and to restart cooperation.

- (4) Decision 2009/472/EC should therefore be repealed, and political dialogue with the Islamic Republic of Mauritania should be resumed with a view to reinforcing democracy, preventing unconstitutional changes of government, reforming the institutions and the role of the armed forces, good political and economic governance, reinforcing the rule of law and human rights and restoring the balance of institutions and power,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2009/472/EC is hereby repealed.

Article 2

Political dialogue with the Islamic Republic of Mauritania under Article 8 of the ACP-EC Partnership Agreement shall be conducted in the form set out in the letter annexed to this Decision.

Article 3

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

It shall expire on 25 January 2012. If necessary, it may be re-examined on the basis of European Union follow-up missions.

Article 4

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

Done at Brussels, 25 January 2010.

For the Council
The President
C. ASHTON

⁽¹⁾ OJ L 317, 15.12.2000, p. 3.

⁽²⁾ OJ L 209, 11.8.2005, p. 27.

⁽³⁾ OJ L 317, 15.12.2000, p. 376.

⁽⁴⁾ OJ L 156, 19.6.2009, p. 26.

ANNEX

DRAFT LETTER

Sir,

It is with great satisfaction that we note Mauritania's return to constitutional rule following the implementation of most of the measures envisaged by the Dakar Agreement, culminating in your appointment as Head of State. It is therefore our pleasure to confirm to you the full resumption of cooperation between the European Union and the Islamic Republic of Mauritania.

We note that, in accordance with Article 4-VII of the Dakar Agreement, the different political forces which signed the Agreement have committed themselves to continuing and stepping up an inclusive national dialogue in order to consolidate national reconciliation and democracy. As stated by the members of the International Contact Group at their last meeting on 10 September 2009, it is desirable that this dialogue should take place. It is already encouraging to see the readiness of the various parties to take part in the dialogue. It seems clear that certain underlying issues cited among the root causes of the coup of 6 August 2008 have yet to be resolved. The topics for dialogue referred to in the Dakar Agreement include reinforcing democracy, preventing unconstitutional changes of government, reforming the institutions and the role of the armed forces, good political and economic governance, reinforcing the rule of law and human rights and restoring the balance of institutions and power. The security threats that have emerged in Mauritania underline the need, in this dialogue, to address security related issues, including the link between security and development.

The European Union attaches great importance to all issues relating to the stability of your country, including those mentioned above. As these are subjects of mutual interest and given the scale of European Union cooperation in Mauritania in the area of governance, we propose that the political dialogue between Mauritania and the European Union, as provided for in Article 8 of the ACP-EC Partnership Agreement, be strengthened and put on a regular and structured footing. The practical arrangements and terms of reference for this dialogue will have to be established by mutual agreement between your Government and the heads of the European Union's diplomatic missions to the Islamic Republic of Mauritania.

One of the objectives of this dialogue will be to promote the inclusive national dialogue mentioned above and to closely monitor its results. We believe that the preconditions and difficulties that have beset the launching of this dialogue could be resolved if the various Mauritanian parties were to focus their discussions on the future and set aside demands and disputes relating to the recent past.

To conclude, the European Union will support Mauritania's efforts to overcome the socio-economic and political difficulties that it is experiencing owing to the long-running political crisis connected with the coup of August 2008, the global economic crisis and the new security and terrorist threats.

We have the honour to be, Sir, yours faithfully,

Done at Brussels, 25 January 2010.

For the European Commission
José Manuel BARROSO

For the Council of the European Union
C. ASHTON

COMMISSION DECISION

of 4 February 2010

amending Decision 2005/629/EC establishing a Scientific, Technical and Economic Committee for Fisheries

(2010/74/EU)

THE EUROPEAN COMMISSION,

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

Having regard to the Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy ⁽¹⁾, and in particular Article 33(1) thereof,

Whereas:

(1) Commission Decision 2005/629/EC ⁽²⁾ establishes a Scientific, Technical and Economic Committee for Fisheries (STECF) which provides to the Commission highly qualified scientific advice.

(2) Decision 2005/629/EC sets up procedures for the appointment of the STECF members, terms of office of its members, invitations of external experts, creation of Working Groups and procedures for the adoption of the rules of procedure of STECF. Those procedures should be simplified allowing administrative decisions to be taken at the appropriate level.

(3) To avoid confusion with daily allowances paid to private experts invited by the Commission, the additional allowances to be allocated in accordance with Decision 2005/629/EC to STECF members and external experts participating in meetings of the STECF, should be named 'compensation'.

(4) Decision 2005/629/EC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Sole Article

Decision 2005/629/EC is amended as follows:

1. Article 4 paragraph 1:

⁽¹⁾ OJ L 358, 31.12.2002, p. 59.

⁽²⁾ OJ L 225, 31.8.2005, p. 18.

'1. The Commission shall appoint the members of the STECF from a list of suitable candidates. That list shall be established following the publication of an open call for applications on the Commission's website.'

2. In Article 7, the expression 'with the approval of the Commission' is replaced by 'after having consulted the Commission's department in charge of the file'.

3. In Article 8, the expression 'with the approval of the Commission' is replaced by 'after having consulted the Commission's department in charge of the file'.

4. Article 9 is amended as follows:

(a) the heading is replaced by the following:

'Reimbursements and compensation'

(b) paragraph 1 is replaced by the following

'1. Members of the STECF and the external experts shall be entitled to compensation for their participation in the activities of the STECF as provided for in the Annex.'

5. Article 10 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Before organising plenary sessions of STECF and its working groups, the STECF shall consult the Commission's department in charge of the file.'

(b) paragraph 3 is replaced by the following:

'3. On request of the Commission's department in charge of the file, experts who are not members of STECF may be invited to participate in STECF meetings and its working groups.'

6. In Article 11(1) the expression 'with the approval of the Commission' is replaced by 'after having consulted the Commission's department in charge of the file'.
7. The Annex is replaced by the text in the Annex to this Decision.

Done at Brussels, 4 February 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

‘ANNEX

COMPENSATION

STECF members and external experts shall be entitled to compensation further to their participation in the activities of the STECF as follows:

— Attendance at STECF plenary sessions and STECF working groups

EUR per full day	STECF plenary sessions	STECF Working Groups
Chairperson	300	300
Vice Chairperson ⁽¹⁾	300	0
Other attendee	250	250

⁽¹⁾ Only foreseen at STECF plenary sessions.

Should the participation only take place in a morning or in an afternoon, the compensation should be of 50 % of the full day compensation.

— Reports

EUR	STECF opinions at plenary sessions or by correspondence ⁽¹⁾	Background reports ⁽²⁾ prior to STECF plenary sessions and working groups
Rapporteur	300	300 ⁽³⁾

⁽¹⁾ Compensation to be paid for the completion of the opinion.

⁽²⁾ Summaries, inquiries and background information.

⁽³⁾ With a maximum of 15 days, the compensation should be paid based on the timeframe decided by the Commission as specified in its prior written agreement. However the Commission may decide to extend the number of days if deemed necessary.’

COMMISSION DECISION

of 5 February 2010

concerning a financial contribution from the Union towards a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat foods to be carried out in the Member States

(notified under document C(2010) 592)

(2010/75/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽¹⁾, and in particular Article 66 thereof,

Having regard to Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents ⁽²⁾, and in particular Article 5 thereof,

Whereas:

(1) Regulation (EC) No 882/2004 lays down, among others, procedures governing a financial support from the Union to conduct measures necessary to ensure the application of the Regulation (EC) No 882/2004.

(2) Reports on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in the Union were issued by the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control in 2006 ⁽³⁾ and 2007 ⁽⁴⁾ (EFSA-ECDC reports). According to those reports, a total of 1 588 cases of listeriosis (*Listeria monocytogenes*) in humans were registered in 25 Member States in 2006. In addition, 1 558 such cases were registered in 26 Member States in 2007. The reports further demonstrated a significant increase in the incidence of such cases in humans over the period 2001-2006. Illness is often severe and mortality is high.

