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Contents			
	Ι	Legislative acts	
		DIRECTIVES	
		★ Directive 2012/33/EU of the European Parliament and of the Council of 21 November 2012 amending Council Directive 1999/32/EC as regards the sulphur content of marine fuels	1
	II	Non-legislative acts	
		REGULATIONS	
		★ Council Regulation (EU) No 1099/2012 of 26 November 2012 amending Regulation (EU) No 270/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Egypt	14
		★ Council Regulation (EU) No 1100/2012 of 26 November 2012 amending Regulation (EU) No 101/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Tunisia	16
		★ Commission Implementing Regulation (EU) No 1101/2012 of 26 November 2012 amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (¹)	18

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(1) Text with EEA relevance

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

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

ISSN 1977-0677

(Continued overleaf)

L 327

DIRECTIVES

*	Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells (1)	24
*	Commission Directive 2012/40/EU of 26 November 2012 correcting Annex I to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (1)	26
*	Commission Directive 2012/41/EU of 26 November 2012 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 nonanoic acid to product type $2 (1)$	28
*	Commission Directive 2012/42/EU of 26 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include hydrogen cyanide as an active substance in Annex I thereto (1)	31
*	Commission Directive 2012/43/EU of 26 November 2012 amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council (1)	34
*	Commission Implementing Directive 2012/44/EU of 26 November 2012 amending Directives 2003/90/EC and 2003/91/EC setting out implementing measures for the purposes of Article 7 of Council Directives 2002/53/EC and 2002/55/EC respectively, as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species and vegetable species (¹)	37

DECISIONS

cerning restrictive measures directed against certain persons, entities and bodies in view he situation in Egypt	44
uncil Decision 2012/724/CFSP of 26 November 2012 amending Decision 2011/72/CFSP cerning restrictive measures directed against certain persons and entities in view of the ation in Tunisia	45
	tion in Tunisia



Ι

(Legislative acts)

DIRECTIVES

DIRECTIVE 2012/33/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 November 2012

amending Council Directive 1999/32/EC as regards the sulphur content of marine fuels

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (²),

Whereas:

- (1) The environmental policy of the Union, as set out in the action programmes on the environment, and in particular in the Sixth Environmental Action Programme adopted by Decision No 1600/2002/EC of the European Parliament and of the Council (³), has as one of its objectives to achieve levels of air quality that do not give rise to significant negative impacts on and risks to human health and the environment.
- (2) Article 191(2) of the Treaty on the Functioning of the European Union (TFEU) provides that Union policy on

the environment is to aim at a high level of protection, taking into account the diversity of situations in the various regions of the Union.

- (3) Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels (⁴) lays down the maximum permitted sulphur content of heavy fuel oil, gas oil, marine gas oil and marine diesel oil used in the Union.
- (4) Emissions from shipping due to the combustion of marine fuels with a high sulphur content contribute to air pollution in the form of sulphur dioxide and particulate matter, which harm human health and the environment and contribute to acid deposition. Without the measures set out in this Directive, emissions from shipping would soon have been higher than emissions from all land-based sources.
- (5) Air pollution caused by ships at berth is a major concern for many harbour cities when it comes to their efforts to meet the Union's air quality limit values.
- (6) Member States should encourage the use of shore-side electricity, as the electricity for present-day ships is usually provided by auxiliary engines.
- (7) Under Directive 1999/32/EC, the Commission is to report to the European Parliament and the Council on the implementation of that Directive and may submit with its report proposals for amending it, in particular as regards the reduction of sulphur limits for marine fuel in SOX Emission Control Areas (SECAs), in accordance with the work of the International Maritime Organisation (IMO).

⁽¹⁾ OJ C 68, 6.3.2012, p. 70.

⁽²⁾ Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 29 October 2012.

^{(&}lt;sup>3</sup>) OJ L 242, 10.9.2002, p. 1.

⁽⁴⁾ OJ L 121, 11.5.1999, p. 13.