(3) The fact that *Listeria monocytogenes* is able to multiply in various foods at temperatures as low as 2 to 4 °C makes the occurrence of *Listeria monocytogenes* in ready-to-eat (RTE) foods with a relatively long shelf-life of particular concern.

(4) Pursuant to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs ⁽⁵⁾, food business operators are to comply with *Listeria monocytogenes* food safety criteria for ready-to-eat foods within the framework of good hygiene practises and hazard analysis of critical control point (HACCP) programmes.

(5) The EFSA-ECDC reports showed that the highest proportions of non-compliance with the *Listeria monocytogenes* criteria were registered in ready-to-eat cheese and in ready-to-eat fishery and heat treated meat products.

(6) The exposure of humans to *Listeria monocytogenes* is mainly food-borne. Therefore the prevalence and level of *Listeria monocytogenes* contamination in ready-to-eat fishery products, cheeses and heat treated meat products should be estimated in a harmonised and comparable way by means of a coordinated monitoring programme at retail level in all Member States.

(7) The growth of *Listeria monocytogenes* in a ready-to-eat product is influenced significantly by the pH, water activity and storage temperature of the product. A modelling can be used for the estimation of the growth of *Listeria monocytogenes* in a ready-to-eat product under various temperature conditions.

(8) Where there are no relevant definitions in the Union legislation, the definitions in the Codex General Standard for Cheese (CODEX STAN 283-1978, amendment 2008) and in the Codex Group Standard for Unripened Cheese including Fresh Cheese (CODEX STAN 221-2001, amendment 2008) issued by the Codex Alimentarius Commission should be used to guarantee the harmonized approach in defining ready-to-eat cheeses.

⁽¹⁾ OJ L 165, 30.4.2004, p. 1.

⁽²⁾ OJ L 325, 12.12.2003, p. 31.

⁽³⁾ The EFSA Journal (2007) 130.

⁽⁴⁾ The EFSA Journal (2009) 223.

⁽⁵⁾ OJ L 338, 22.12.2005, p. 1.

- (9) Directive 2003/99/EC provides that coordinated monitoring programmes may be established, especially when specific needs are identified, to assess risks and to establish baseline values related to zoonoses and zoonotic agents.
- (10) In May 2009, the Task Force on Monitoring of Zoonoses Data Collection of EFSA adopted a Report on proposed technical specifications for a co-ordinated monitoring programme for *Listeria monocytogenes* in certain categories of RTE foods at retail in the EU ⁽¹⁾.
- (11) Given the importance of collecting comparable data on the prevalence of *Listeria monocytogenes* in ready-to-eat foods, a financial contribution from the Union for carrying out such coordinated monitoring programme should be granted.
- (12) It is appropriate to reimburse costs incurred on the laboratory testing, subject to a ceiling. All other costs incurred, such as costs for sampling, travel and administration, should not be eligible for any financial contribution from the Union.
- (13) A financial contribution from the Union should be granted insofar as the coordinated monitoring programme is carried out in accordance with this Decision and provided that the competent authorities furnish all the necessary information within the time limits provided for therein.
- (14) For reasons of administrative efficiency all expenditure presented for a financial contribution from the Union should be expressed in euro. In accordance with Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy ⁽²⁾, the conversion rate for expenditure in a currency other than euro should be the rate most recently set by the European Central Bank prior to the first day of the month in which the application for reimbursement is submitted by the Member State concerned.
- (15) The present Decision constitutes a financing Decision within the meaning of Article 75 of the Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (Financial Regulation) ⁽³⁾, Article 90 of the detailed rules for the implementation of the Financial Regulation, and Article 15 of the Internal Rules on the Implementation of the general budget of the European Communities.

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

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

This Decision establishes a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat food categories provided for in Article 2 at retail level, and lays down rules on a financial contribution from the Union to the Member States for its implementation.

Article 2

Scope and duration of the coordinated monitoring programme

1. The Member States shall carry out a coordinated monitoring programme to assess the prevalence of *Listeria monocytogenes* in the following ready-to-eat food categories in samples selected at random at retail level:

- (a) packaged (not frozen) hot or cold smoked or gravad fish;
- (b) soft or semi-soft cheeses, excluding fresh cheeses;
- (c) packaged heat treated meat products.

2. The sampling for the coordinated monitoring programme provided for in paragraph 1 shall be carried out from 1 January 2010 to 31 December 2010 at the latest.

Article 3

Definitions

For the purposes of this Decision, the following definitions shall apply:

- 1. 'ready-to-eat food' means ready-to-eat food as defined in Article 2(g) of Regulation (EC) No 2073/2005.
- 2. 'shelf-life' means shelf-life as defined in Article 2(f) of Regulation (EC) No 2073/2005.
- 3. 'batch' means batch as defined in Article 2(e) of Regulation (EC) No 2073/2005.

⁽¹⁾ The EFSA Journal (2009) 300, pp. 1-66.

⁽²⁾ OJ L 209, 11.8.2005, p. 1.

⁽³⁾ OJ L 248, 16.9.2002, p. 1.

4. 'retail' means retail as defined in Article 3(7) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽¹⁾; however, for the purposes of this Decision, retail covers only shops, supermarkets and other similar outlets that sell directly to the final consumer; it does not include distribution terminals or centres, catering operations, institutional catering, factory canteens, restaurants and other similar food service operations and wholesale outlets.
5. 'processing' means processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁽²⁾.
6. 'meat products' means meat products as defined in point 7.1 of Annex I to 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⁾.
7. 'country of production' means the country indicated on the identification mark as provided for in point 6 of part B of Section I of Annex II to Regulation (EC) No 853/2004.
8. 'packaged food' means food that has its entire surface covered in order to prevent direct contact of the food with the environment, either by permeable or impermeable wrapping.
9. 'modified atmosphere packaged food' means food that was packaged and hermetically sealed after the removal of air from the package and the replacement of that air with a strictly controlled gaseous mixture of carbon dioxide, oxygen, and/or nitrogen.
10. 'vacuum packaged food' means food that was packaged and hermetically sealed after the removal of the air from the package.
11. 'smoked fish' means fish cured by smoking.
12. 'gravad fish' means fish that has been cured in salt and sugar without thermal treatment.
13. 'ripened cheeses' means cheeses which are not ready for consumption shortly after manufacture but which must be held for such time, at such temperature, and under such other conditions as will result in the necessary biochemical and physical changes characterizing the cheese in question.
14. 'soft cheeses' means cheeses that have a percentage moisture, on a fat-free basis, higher than 67 %.
15. 'semi-soft cheeses' means cheeses that have a texture which is only slightly harder than the soft cheese category. These cheeses have a percentage moisture, on a fat-free basis, ranging from 62 to 67 %. Semi-soft cheeses are characterized by their firm but elastic feel.
16. 'mould ripened cheeses' means cheeses in which the ripening has been accomplished primarily by the development of characteristic mould growth throughout the interior and/or on the surface of the cheese.
17. 'smear-ripened cheeses' means cheeses in which during or after ripening, the cheese rind is treated or naturally colonized with desired cultures of microorganisms, for instance *Penicillium candidum* or *Brevibacterium linens*. The resulting layer or smear forms a part of the rind.
18. 'brine matured cheeses' means cheeses matured and stored in brine until they are sold or packed.
19. 'fresh cheeses' means curd-style cheeses which do not undergo any ripening, for example cottage cheese, mozzarella, ricotta and quark. Fresh cheeses are not included in this coordinated monitoring programme.

Article 4

Sampling, analyses and recording of data by the Member States

1. Sampling shall be performed by the competent authority or under its supervision.
2. National reference laboratories for *Listeria monocytogenes* shall perform the *Listeria monocytogenes*, pH and water activity analyses.
3. The competent authority may designate other laboratories than the national reference laboratories which are accredited for and involved in official controls of *Listeria monocytogenes* to perform the *Listeria monocytogenes*, pH and water activity analyses.
4. The sampling and analyses provided for in paragraphs 1, 2 and 3, as well as recording of all relevant data, shall be performed in accordance with the technical specifications set out in Annex I.
5. The number of samples to be taken per ready-to-eat food category in each Member State is set out in Annex II.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 139, 30.4.2004, p. 1.