- (8) In 2008, the IMO adopted a resolution to amend Annex VI of the Protocol of 1997 to amend the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL), containing regulations for the prevention of air pollution from ships. The revised Annex VI to MARPOL entered into force on 1 July 2010.
- The revised Annex VI to MARPOL introduces, inter alia, (9) stricter sulphur limits for marine fuel in SECAs (1,00 % as of 1 July 2010 and 0,10 % as of 1 January 2015) as well as in sea areas outside SECAs (3,50 % as of 1 January 2012 and, in principle, 0,50 % as of 1 January 2020). Most Member States are obliged, in accordance with their international commitments, to require ships to use fuel with a maximum sulphur content of 1,00 % in SECAs as of 1 July 2010. In order to ensure coherence with international law as well as to secure proper enforcement of new globally established sulphur standards in the Union, Directive 1999/32/EC should be aligned with the revised Annex VI to MARPOL. In order to ensure a minimum quality of fuel used by ships either for fuel-based or technologybased compliance, marine fuel the sulphur content of which exceeds the general standard of 3,50 % by mass should not be allowed for use in the Union, except for fuels supplied to ships using emission abatement methods operating in closed mode.
- (10) Amendments to Annex VI to MARPOL regarding SECAs are possible under IMO procedures. In the event that further changes, including exemptions, are introduced with regard to the application of SECA limits in Annex VI to MARPOL, the Commission should consider any such changes and, where appropriate, without delay make the necessary proposal in accordance with the TFEU to fully align Directive 1999/32/EC with the IMO rules regarding SECAs.
- (11) The introduction of any new emission control areas should be subject to the IMO process under Annex VI to MARPOL and should be underpinned by a wellfounded case based on environmental and economic grounds and supported by scientific data.
- (12) In accordance with regulation 18 of the revised Annex VI to MARPOL, Member States should endeavour to ensure the availability of marine fuels which comply with this Directive.
- (13) In view of the global dimension of environmental politics and shipping emissions, ambitious emission standards should be set at a global level.
- (14) Passenger ships operate mostly in ports or close to coastal areas and their impacts on human health and the environment are significant. In order to improve air quality around ports and coasts, those ships are required

to use marine fuel with a maximum sulphur content of 1,50 % until stricter sulphur standards apply to all ships in territorial seas, exclusive economic zones and pollution control zones of Member States.

- (15) In accordance with Article 193 TFEU, this Directive should not prevent any Member State from maintaining or introducing more stringent protective measures in order to encourage early implementation with respect to the maximum sulphur content of marine fuels, for instance using emission abatement methods outside SECAs.
- (16) In order to facilitate the transition to new engine technologies with the potential for significant further emission reductions in the maritime sector, the Commission should further explore opportunities to enable and encourage the uptake of gas-powered engines in ships.
- (17)Proper enforcement of the obligations with regard to the sulphur content of marine fuels is necessary in order to achieve the aims of Directive 1999/32/EC. The experience from the implementation of Directive 1999/32/EC has shown that there is a need for a stronger monitoring and enforcement regime in order to ensure the proper implementation of that Directive. To that end, it is necessary that Member States ensure sufficiently frequent and accurate sampling of marine fuel placed on the market or used on board ship as well as regular verification of ships' log books and bunker delivery notes. It is also necessary for Member States to establish a system of effective, proportionate and dissuasive penalties for non-compliance with the provisions of Directive 1999/32/EC. In order to ensure more transparency of information, it is also appropriate to provide that the register of local suppliers of marine fuel be made publicly available.
- (18) Reporting by Member States under Directive 1999/32/EC has proved insufficient for the purpose of verification of compliance with that Directive due to the lack of harmonised and sufficiently precise provisions on the content and the format of the Member States' reports. Therefore, more detailed indications as regards the content and the format of the report are necessary to ensure more harmonised reporting.
- (19) Following the adoption of Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (¹), which recasts the Union legislation on industrial emissions, it is necessary to amend the provisions of Directive 1999/32/EC relating to maximum sulphur content of heavy fuel oil accordingly.

⁽¹⁾ OJ L 334, 17.12.2010, p. 17.