⁽³⁾ OJ L 139, 30.4.2004, p. 55.

Article 5

Collection, assessment, reporting and use of data at Union level

1. Member State shall collect and assess the results of the sampling and *Listeria monocytogenes*, pH and water activity analyses provided for in Article 4(1), (2) and (3) of this Decision.

Those results and their assessment, together with all relevant data, shall be included in a final report on the completion of the coordinated monitoring programme that shall be transmitted to the Commission before 31 May 2011.

2. The Commission shall establish by the 31 December 2009 the format of the Data Dictionary and data collection forms to be used in the drawing up of the report referred to in paragraph 1 by the competent authorities.

3. The Commission shall forward the final reports provided for in paragraph 1 to the European Food Safety Authority (EFSA), which shall examine them, develop predictive models for the compliance with the *Listeria monocytogenes* food safety criteria and for the microbial growth under various storage conditions and issue a Summary Report within six months.

4. Any use of the data submitted by the Member States for purposes other than the coordinated monitoring programme shall be subject to prior agreement of the Member States.

5. Data and results shall be made publicly available in a form that ensures confidentiality of the individual results.

Article 6

Conditions for granting a Union financial contribution

1. A financial contribution from the Union of a total amount of 1 555 300 euros from budget line 17 04 02 towards the costs of the analyses provided for in Article 4(2) shall be granted to the Member States up to the maximum total amount for co-financing set out in Annex III.

2. The financial contribution from the Union provided for in paragraph 1 shall be paid to the Member States provided that the coordinated monitoring programme is carried out in accordance with the relevant provisions of Union law, including rules on competition and on the award of public contracts, and subject to compliance with the following conditions:

The final report on the completion of the coordinated monitoring programme must be submitted to the Commission before 31 May 2011; the report must contain:

(i) all the information set out in Part D of Annex I;

(ii) supporting evidence for the costs incurred by the Member States for the analyses; that evidence must comprise at least the information set out in Annex IV.

3. In the case of late submission of the final report referred to in paragraph 2 the financial contribution from the Union shall be reduced by 25 % on 1 July 2011, 50 % on 1 August 2011 and 100 % on 1 September 2011.

Article 7

Maximum amounts to be reimbursed

The maximum amounts of the financial contribution from the Union towards the costs to be reimbursed to the Member States for each analysis shall not exceed the following:

(a) EUR 60 for each analysis for the detection of *Listeria monocytogenes*;

(b) EUR 60 for each analysis for the enumeration of *Listeria monocytogenes*;

(c) EUR 15 for each pH analysis;

(d) EUR 20 for each water activity (a_w) analysis.

Article 8

Conversion rate for expenditure

Where a Member State's expenditure is in a currency other than euro, the Member State concerned shall convert it into euro by applying the most recent exchange rate set by the European Central Bank prior to the first day of the month in which the application is submitted by the Member State.

Article 9

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 5 February 2010.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX I

(referred to in Article 4(4))

PART A

SAMPLING FRAME

1. The products to be sampled

The following categories of ready-to-eat food shall be sampled at retail level:

1.1. *Packaged (not frozen) hot or cold smoked or gravad fish*

Products belonging to this category must be vacuum packaged or modified atmosphere packaged.

The fish may be sliced or not. The package may contain a whole fish, or half or a part of a fish. The skin of the fish may be present or absent.

1.2. *Soft or semi-soft cheeses, excluding fresh cheeses*

This category shall include cheese made from raw, thermised or pasteurised milk of any animal species. The cheese can be ripened, smear-ripened, mould-ripened or brine-matured.

The cheese may be packaged including wrapped in muslin, or may be unpackaged at retail but packaged at the point of sale for the consumer.

1.3. *Packaged heat-treated meat products*

1.3.1. Products belonging to this category must have undergone heat treatment and after that must have been handled and vacuum or modified atmosphere packaged.

1.3.2. Products belonging to this category cover both exposed meat products and meat products in a permeable skin that have been sliced or otherwise handled between heat treatment and packaging. Products may have been smoked after the heat treatment.

This category includes in particular:

(a) Cold, cooked meat products: meat products typically made with whole or large parts of anatomical or reformed structures (such as cooked sliced ham and cooked chicken fillet);

(b) sausages;

(c) pâtés.

1.3.3. This category does not include:

(a) meat products dried after heat treatment, such as jerky products;

(b) meat products heat-treated in an impermeable package which are not handled thereafter;

(c) fermented meat products, including fermented sausages.

2. Sampling design

A proportionate stratified sampling scheme is used for the coordinated monitoring programme whereby the samples are allocated to every Member State proportionally to the size of the human population in that Member State.

2.1. *Sampling plan*

2.1.1. Each Member State must have a sampling plan, based on a multistage cluster design:

(a) the first level is composed of the major cities/towns to be sampled;

(b) the second level is composed of the retail outlets to be sampled;

- (c) the third level is composed of the different food products within the three ready-to-eat food categories to be sampled.

2.1.2. The sampling plan must be drawn up by the competent authority and must include the following:

- (a) the cities/towns included in the coordinated monitoring programme;
- (b) the types of retail outlets covered and the percentage of samples taken from each category;
- (c) the timing of the sampling throughout the year.

2.1.3. Where relevant marketing data is available, the sampling plan must also include:

- (a) the types of products to be sampled within each of the three ready-to-eat food categories;
- (b) the number of samples to be taken from each type of product referred to in (a).

2.1.4. Member States shall draw up a sampling plan following the rules described below and based on the best marketing data available. These marketing data, or assistance with how to obtain the information, may often be available from a national trade association. In the absence of marketing data, the best estimate of market shares shall be used to inform the sampling plan at a central level. In the absence of any reliable marketing information it may be necessary for competent authorities to devolve the selection of the type of product to sample within a category to the sampler in the field.

2.2. *Selection of the retail outlet categories to be targeted*

The competent authorities shall choose the retail outlets from which samples are to be taken. Typical types of retail outlets that shall be included for sampling are: supermarkets, small shops, speciality delis, and street markets (such as farmers' or country markets).

If the biggest category of outlets (for example supermarkets) supply at least 80 % of the market of a RTE category then samples only need to be taken from those outlets. Where that is not the case, the second largest outlet category shall be added until at least 80 % of the market is covered.

When sampling is performed according to a sampling plan, the number of samples that shall be taken for each category of ready-to-eat food from each retail outlet type shall be proportionate to the market share of that outlet type within the targeted outlet types.

2.3. *Selection of the cities or towns to be sampled*

The sampling shall take place in large cities/towns. At least two large cities/towns in each Member State must be sampled.

The cities/towns in which sampling is performed must, taken together, cover at least 30 % of the human population in the Member State. However, if the eight largest cities/towns are included in the plan, the human population coverage may be less than 30 %.

2.4. *Selection of sample timing*

The contamination level of *Listeria monocytogenes* in ready-to-eat food may vary over the year. In order to ensure accurate results of the coordinated monitoring programme, its duration is divided in 12 periods of one month during which equal numbers of samples must be taken.

2.5. *Selection of the ready-to-eat foods within the three main categories to be sampled*

The ready-to-eat foods within the three ready-to-eat food categories to be sampled shall be selected based on the marketing data and detailed in the sampling plan.

However, the diverse nature of products within a category may not permit estimation of market share with a high degree of reliability. In this case, the competent authorities may choose to instruct samplers to select cheeses for sampling based upon an estimated contribution to market share, according to the national sampling plan. Such sampling may be informed by turnover details provided by local retail management, or more roughly by prominence in the marketplace, e.g. what is displayed at the retail outlet. With such an approach competent authorities should provide some direction on approximate market share of major types of food within categories to best approach a sample representative of market e.g. raw/pasteurised milk cheeses.