- Complying with the low sulphur limits for marine fuels, (20)particularly in SECAs, can result in a significant increase in the price of such fuels, at least in the short term, and can have a negative effect on the competitiveness of short sea shipping in comparison with other transport modes, as well as on the competitiveness of the industries in the countries bordering SECAs. Suitable solutions are necessary in order to reduce compliance costs for the affected industries, such as allowing for alternative, more cost-effective methods of compliance than fuel-based compliance and providing support, where necessary. The Commission will, based inter alia on reports from Member States, closely monitor the impacts of the shipping sector's compliance with the new fuel quality standards, particularly with respect to possible modal shift from sea to land-based transport and will, if appropriate, propose proper measures to counteract such a trend.
- (21) Limiting modal shift from sea to land-based transport is important given that an increasing share of goods being transported by road would in many cases run counter to the Union's climate change objectives and increase congestion.
- (22) The costs of the new requirements to reduce sulphur dioxide emissions could result in modal shift from sea to land-based transport and could have negative effects on the competitiveness of the industries. The Commission should make full use of instruments such as Marco Polo and the trans-European transport network to provide targeted assistance so as to minimise the risk of modal shift. Member States may consider it necessary to provide support to operators affected by this Directive in accordance with the applicable State aid rules.
- (23) In accordance with existing guidelines on State aid for environmental protection, and without prejudice to future changes thereto, Member States may provide State aid in favour of operators affected by this Directive, including aid for retrofitting operations of existing vessels, if such aid measures are deemed to be compatible with the internal market in accordance with Articles 107 and 108 TFEU, in particular in light of the applicable guidelines on State aid for environmental protection. In this context, the Commission may take into account that the use of some emission abatement methods go beyond the requirements of this Directive by reducing not only the sulphur dioxide emissions but also other emissions.
- (24) Access to emission abatement methods should be facilitated. Those methods can provide emission reductions at least equivalent to, or even greater than, those achievable using low sulphur fuel, provided that they have no significant negative impacts on the environment, such as marine ecosystems, and that they are developed subject to appropriate approval and control mechanisms.

The already known alternative methods, such as the use of on-board exhaust gas cleaning systems, the mixture of fuel and liquefied natural gas (LNG) or the use of biofuels should be recognised in the Union. It is important to promote the testing and development of new emission abatement methods in order, among other reasons, to limit modal shift from sea to land-based transport.

- (25) Emission abatement methods hold the potential for significant emission reductions. The Commission should therefore promote the testing and development of these technologies, inter alia by considering the establishment of a co-financed joint programme with industry, based on principles from similar programmes, such as the Clean Sky Programme.
- (26) The Commission, in cooperation with Member States and stakeholders, should further develop measures identified in the Commission's staff working paper of 16 September 2011 entitled 'Pollutant emission reduction from maritime transport and the sustainable waterborne transport toolbox'.
- Alternative emission abatement methods such as some (27)types of scrubbers could generate waste that should be handled properly and not be discharged into the sea. Pending the revision of Directive 2000/59/EC of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residues (1), Member States should ensure, in accordance with their international commitments, the availability of port reception facilities adequate to meet the needs of ships using exhaust gas cleaning systems. In the revision of Directive 2000/59/EC, the Commission should consider the inclusion of waste from exhaust gas cleaning systems under the principle of no special fee applying to port fees for ship-generated waste provided for in that Directive.
- (28) The Commission should, as part of its air quality policy review in 2013, consider the possibility of reducing air pollution, including in the territorial seas of Member States.
- (29) Effective, proportionate and dissuasive penalties are important for the implementation of Directive 1999/32/EC. Member States should include in those penalties fines calculated in such a way as to ensure that the fines at least deprive those responsible of the economic benefits derived from their infringement and that those fines gradually increase for repeated infringements. Member States should notify the provisions on penalties to the Commission.

⁽¹⁾ OJ L 332, 28.12.2000, p. 81.

- The power to adopt acts in accordance with Article 290 (30) TFEU should be delegated to the Commission in respect of the amendment of the equivalent emission values for and the criteria for the use of emission abatement methods in order to adapt the provisions of Directive 1999/32/EC to scientific and technical progress and in such a way as to ensure strict consistency with the relevant instruments of the IMO and in respect of the amendment of points 1, 2, 3, 3a, 3b and 4 of Article 2, point (b) of Article 6(1a) and Article 6(2) of Directive 1999/32/EC in order to adapt the provisions of that Directive to scientific and technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (31) In order to ensure uniform conditions for the implementation of Directive 1999/32/EC, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (1).
- It is appropriate for the Committee on Safe Seas and the (32)Prevention of Pollution from Ships established by Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) (2) to assist the Commission in the approval of the emission abatement methods which are not covered by Council Directive 96/98/EC of 20 December 1996 on marine equipment (3).
- In accordance with the Joint Political Declaration of (33)28 September 2011 of Member States and the Commission on explanatory documents (4), Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- Directive 1999/32/EC should therefore be amended (34)accordingly,
- ⁽¹⁾ OJ L 55, 28.2.2011, p. 13.