PART B

SAMPLE COLLECTION AND TRANSPORT

1. Type and detail of sample

Samples shall be taken at random from the customer display and must weight at least 100 g each. It is possible to take more than one sample from each three ready-to-eat food category during the same visit to the retail outlet. However, no more than five batches from each category should be sampled at the same visit.

Only packaged and intact (sealed) packages, packaged by the manufacturer, shall be collected for sampling. However, in case of cheeses, products packaged at the retail outlet may also be collected for sampling.

The products collected for sampling must be labelled in order to make it possible to record information concerning the products. Information on the label shall include the following:

- (a) details of the country of production;
- (b) batch number;
- (c) durability date;
- (d) instructions on temperature storage conditions, if available;
- (e) other information which is normally on the label of packaged ready-to-eat food.

If not all the information referred to in points (a) to (d) is present on the label, the sampler shall ask the owner or manager of the retail outlet for the missing information on the product and labelling details and/or refer to the wholesale pack for that information.

If the label on the ready-to-eat food is not clear or is otherwise damaged, then the product shall not be collected for sampling. Two samples shall be collected from each batch of smoked or gravad fish sampled. Labelling information, such as batch numbers, date until which the product may be sold must be examined to ensure that the two samples are from the same batch. One of those two samples must be analysed on the day of receipt of the sample at the laboratory and the other at the end of shelf-life.

For soft and semi-soft cheeses and heat-treated meat products, only one sample is taken from a batch that must be analysed at the end of shelf-life.

The samples must be placed in a separate sampling bag and sent immediately to the laboratory for analysis

Precautions must be taken at all stages to ensure that the equipment used during sampling, transport and storage is not contaminated with *Listeria monocytogenes*.

2. Sample information

All relevant information available concerning the sample shall be recorded on a sampling form, the model of which shall be drawn up by the competent authority. The sampling form shall accompany the sample at all times. In the case of cheese samples packaged at the retail outlet, it may be necessary to ask for the information on the required product and labelling details and/or refer to the wholesale pack for this information.

When samples are collected, the surface temperature of the packaged samples shall be measured and recorded on the sampling form.

Each sample and its sample form shall be labelled with a unique number which shall be used from sampling to testing. The competent authority shall use for this purpose a unique numbering system.

3. Transport of samples

The samples shall be transported in refrigerated containers and must be kept at between 2 to 8 °C and free from external contamination during transportation.

All ready-to-eat food samples must reach the laboratory within 24 hours of the time of sampling.

In exceptional circumstances the transportation time may exceed 24 hours. However, the transportation time shall not be longer than 48 hours and shall in no circumstances lead to testing being carried out after the sell by date of the product collected for sampling.

PART C

SAMPLE PREPARATION AND ANALYTICAL METHODS

1. Receipt of samples

1.1. General rules

On receipt of the samples, laboratories shall check the information recorded by the sampler on the sampling form and complete the relevant sections of that form. All samples received shall be examined to ensure that the packaging used for transportation is intact before storing. Samples received at a temperature higher than 8 °C shall be rejected unless the temperature at retail was higher than 8 °C.

Without prejudice to point 1.2, all samples are kept refrigerated until the end of their shelf-life.

In cases where samples must be stored until the end of their shelf-life, they shall be refrigerated:

- (a) at the storage temperature indicated on the label of the packaging. If the label indicates a temperature interval, the sample must be stored at the upper limit of the temperature interval;
- (b) if there is no specific storage temperature indicated on the label of the packaging, the sample must be kept at:
 - (i) the maximum refrigeration temperatures defined by the legislation or guidance in force in the Member State where the sample is collected, with a tolerance of ± 2 °C,
 - (ii) 8 °C (± 2 °C) where no such legislation or guidance exists.

If the shelf-life of the product sampled ends during a weekend or a national holiday, the sample must be analyzed on the last working day before the end of the shelf-life.

1.2. Special rules concerning smoked and gravad fish

One of the two samples is analyzed within 24 hours from the time of arrival at the laboratory. If that sample is not analysed immediately upon arrival, it must be kept refrigerated at 3 °C (± 2 °C) in the laboratory before analysis.

The second sample shall be kept refrigerated until the end of its shelf-life.

2. Sample preparation and initial suspension preparation

Cross contamination between samples and from the surrounding environment shall be avoided at all stages. Samples are discarded once laboratory analyses have been initiated. If the analysis is stopped, for example due to unacceptable deviations in the analysis process, new samples must be obtained.

Either the entire product, or a representative test portion of 100 to 150 g, shall be taken to the initial dilution. Food shall be sampled to include surfaces reflecting the proportion that would be consumed (such as 20 % rind/surface and 80 % inside). When a packaged product is sliced, the respective sample is taken from more than one slice of the product. The test portion shall be cut in small pieces and placed into a stomacher bag, using a sterile instrument and an aseptic technique. From that mixture, a test portion of 10 g shall be taken for enumeration and a test portion of 25 g shall be taken for detection.

To the volume of the test portion (10 g), 9 volumes (90 ml) of diluent are added and subsequently the mixture is homogenized using a stomacher or a pulsifier for 1 to 2 min.

Buffered peptone water, as described in EN ISO 11290-2 'Microbiology of food and animal feeding stuffs — Horizontal method for detection and enumeration of *Listeria monocytogenes* — Part 2: Colony-count technique', may be applied as a diluent for general use.

For the dilution of cheese, a sodium citrate solution, as described in EN ISO 6887-5 'Microbiology of food and animal feeding stuffs — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination — Part 5: Specific rules for the preparation of milk and milk products' shall be used.

Detection and enumeration analyses of *Listeria monocytogenes* shall be performed in accordance with the following:

(a) for smoked and gravad fish samples two sets of analyses must be carried out:

- (i) immediately after sample collection at retail level and
- (ii) at the end of shelf-life;

(b) for soft and semi-soft cheese samples and heat-treated meat product samples the analyses must be carried out only at the end of shelf-life.

2.1. Detection of *Listeria monocytogenes*

Detection of *Listeria monocytogenes* shall be performed according to the amended version of EN ISO 11290-1:1996 'Microbiology of food and animal feeding stuffs — Horizontal method for the detection and enumeration of *Listeria monocytogenes* — Part 1: Detection method'.

2.2. Enumeration of *Listeria monocytogenes*

The enumeration of *Listeria monocytogenes* shall be performed according to EN ISO 11290-2:1998 'Microbiology of food and animal feeding stuffs — Horizontal method for the detection and enumeration of *Listeria monocytogenes* — Part 2: Enumeration method' and its modification EN ISO 11290-2:1998/Amd 1:2004 'Modification of the enumeration medium'.

If the sample is found to be contaminated, it is assumed that the majority of products would contain low contamination levels of *Listeria monocytogenes*. To enable the estimation of low numbers in samples (between 10 and 100 cfu/g), 1 ml of the primary dilution shall be tested in duplicate as indicated in EN ISO 11290-2:1998/Amd 1:2004:

- (a) spread onto the surface of three 90-mm diameter plates, or
- (b) spread onto the surface of one 140-mm diameter plate.

Because of the possibility of higher contamination levels of *Listeria monocytogenes*, 0,1 ml of the primary dilution must be spread onto the surface of one plate to allow the enumeration of up to $1,5 \times 10^4$ cfu/g. This plating must be performed in single as provided in ISO 7218:2007 'Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations'.

3. pH and water activity (a_w) analyses of smoked and gravad fish

3.1. Determination of the pH

The determination of the pH of the sample shall be performed according to EN ISO 2917:1999 'Meat and meat products — Measurement of pH — Reference method'.

The analysis must be carried out on the sample tested on the arrival at the laboratory. The non-destructive technique listed in the ISO method is recommended for measuring the pH of the sample.

The result must be reported to the nearest 0,05 unit of pH.

3.2. Determination of the water activity (a_w)

The determination of the water activity (a_w) of the sample shall be performed according to EN ISO 21807:2004 'Microbiology of food and animal feeding stuffs — Determination of water activity'.

The analysis must be carried out on the sample tested on the arrival at the laboratory. The method shall be able of operating in the range 0,999 to 0,9000 and the repeatability limit shall correspond to a standard deviation of 0,002.

The reported value should contain at least two significant figures.

4. Storage of isolates

One confirmed *Listeria monocytogenes* strain per positive sample shall be stored for possible further typing studies. If *Listeria monocytogenes* strains are recovered both from the detection and enumeration methods, only the isolates from the enumeration method shall be stored.

Isolates shall be stored by the national reference laboratories using appropriate methods for culture collection as long as it ensures viability of the strains for a minimum of two years for the typing.

PART D REPORTING

1. General provisions

The information to be reported by Member States, as far as it is available or accessible, consists of two broad categories:

- (a) an overview of the coordinated monitoring programme and results; the overview must take the form of a textual account;
- (b) individual detailed data for each sample tested as part of the sampling plan; that information must be submitted in as raw data using the 'Data Dictionary' and the data collection forms provided for in Article 5(2).

2. Information to be included in the overview of the coordinated monitoring programme and results

- (a) Member State name;
- (b) Date of start and end of the sampling and analysis;
- (c) Number of ready-to-eat food samples collected and analysed from retail outlets:
 - (i) soft and semi-soft cheeses,
 - (ii) packaged smoked and gravad fish,
 - (iii) packaged heat-treated meat products;
- (d) Overall results:

prevalence and proportion of samples exceeding the limit of 100 cfu/g of *Listeria monocytogenes* in soft and semi-soft cheeses, smoked and gravad fish as well as in heat-treated meat products covered by the coordinated monitoring programme;
- (e) Description of the markets in soft and semi-soft cheeses, smoked and gravad fish as well as in heat-treated meat products in the Member State:
 - (i) overall absolute market size (if available),
 - (ii) market share of different types of retail outlets, such as supermarket, small shops, speciality delis, street markets (if available),
 - (iii) market share of imported (trade within the Union and imports from third countries) and domestic production (if available),
 - (iv) market share of different types of products, (if available);
- (f) Retail outlets sampled:

type of outlet categories covered: e.g. supermarkets, small shops etc.;
- (g) Geographical distribution of sampling — cities/towns covered (% of human population covered);
- (h) Description of randomisation procedure for retail sampling:

month randomisation;
- (i) Comment on overall representativeness of the sampling programme;

- (j) Preparation of test sample used for pH measurement;
- (k) Analytical method used for water activity (a_w) determination.

3. Information to be included in the individual detailed data for each sample

- (a) Type of sample:
 - (i) packaged soft and semi-soft cheeses,
 - (ii) packaged smoked and gravad fish,
 - (iii) packaged heat-treated meat products;
- (b) Subtype of the sample:
 - (i) cheeses made from raw/thermised/pasteurised milk,
 - (ii) cheeses made from cow/goat/sheep/buffalo/mixed milk,
 - (iii) smear-ripened, mould-ripened, brine-matured or other ripened cheeses,
 - (iv) sliced and non-sliced products,
 - (v) cold/hot smoked or gravad fish,
 - (vi) species of the fish;
- (c) Preservatives used in smoked or gravad fish (as indicated in the label);
- (d) Cheese rind included in the specimen analyses (yes/no, if yes then also proportion if available);
- (e) Code of the laboratory involved in initial analysis;
- (f) Date of sample collection;
- (g) Use by date of the sampled product;
- (h) Production/packaging date (if available);
- (i) Surface temperature of the sample in the retail outlet;
- (j) Storage temperature in the laboratory up to the end of shelf-life;
- (k) Analysis immediately after sampling (only for smoked and gravad fish)/end of shelf-life;
- (l) Date of beginning of the analysis at the laboratory;
- (m) Detection of *Listeria monocytogenes*:
 - qualitative results (absence/presence in 25 g);
- (n) Quantification of *Listeria monocytogenes*:
 - quantitative results (cfu/g);

- (o) pH (only smoked and gravad fish);
 - (p) Water activity (a_w) (only smoked and gravad fish);
 - (q) Code of the city/town;
 - (r) Code of the outlet;
 - (s) Type of retailer:
 - (i) supermarket,
 - (ii) small shop/independent retailer,
 - (iii) speciality delis,
 - (iv) street market/farmers' market;
 - (t) Country of production:
as ascertained with reference to the identification mark on packaging or commercial documentation;
 - (u) Pre-packaged:
 - (i) modified atmosphere packaged,
 - (ii) vacuum packaged,
 - (iii) packed at retail level (only for cheeses);
 - (v) Organoleptic quality of the sample.
-

ANNEX II

**Number of samples to be taken per ready-to-eat food category in the Member States
(referred to in Article 4(5))**

Member State	Population on 1.1.2008 (EUROSTAT data)		Harmonized stratified sample size	
	N (Million)	%	Per food category and analysis stage (*)	Total sample size
Belgium — BE	10,7	2,1	60	240
Bulgaria — BG	7,6	1,5	60	240
Czech Republic — CZ	10,4	2,1	60	240
Denmark — DK	5,576	1,1	60	240
Germany — DE	82,2	16,5	400	1 600
Estonia — EE	1,3	0,3	30	120
Ireland — IE	4,4	0,9	30	120
Greece — EL	11,2	2,3	60	240
Spain — ES	45,3	9,1	200	800
France — FR	63,8	12,8	400	1 600
Italy — IT	59,6	12,0	400	1 600
Cyprus — CY	0,8	0,2	30	120
Latvia — LV	2,3	0,5	30	120
Lithuania — LT	3,4	0,7	30	120
Luxembourg — LU	0,5	0,1	30	120
Hungary — HU	10,0	2,0	60	240
Malta — MT	0,4	0,1	30	120
Netherlands — NL	16,4	3,3	60	240
Austria — AT	8,3	1,7	60	240
Poland — PL	38,1	7,7	200	800
Portugal — PT	10,6	2,1	60	240
Romania — RO	21,5	4,3	60	240
Slovenia — SI	2,0	0,4	30	120
Slovakia — SK	5,4	1,1	60	240
Finland — FI	5,3	1,1	60	240
Sweden — SE	9,2	1,8	60	240
United Kingdom — UK	61,2	12,3	400	1 600
Total EU	497,5	100,0	3 020	12 080

(*) For smoked and gravad fish: two samples are collected from each batch. One of these samples is analysed on the day of receipt at the laboratory and the other one is analysed at the end of the shelf-life. (see point 1.2 of part C of Annex I)

ANNEX III

Maximum financial contribution from the Union to the Member States

(in EUR)

Member State	Maximum total amount for co-financing of analyses for the				
	<i>Listeria monocytogenes</i> detection	<i>Listeria monocytogenes</i> enumeration	pH	Water activity	Total
Belgium — BE	14 400	14 400	900	1 200	30 900
Bulgaria — BG	14 400	14 400	900	1 200	30 900
Czech Republic — CZ	14 400	14 400	900	1 200	30 900
Denmark — DK	14 400	14 400	900	1 200	30 900
Germany — DE	96 000	96 000	6 000	8 000	206 000
Estonia — EE	7 200	7 200	450	600	15 450
Ireland — IE	7 200	7 200	450	600	15 450
Greece — EL	14 400	14 400	900	1 200	30 900
Spain — ES	48 000	48 000	3 000	4 000	103 000
France — FR	96 000	96 000	6 000	8 000	206 000
Italy — IT	96 000	96 000	6 000	8 000	206 000
Cyprus — CY	7 200	7 200	450	600	15 450
Latvia — LV	7 200	7 200	450	600	15 450
Lithuania — LT	7 200	7 200	450	600	15 450
Luxembourg — LU	7 200	7 200	450	600	15 450
Hungary — HU	14 400	14 400	900	1 200	30 900
Malta — MT	7 200	7 200	450	600	15 450
Netherlands — NL	14 400	14 400	900	1 200	30 900
Austria — AT	14 400	14 400	900	1 200	30 900
Poland — PL	48 000	48 000	3 000	4 000	103 000
Portugal — PT	14 400	14 400	900	1 200	30 900
Romania — RO	14 400	14 400	900	1 200	30 900
Slovenia — SI	7 200	7 200	450	600	15 450
Slovakia — SK	14 400	14 400	900	1 200	30 900
Finland — FI	14 400	14 400	900	1 200	30 900
Sweden — SE	14 400	14 400	900	1 200	30 900
United Kingdom — UK	96 000	96 000	6 000	8 000	206 000
Total EU	724 800	724 800	45 300	60 400	1 555 300