- (3) OJ L 46, 17.2.1997, p. 25.
 (4) OJ C 369, 17.12.2011, p. 14.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 1999/32/EC

Directive 1999/32/EC is amended as follows:

- (1) in Article 1(2), point (h) is replaced by the following:
 - '(h) without prejudice to Article 3a, fuels used on board vessels employing emission abatement methods in accordance with Articles 4c and 4e.';
- (2) Article 2 is amended as follows:
 - (a) points 1 and 2 are replaced by the following:
 - '(1) heavy fuel oil means:
 - any petroleum-derived liquid fuel, excluding marine fuel, falling within CN code 2710 19 51 to 2710 19 68, 2710 20 31, 2710 20 35, 2710 20 39, or
 - any petroleum-derived liquid fuel, other than gas oil as defined in points 2 and 3, which, by reason of its distillation limits, falls within the category of heavy oils intended for use as fuel and of which less than 65 % by volume (including losses) distils at 250 $^\circ C$ by the ASTM D86 method. If the distillation cannot be determined by the ASTM D86 method, the petroleum product is likewise categorised as a heavy fuel oil;
 - (2) gas oil means:
 - any petroleum-derived liquid fuel, excluding marine fuel, falling within CN code 2710 19 29, 2710 19 47, 2710 19 25, 2710 19 48, 2710 20 17 or 2710 20 19, or
 - any petroleum-derived liquid fuel, excluding marine fuel, of which less than 65 % by volume (including losses) distils at 250 °C and of which at least 85 % by volume (including losses) distils at 350 °C by the ASTM D86 method.

Diesel fuels as defined in point 2 of Article 2 of Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (*) are excluded from this definition. Fuels used in non-road mobile machinery and agricultural tractors are also excluded from this definition;

⁽²⁾ OJ L 324, 29.11.2002, p. 1.

^(*) OJ L 350, 28.12.1998, p. 58.';

- (b) points 3a and 3b are replaced by the following:
 - '(3a) marine diesel oil means any marine fuel as defined for DMB grade in Table I of ISO 8217 with the exception of the reference to the sulphur content;
 - (3b) marine gas oil means any marine fuel as defined for DMX, DMA and DMZ grades in Table I of ISO 8217 with the exception of the reference to the sulphur content;';
- (c) point 3m is replaced by the following:
 - '(3m) emission abatement method means any fitting, material, appliance or apparatus to be fitted in a ship or other procedure, alternative fuel, or compliance method, used as an alternative to low sulphur marine fuel meeting the requirements set out in this Directive, that is verifiable, quantifiable and enforceable;';
- (3) Article 3 is amended as follows:
 - (a) paragraphs 1 and 2 are replaced by the following:

'1. Member States shall ensure that heavy fuel oils are not used within their territory if their sulphur content exceeds 1 % by mass.

2. Until 31 December 2015, subject to appropriate monitoring of emissions by competent authorities, paragraph 1 shall not apply to heavy fuel oils used:

- (a) in combustion plants which fall within the scope of Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants into the air from large combustion plants (*), which are subject to Article 4(1) or (2) or Article 4(3)(a) of that Directive and which comply with the emission limits for sulphur dioxide for such plants as set out in that Directive;
- (b) in combustion plants which fall within the scope of Directive 2001/80/EC, which are subject to Article 4(3)(b) and Article 4(6) of that Directive and the monthly average sulphur dioxide emissions of which do not exceed 1 700 mg/Nm³ at an oxygen content in the flue gas of 3 % by volume on a dry basis;

- (c) in combustion plants which do not fall under points (a) or (b), and the monthly average sulphur dioxide emissions of which do not exceed 1 700 mg/Nm³ at an oxygen content in the flue gas of 3 % by volume on a dry basis;
- (d) for combustion in refineries, where the monthly average of emissions of sulphur dioxide averaged over all combustion plants in the refinery, irrespective of the type of fuel or fuel combination used, but excluding plants which fall under points (a) and (b), gas turbines and gas engines, do not exceed 1 700 mg/Nm³ at an oxygen content in the flue gas of 3 % by volume on a dry basis.

3. As from 1 January 2016, subject to appropriate monitoring of emissions by competent authorities, paragraph 1 shall not apply to heavy fuel oils used:

- (a) in combustion plants which fall within the scope of Chapter III of Directive 2010/75/EU of the European Parliament and of the Council (**), and which comply with the emission limits for sulphur dioxide for such plants as set out in Annex V to that Directive or, where those emission limit values are not applicable according to that Directive, for which the monthly average sulphur dioxide emissions do not exceed 1 700 mg/Nm³ at an oxygen content in the flue gas of 3 % by volume on a dry basis;
- (b) in combustion plants which do not fall under point (a), and the monthly average sulphur dioxide emissions of which do not exceed 1 700 mg/Nm³ at an oxygen content in the flue gas of 3 % by volume on a dry basis;
- (c) for combustion in refineries, where the monthly average of emissions of sulphur dioxide averaged over all combustion plants in the refinery, irrespective of the type of fuel or fuel combination used, but excluding plants falling under point (a), gas turbines and gas engines, do not exceed 1 700 mg/Nm³ at an oxygen content in the flue gas of 3 % by volume on a dry basis.

Member States shall take the necessary measures to ensure that no combustion plant using heavy fuel oil with a sulphur concentration greater than that referred to in paragraph 1 is operated without a permit issued by a competent authority, which specifies the emission limits.

^(*) OJ L 309, 27.11.2001, p. 1.

^(**) OJ L 334, 17.12.2010, p. 17.';

(b) paragraph 3 is deleted;

(4) the following Article is inserted:

'Article 3a

Maximum sulphur content in marine fuel

Member States shall ensure that marine fuels are not used within their territory if their sulphur content exceeds 3,50 % by mass, except for fuels supplied to ships using emission abatement methods subject to Article 4c operating in closed mode.';

(5) in Article 4, paragraph 1 is replaced by the following:

'1. Member States shall ensure that gas oils are not used within their territory if their sulphur content exceeds 0,10 % by mass.';

(6) Article 4a is amended as follows:

(a) the title is replaced by the following:

'Maximum sulphur content of marine fuels used in territorial seas, exclusive economic zones and pollution control zones of Member States, including SOx Emission Control Areas and by passenger ships operating on regular services to or from Union ports';

(b) paragraph 1 is replaced by the following:

'1. Member States shall take all necessary measures to ensure that marine fuels are not used in the areas of their territorial seas, exclusive economic zones and pollution control zones falling within SOx Emission Control Areas if the sulphur content of those fuels by mass exceeds:

- (a) 1,00 % until 31 December 2014;
- (b) 0,10 % as from 1 January 2015.

This paragraph shall apply to all vessels of all flags, including vessels whose journey began outside the Union. The Commission shall have due regard to any future changes to the requirements pursuant to Annex VI to MARPOL applicable within SOx Emission Control Areas, and, where appropriate, without undue delay make any relevant proposals with a view to amending this Directive accordingly.';

(c) the following paragraph is inserted:

'1a. Member States shall take all necessary measures to ensure that marine fuels are not used in the areas of

their territorial seas, exclusive economic zones and pollution control zones if the sulphur content of those fuels by mass exceeds:

- (a) 3,50 % as from 18 June 2014;
- (b) 0,50 % as from 1 January 2020.

This paragraph shall apply to all vessels of all flags, including vessels whose journey began outside of the Union, without prejudice to paragraphs 1 and 4 of this Article and Article 4b.';

(d) paragraphs 4, 5, 6 and 7 are replaced by the following:

'4. Member States shall take all necessary measures to ensure that marine fuels are not used in their territorial seas, exclusive economic zones and pollution control zones falling outside SOx Emission Control Areas by passenger ships operating on regular services to or from any Union port if the sulphur content of those fuels exceeds 1,50 % by mass until 1 January 2020.

Member States shall be responsible for the enforcement of this requirement at least in respect of vessels flying their flag and vessels of all flags while in their ports.