ANNEX IV

Certified financial report on the implementation of a coordinated monitoring programme of *Listeria monocytogenes* in selected categories of ready-to-eat foods

Reporting period: to

Statement on costs incurred on the coordinated monitoring programme and eligible for financial contribution from the Union

Reference number of Commission Decision providing a financial contribution from the Union:

Costs incurred related to	Number of tests	Total costs of analysis incurred during reporting period (national currency)
Analyses for the detection of <i>Listeria monocytogenes</i>		
Analyses for the enumeration of <i>Listeria monocytogenes</i>		
Analyses for the determination of the pH		
Analyses for the water activity (a_w)		

Declaration by the beneficiary

I certify that

- the above costs are genuine and have been incurred in carrying out the tasks laid down in Decision 2010/75/EU and were essential for the proper performance of those tasks;
- all supporting documents supporting the costs are available for audit purposes;
- no other contribution from the Union was requested for this coordinated monitoring programme.

Date:

Person financially responsible:

Signature:

COMMISSION DECISION

of 9 February 2010

according a transitional period for implementing Regulation (EC) No 762/2008 of the European Parliament and of the Council on the submission by Member States of statistics on aquaculture with regard to the Czech Republic, Germany, Greece, Austria, Poland, Portugal and Slovenia

*(notified under document C(2010) 735)***(Only the Czech, German, Greek, Polish, Portuguese and Slovenian texts are authentic)**

(2010/76/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 762/2008 of the European Parliament and of the Council of 9 July 2008 on the submission by Member States of statistics on aquaculture and repealing Council Regulation (EC) No 788/96 ⁽¹⁾, and in particular Article 5(2) and Article 7(1) thereof,

Having regard to the request made by Slovenia on 25 November 2008,

Having regard to the request made by the Czech Republic on 17 December 2008,

Having regard to the request made by Germany on 19 December 2008,

Having regard to the request made by Greece on 2 December 2008,

Having regard to the request made by Austria on 19 December 2008,

Having regard to the request made by Portugal on 22 December 2008,

Having regard to the request made by Poland on 31 December 2008,

Whereas:

- (1) In accordance with Article 7 of Regulation (EC) No 762/2008, the Commission may grant Member States a transitional period for implementing this Regulation in so far as the application of this Regulation to their national statistical systems requires major adaptations and is likely to cause significant practical problems.

- (2) Such transitional periods should be granted, at their request, to the Czech Republic, Germany, Greece, Austria, Poland, Portugal and Slovenia.

- (3) In accordance with Regulation (EC) No 762/2008, a Member State having been granted a transitional period shall continue to apply the provisions of Regulation (EC) No 788/96 for the duration of the transitional period granted.

- (4) In accordance with Article 5(2) of Regulation (EC) No 762/2008, the data on the structure of the aquaculture sector referred to in Annex V shall be submitted at intervals of three years.

- (5) The measures provided for in this Decision are in line with the opinion of the Standing Committee on Agricultural Statistics, instituted by Council Decision 72/279/EEC ⁽²⁾,

HAS ADOPTED THIS DECISION:

*Article 1***Transitional periods regarding the submission of the data referred to in Annexes II, III and IV to Regulation (EC) No 762/2008**

For the purposes of implementing Article 5(1) of Regulation (EC) No 762/2008:

1. The Czech Republic shall be granted a transitional period ending on 31 December 2009. The first reference calendar year shall be 2009.
2. Portugal shall be granted a transitional period ending on 31 December 2010. The first reference calendar year shall be 2010.
3. Germany, Greece, Austria, Poland and Slovenia shall be granted a transitional period ending on 31 December 2011. The first reference calendar year shall be 2011.

⁽¹⁾ OJ L 218, 13.8.2008, p. 1.

⁽²⁾ OJ L 179, 7.8.1972, p. 1.

*Article 2***Transitional periods regarding the submission of the data referred to in Annex V to Regulation (EC) No 762/2008**

For the purposes of implementing Article 5(2) of Regulation (EC) No 762/2008, the Czech Republic, Germany, Greece, Austria, Poland, Portugal and Slovenia shall be granted a transitional period ending on 31 December 2011. The first reference calendar year shall be 2011.

*Article 3***Transitional periods regarding the annual quality assessment report**

The transitional periods referred to in Articles 1 and 2 of this Decision shall apply mutatis mutandis for the purposes of implementing Article 6 of Regulation (EC) No 762/2008.

Article 4

This Decision is addressed to the Czech Republic, the Federal Republic of Germany, the Hellenic Republic, the Republic of Austria, the Republic of Poland, the Portuguese Republic and the Republic of Slovenia.

Done at Brussels, 9 February 2010.

For the Commission

Joaquín ALMUNIA

Member of the Commission

COMMISSION DECISION

of 9 February 2010

setting a new deadline for the submission of a dossier for terbutryn to be examined under the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council

*(notified under document C(2010) 752)***(Text with EEA relevance)**

(2010/77/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market⁽¹⁾, and in particular Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market⁽²⁾ establishes a list of active substances to be examined with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. Terbutryn is included in that list for product types 7, 9 and 10.

(2) The initial participant who notified terbutryn for product types 7, 9 and 10 withdrew from the review programme. Consequently, and pursuant to Article 11(2) of Regulation (EC) No 1451/2007, the Commission informed the Member States thereof. That information was also made public by electronic means on 22 June 2007.

(3) Within three months of the electronic publication of that information, three undertakings demonstrated an interest in taking over the role of participant for terbutryn for one or more of product types 7, 9 and 10, in accordance with Article 12(1) of Regulation (EC) No 1451/2007.

(4) Pursuant to Article 9(2)(d) of Regulation (EC) No 1451/2007, the deadline for submission of complete

dossiers for product types 7, 9 and 10 was 31 October 2008. Pursuant to the second subparagraph of Article 12(3) of Regulation (EC) No 1451/2007, where the Commission allows an interested person to take over the role of a participant who has withdrawn, it may decide to extend, if necessary, the relevant period for the submission of a complete dossier.

(5) Due to a misunderstanding regarding the deadline, it is appropriate to extend the deadline for the submission of dossiers for terbutryn for product types 7, 9 and 10 until 1 March 2010.

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

HAS ADOPTED THIS DECISION:

Article 1

The new deadline for the submission of dossiers for terbutryn (EC number 212-950-5; CAS number 886-50-0) for product types 7, 9 and 10 is 1 March 2010.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 9 February 2010.