5. Member States shall require the correct completion of ships' logbooks, including fuel-changeover operations.

5a. Member States shall endeavour to ensure the availability of marine fuels which comply with this Directive and inform the Commission of the availability of such marine fuels in its ports and terminals.

5b. If a ship is found by a Member State not to be in compliance with the standards for marine fuels which comply with this Directive, the competent authority of the Member State is entitled to require the ship to:

- (a) present a record of the actions taken to attempt to achieve compliance; and
- (b) provide evidence that it attempted to purchase marine fuel which complies with this Directive in accordance with its voyage plan and, if it was not made available where planned, that attempts were made to locate alternative sources for such marine fuel and that, despite best efforts to obtain marine fuel which complies with this Directive, no such marine fuel was made available for purchase.

The ship shall not be required to deviate from its intended voyage or to delay unduly the voyage in order to achieve compliance.

If a ship provides the information referred to in the first subparagraph, the Member State concerned shall take into account all relevant circumstances and the evidence presented to determine the appropriate action to take, including not taking control measures.

A ship shall notify its flag State, and the competent authority of the relevant port of destination, when it cannot purchase marine fuel which complies with this Directive.

A port State shall notify the Commission when a ship has presented evidence of the non-availability of marine fuels which comply with this Directive.

6. Member States shall, in accordance with regulation 18 of Annex VI to MARPOL:

- (a) maintain a publicly available register of local suppliers of marine fuel;
- (b) ensure that the sulphur content of all marine fuels sold in their territory is documented by the supplier on a bunker delivery note, accompanied by a sealed sample signed by the representative of the receiving ship;
- (c) take action against marine fuel suppliers that have been found to deliver fuel that does not comply with the specification stated on the bunker delivery note;
- (d) ensure that remedial action is taken to bring any non-compliant marine fuel discovered into compliance.

7. Member States shall ensure that marine diesel oils are not placed on the market in their territory if the sulphur content of those marine diesel oils exceeds 1,50 % by mass.';

- (e) paragraph 8 is deleted;
- (7) Articles 4b and 4c are replaced by the following:

'Article 4b

Maximum sulphur content of marine fuels used by ships at berth in Union ports

1. Member States shall take all necessary measures to ensure that ships at berth in Union ports do not use marine fuels with a sulphur content exceeding 0,10 % by

mass, allowing sufficient time for the crew to complete any necessary fuel-changeover operation as soon as possible after arrival at berth and as late as possible before departure.

Member States shall require the time of any fuelchangeover operation to be recorded in ships' logbooks.

- 2. Paragraph 1 shall not apply:
- (a) whenever, according to published timetables, ships are due to be at berth for less than two hours;
- (b) to ships which switch off all engines and use shoreside electricity while at berth in ports.

3. Member States shall ensure that marine gas oils are not placed on the market in their territory if the sulphur content of those marine gas oils exceeds 0,10 % by mass.

Article 4c

Emission abatement methods

1. Member States shall allow the use of emission abatement methods by ships of all flags in their ports, territorial seas, exclusive economic zones and pollution control zones, as an alternative to using marine fuels that meet the requirements of Articles 4a and 4b, subject to paragraphs 2 and 3 of this Article.

2. Ships using the emission abatement methods referred to in paragraph 1 shall continuously achieve reductions of sulphur dioxide emissions that are at least equivalent to the reductions that would be achieved by using marine fuels that meet the requirements of Articles 4a and 4b. Equivalent emission values shall be determined in accordance with Annex I.

2a. Member States shall, as an alternative solution for reducing emissions, encourage the use of onshore power supply systems by docked vessels.

3. The emission abatement methods referred to in paragraph 1 shall comply with the criteria specified in the instruments referred to in Annex II.

4. Where justified in the light of scientific and technical progress regarding alternative emission abatement methods and in such a way as to ensure strict consistency with the relevant instruments and standards adopted by the IMO, the Commission shall:

(a) be empowered to adopt delegated acts in accordance with Article 9a amending Annexes I and II;

- (b) adopt implementing acts laying down the detailed requirements for monitoring of emissions, where appropriate. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 9(2).';
- (8) the following Articles are inserted:

'Article 4d

Approval of emission abatement methods for use on board ships flying the flag of a Member State

1. Emission abatement methods falling within the scope of Council Directive 96/98/EC(*) shall be approved in accordance with that Directive.