For the Commission

Stavros DIMAS

Member of the Commission

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

COMMISSION DECISION

of 9 February 2010

**adjusting the thresholds referred to in Article 157(b) and Article 158(1) of Regulation (EC, Euratom)
No 2342/2002 laying down detailed rules for the implementation of the Financial Regulation**

(2010/78/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽¹⁾, and in particular Article 271 thereof,

Whereas:

- (1) Commission Regulation (EC) No 1177/2009 ⁽²⁾ adjusted the thresholds applicable to public procurement contracts pursuant to Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts ⁽³⁾.
- (2) For reasons of consistency, it is therefore necessary to establish the thresholds referred to in Articles 157(b) and 158(1) of Regulation (EC, Euratom) No 2342/2002.
- (3) Since the thresholds adjusted by Regulation (EC) No 1177/2009 are applicable from 1 January 2010, this Decision should also apply from 1 January 2010. This Decision should therefore enter into force on the day following its publication in the *Official Journal of the European Union*.
- (4) Commission Decision 2004/121/EC of 6 February 2004 adjusting the thresholds referred to in Article 157(b) and Article 158(1)(a) and (c) of Regulation (EC, Euratom) No 2342/2002 laying down detailed rules for the implementation of the Financial Regulation ⁽⁴⁾, Commission Decision 2006/103/EC of 14 February 2006 adjusting the thresholds referred to in Articles 157(b) and 158(1)(a) and (c) of Regulation (EC, Euratom) No 2342/2002 laying down detailed rules for the implementation of the Financial Regulation ⁽⁵⁾ and Commission

Decision 2008/102/EC of 1 February 2008 adjusting the thresholds referred to in Article 157(b) and Article 158(1) of Regulation (EC, Euratom) No 2342/2002 laying down detailed rules for the implementation of the Financial Regulation ⁽⁶⁾ have lapsed and should therefore be repealed,

HAS ADOPTED THIS DECISION:

Article 1

The euro equivalents of the thresholds applicable to public procurement contracts shall be established as follows:

- EUR 4 845 000 in Article 157(b),
- EUR 125 000 in Article 158(1)(a),
- EUR 193 000 in Article 158(1)(b),
- EUR 4 845 000 in Article 158(1)(c).

Article 2

Decisions 2004/121/EC, 2006/103/EC and 2008/102/EC are repealed.

Article 3

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

It shall apply from 1 January 2010.

Done at Brussels, 9 February 2010.

*For the Commission
The President*

José Manuel BARROSO

⁽¹⁾ OJ L 357, 31.12.2002, p. 1.

⁽²⁾ OJ L 314, 1.12.2009, p. 64.

⁽³⁾ OJ L 134, 30.4.2004, p. 114.

⁽⁴⁾ OJ L 36, 7.2.2004, p. 58.

⁽⁵⁾ OJ L 46, 16.2.2006, p. 52.

⁽⁶⁾ OJ L 36, 9.2.2008, p. 5.

IV

(Acts adopted before 1 December 2009 under the EC Treaty, the EU Treaty and the Euratom Treaty)

COMMISSION DECISION

of 19 October 2009

amending Decisions 2006/679/EC and 2006/860/EC as regards technical specifications for interoperability relating to subsystems of the trans-European conventional and high-speed rail systems

(notified under document C(2009) 7787)

(Text with EEA relevance)

(2010/79/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community ⁽¹⁾, and in particular Article 6(1) thereof,

Having regard to the recommendation of the European Railway Agency (ERA-REC-38-2009-ERTMS) of 24 April 2009, on updating the Annex A of the TSI Control Command and Signalling for High Speed and Conventional Rail systems,

Whereas:

(1) Commission Decision 2006/679/EC of 28 March 2006 concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European conventional rail system ⁽²⁾ laid down the technical specification for interoperability (TSI) relating to the control-command and signalling subsystem of the trans-European conventional rail system.

(2) Commission Decision 2006/860/EC of 7 November 2006 concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European high speed rail system ⁽³⁾ laid down the TSI relating to the control-command and signalling subsystem of the trans-European high speed rail system.

(3) In accordance with Article 2 of Commission Decision 2008/386/EC of 23 April 2008 modifying Annex A to

Decision 2006/679/EC concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European conventional rail system and Annex A to Decision 2006/860/EC concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European high-speed rail system ⁽⁴⁾, the ETCS specifications should be completed to include updated common test specifications.

(4) A number of technical documents referred to in Annex A to Decisions 2006/679/EC and 2006/860/EC must be updated to adapt them to technical progress.

(5) Decisions 2006/679/EC and 2006/860/EC should therefore be amended accordingly.

(6) The measures provided for in this Decision are in accordance with the opinion of the Railway Interoperability and Safety Committee, established in accordance with Article 29 of Directive 2008/57/EC,

HAS ADOPTED THIS DECISION:

Article 1

The list of mandatory specifications and the list of informative specifications set out in Annex A to Decision 2006/679/EC and in Annex A to Decision 2006/860/EC, are replaced by the list of mandatory specifications and the list of informative specifications contained in the Annex to this Decision. The footnotes referring to Decision 2002/731/EC in Annex H to the TSI attached to Decision 2006/679/EC and in Annex H to the TSI attached to Decision 2006/860/EC are deleted.

⁽¹⁾ OJ L 191, 18.7.2008, p. 1.

⁽²⁾ OJ L 284, 16.10.2006, p. 1.

⁽³⁾ OJ L 342, 7.12.2006, p. 1.

⁽⁴⁾ OJ L 136, 24.5.2008, p. 11.

Article 2

This Decision shall apply from 1 April 2010.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 19 October 2009.

For the Commission

Antonio TAJANI

Vice-President

ANNEX

LIST OF MANDATORY SPECIFICATIONS

Index No	Reference	Document name	Version
1	ERA/ERTMS/003204	ERTMS/ETCS Functional Requirement Specification	5.0
2	Intentionally deleted		
3	UNISIG SUBSET-023	Glossary of Terms and Abbreviations	2.0.0
4	UNISIG SUBSET-026	System Requirement Specification	2.3.0
5	UNISIG SUBSET-027	FFIS Juridical Recorder-Downloading Tool	2.3.0
6	UNISIG SUBSET-033	FIS for Man-Machine Interface	2.0.0
7	UNISIG SUBSET-034	FIS for the Train Interface	2.0.0
8	UNISIG SUBSET-035	Specific Transmission Module FFFIS	2.1.1
9	UNISIG SUBSET-036	FFIS for Eurobalise	2.4.1
10	UNISIG SUBSET-037	Euroradio FIS	2.3.0
11	Reserved 05E537	Off line key management FIS	
12	UNISIG SUBSET-039	FIS for the RBC/RBC Handover	2.3.0
13	UNISIG SUBSET-040	Dimensioning and Engineering rules	2.3.0
14	UNISIG SUBSET-041	Performance Requirements for Interoperability	2.1.0
15	ERA SUBSET-108	Interoperability-related consolidation on TSI Annex A documents	1.2.0
16	UNISIG SUBSET-044	FFIS for Euroloop sub-system	2.3.0
17	Intentionally deleted		
18	UNISIG SUBSET-046	Radio In-fill FFIS	2.0.0
19	UNISIG SUBSET-047	Track-side-Trainborne FIS for Radio In-Fill	2.0.0
20	UNISIG SUBSET-048	Trainborne FFFIS for Radio In-Fill	2.0.0
21	UNISIG SUBSET-049	Radio In-fill FIS with LEU/Interlocking	2.0.0
22	Intentionally deleted		
23	UNISIG SUBSET-054	Assignment of Values to ETCS variables	2.0.0
24	Intentionally deleted		
25	UNISIG SUBSET-056	STM FFFIS Safe Time Layer	2.2.0

Index No	Reference	Document name	Version
26	UNISIG SUBSET-057	STM FFFIS Safe Link Layer	2.2.0
27	UNISIG SUBSET-091	Safety Requirements for the Technical Interoperability of ETCS in Levels 1 & 2	2.5.0
28	Reserved	Reliability — Availability Requirements	
29	UNISIG SUBSET-102	Test specification for Interface 'k'	1.0.0
30	Intentionally deleted		
31	UNISIG SUBSET-094	UNISIG Functional Requirements for an On-board Reference Test Facility	2.0.2
32	EIRENE FRS	GSM-R Functional Requirements Specification	7
33	EIRENE SRS	GSM-R System Requirements Specification	15
34	A11T6001 12	(MORANE) Radio Transmission FFFIS for EuroRadio	12
35	ECC/DC(02)05	ECC Decision of 5 July 2002 on the designation and availability of frequency bands for railway purposes in the 876-880 and 921-925 MHz bands	
36a	Intentionally deleted		
36b	Intentionally deleted		
36c	UNISIG SUBSET-074-2	FFFIS STM Test cases document	1.0.0
37a	Intentionally deleted		
37b	UNISIG SUBSET-076-5-2	Test cases related to features	2.3.1
37c	UNISIG SUBSET-076-6-3	Test sequences	2.3.1
37d	UNISIG SUBSET-076-7	Scope of the test specifications	1.0.2
37e	Intentionally deleted		
38	06E068	ETCS marker board definition	1.0
39	UNISIG SUBSET-092-1	ERTMS EuroRadio Conformance Requirements	2.3.0
40	UNISIG SUBSET-092-2	ERTMS EuroRadio Test cases Safety Layer	2.3.0
41	Reserved UNISIG SUBSET 028	JRU Test Specification	
42	Intentionally deleted		
43	UNISIG SUBSET 085	Test Specification for Eurobalise FFFIS	2.2.2
44	Reserved	Odometry FIS	

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45	UNISIG SUBSET-101	Interface 'K' specification	1.0.0
46	UNISIG SUBSET-100	Interface 'G' specification	1.0.1
47	Reserved	Safety Requirements and Requirements to Safety Analysis for Interoperability for the Control-Command and Signalling Sub-System	
48	Reserved	Test specification for mobile equipment GSM-R	
49	UNISIG SUBSET-059	Performance requirements for STM	2.1.1
50	UNISIG SUBSET-103	Test specification for EUROLOOP	1.0.0
51	Reserved	Ergonomic aspects of the DMI	
52	UNISIG SUBSET-058	FFIS STM Application Layer	2.1.1
53	Reserved AEIF-ETCS-Variables-Manual	AEIF-ETCS-Variables-Manual	
54	Intentionally deleted		
55	Reserved	Juridical recorder baseline requirements	
56	Reserved 05E538	ERTMS Key Management Conformance Requirements	
57	Reserved UNISIG SUBSET-107	Requirements on pre-fitting of ERTMS on-board equipment	
58	UNISIG SUBSET-097	Requirements for RBC-RBC Safe Communication Interface	1.1.0
59	Reserved UNISIG SUBSET-105	Requirements on pre-fitting of ERTMS track side equipment	
60	Reserved UNISIG SUBSET-104	ETCS version management	
61	Reserved	GSM-R version management	
62	Reserved UNISIG SUBSET-099	RBC-RBC Test specification for Safe Communication Interface	
63	UNISIG SUBSET-098	RBC-RBC Safe Communication Interface	1.0.0

LIST OF INFORMATIVE SPECIFICATIONS

Notes:

Type '1' specifications represent the current state of the work for the preparation of a mandatory specification still 'reserved'.

Type '2' specifications give additional information, justifying the requirements in mandatory specifications and providing help for their application.

Index B32 is intended to ensure unique references in the Annex A documents. As this is used for editorial purposes and to support future changes of documents referred only, it is not classified as a 'Type' and not linked to a mandatory Annex A document.

Documents B25, B27, B28, B29 and B30 are applicable only for the GSM-R DMI. For the ETCS DMI only B34 applies.

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B1	EEIG 02S126	RAM requirements (chapter 2 only)	6	2 (index 28)
B2	EEIG 97S066	Environmental conditions	5	2 (index A5)
B3	UNISIG SUBSET-074-1	Methodology for testing FFFIS STM	1.0.0	2 (index 36)
B4	EEIG 97E267	ODOMETER FFFIS	5	1 (index 44)
B5	O_2475	ERTMS GSM-R QoS Test Specification	1.0.0	2
B6	UNISIG SUBSET-038	Off-line Key Management FIS	2.1.9	1 (index 11)
B7	UNISIG SUBSET-074-3	FFFIS STM test specification traceability of test cases with Specific Transmission Module FFFIS	1.0.0	2 (index 36)
B8	UNISIG SUBSET-074-4	FFFIS STM Test Specification Traceability of testing the packets specified in the FFFIS STM Application Layer	1.0.0	2 (index 36)
B9	UNISIG SUBSET 076-0	ERTMS/ETCS Class 1, Test plan	2.3.1	2 (index 37)
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B12	UNISIG SUBSET 076-4-1	Test sequence generation: Methodology and Rules	1.0.2	2 (index 37)
B13	UNISIG SUBSET 076-4-2	ERTMS ETCS Class 1 States for Test Sequences	1.0.2	2 (index 37)
B14	UNISIG SUBSET 076-5-3	On-Board Data Dictionary	2.3.0	2 (index 37)
B15	UNISIG SUBSET 076-5-4	SRS v.2.2.2 Traceability	2.3.1	2 (index 37)
B16	UNISIG SUBSET 076-6-1	UNISIG test data base	2.3.1	2 (index 37)
B17	UNISIG SUBSET 076-6-4	Test Cases Coverage	2.3.1	2 (index 37)
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B19	UNISIG SUBSET 077	UNISIG Causal Analysis Process	2.2.2	2 (index 27)
B20	UNISIG SUBSET 078	RBC interface: Failure modes and effects analysis	2.4.0	2 (index 27)
B21	UNISIG SUBSET 079	MMI: Failure Modes and Effects Analysis	2.2.2	2 (index 27)
B22	UNISIG SUBSET 080	TIU: Failure Modes and Effects Analysis	2.2.2	2 (index 27)
B23	UNISIG SUBSET 081	Transmission system: Failure Modes and Effects Analysis	2.3.0	2 (index 27)

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B24	UNISIG SUBSET 088	ETCS Application Levels 1 & 2 — Safety Analysis	2.3.0	2 (index 27)
B25	TS50459-1	Railway applications — European Rail Traffic Management System — Driver Machine Interface — part 1 — Ergonomic principles of ERTMS/ETCS/GSM-R Information	2005	2 (index 51)
B26	intentionally deleted	superseded by B34		
B27	TS50459-3	Railway applications — Communication, signalling and processing systems — European Rail Traffic Management System — Driver Machine Interface — part 3 — Ergonomic arrangements of ERTMS/GSM-R Information	2005	2 (index 51)
B28	TS50459-4	Railway applications — Communication, signalling and processing systems — European Rail Traffic Management System — Driver Machine Interface — part 4 — Data entry for the ERTMS/ETCS/GSM-R systems	2005	2 (index 51)
B29	TS50459-5	Railway applications — Communication, signalling and processing systems — European Rail Traffic Management System — Driver Machine Interface — part 5 — Symbols	2005	2 (index 51)
B30	TS50459-6	Railway applications — Communication, signalling and processing systems — European Rail Traffic Management System — Driver Machine Interface — part 6 — Audible Information	2005	2 (index 51)
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B32	Reserved	Guideline for references		None
B33	EN 301515	Global System for Mobile communication (GSM); Requirements for GSM operation in railways	2.1.0	2 (index 32, 33)
B34	ERA-ERTMS-015560	ERTMS/ETCS Driver Machine Interface	2.3	1 (index 51)
B35	Reserved UNISIG SUBSET-069	ERTMS Key Management Conformance Requirements		1 (index 56)
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B37	UNISIG SUBSET-093	GSM-R Interfaces — Class 1 requirements	2.3.0	1 (index 32, 33)
B38	UNISIG SUBSET-107A	Requirements on pre-fitting of ERTMS on-board equipment	1.0.0	2 (index 57)

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B39	UNISIG SUBSET-076-5-1	ERTMS ETCS Class 1 Feature List	2.3.1	2 (index 37)
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B41	UNISIG SUBSET-076-6-8	Generic train data for test Sequences	1.0.1	2 (index 37)
B42	UNISIG SUBSET-076-6-10	Test Sequence Viewer (TSV)	3.0.8	2 (index 37)
B43	04E083	Safety Requirements and Requirements to Safety Analysis for Interoperability for the Control-Command and Signalling Sub-System	1.0	1 (index 47)
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B45	ERA/ERTMS/003205	Traceability Of Changes To ETCS FRS	0.1	2 (index 1)
B46	UNISIG SUBSET-099	RBC-RBC Safe Communication Interface Test Specifications	1.0.0	1 (index 62)

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