2. Emission abatement methods not covered by paragraph 1 of this Article shall be approved in accordance with the procedure referred to in Article 3(2) of Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) (**), taking into account:

- (a) guidelines developed by the IMO;
- (b) the results of any trials conducted under Article 4e;
- (c) effects on the environment, including achievable emission reductions, and impacts on ecosystems in enclosed ports, harbours and estuaries; and
- (d) the feasibility of monitoring and verification.

Article 4e

Trials of new emission abatement methods

Member States may, in cooperation with other Member States, as appropriate, approve trials of ship emission abatement methods on vessels flying their flag, or in sea areas within their jurisdiction. During those trials, the use of marine fuels meeting the requirements of Articles 4a and 4b shall not be mandatory, provided that all of the following conditions are fulfilled:

- (a) the Commission and any port State concerned are notified in writing at least six months before trials begin;
- (b) permits for trials do not exceed 18 months in duration;
- (c) all ships involved install tamper-proof equipment for the continuous monitoring of funnel gas emissions and use it throughout the trial period;

- (d) all ships involved achieve emission reductions which are at least equivalent to those which would be achieved through the sulphur limits for fuels specified in this Directive;
- (e) there are proper waste management systems in place for any waste generated by the emission abatement methods throughout the trial period;
- (f) there is an assessment of impacts on the marine environment, particularly ecosystems in enclosed ports, harbours and estuaries throughout the trial period; and
- (g) full results are provided to the Commission, and made publicly available, within six months of the end of the trials.

Article 4f

Financial measures

Member States may adopt financial measures in favour of operators affected by this Directive where such financial measures are in accordance with State aid rules applicable and to be adopted in this area.

(*) OJ L 46, 17.2.1997, p. 25. (**) OJ L 324, 29.11.2002, p. 1.';

(9) Article 6 is replaced by the following:

'Article 6

Sampling and analysis

1. Member States shall take all necessary measures to check by sampling that the sulphur content of fuels used complies with Articles 3, 3a, 4, 4a and 4b. The sampling shall commence on the date on which the relevant limit for maximum sulphur content in the fuel comes into force. It shall be carried out periodically with sufficient frequency and quantities in such a way that the samples are representative of the fuel examined, and in the case of marine fuel, of the fuel being used by vessels while in relevant sea areas and ports. The samples shall be analysed without undue delay.

1a. The following means of sampling, analysis and inspection of marine fuel shall be used:

(a) inspection of ships' log books and bunker delivery notes;

and, as appropriate, the following means of sampling and analysis:

- (b) sampling of the marine fuel for on-board combustion while being delivered to ships, in accordance with the Guidelines for the sampling of fuel oil for determination of compliance with the revised MARPOL Annex VI adopted on 17 July 2009 by Resolution 182(59) of the Marine Environment Protection Committee (MEPC) of the IMO, and analysis of its sulphur content; or
- (c) sampling and analysis of the sulphur content of marine fuel for on-board combustion contained in tanks, where technically and economically feasible, and in sealed bunker samples on board ships.

1b. The Commission shall be empowered to adopt implementing acts concerning:

- (a) the frequency of sampling;
- (b) the sampling methods;
- (c) the definition of a sample representative of the fuel examined.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 9(2).

2. The reference method adopted for determining the sulphur content shall be ISO method 8754 (2003) or PrEN ISO 14596 (2007).

In order to determine whether marine fuel delivered to and used on board ships is compliant with the sulphur limits required by Articles 3a, 4, 4a and 4b the fuel verification procedure set out in Appendix VI to Annex VI to MARPOL shall be used.';

- (10) Article 7 is amended as follows:
 - (a) paragraph 1 is replaced by the following:

'1. Each year by 30 June, Member States shall, on the basis of the results of the sampling, analysis and inspections carried out in accordance with Article 6, submit a report to the Commission on the compliance with the sulphur standards set out in this Directive for the preceding year.

On the basis of the reports received in accordance with the first subparagraph of this paragraph and the notifications regarding the non-availability of marine fuel which complies with this Directive submitted by Member States in accordance with the fifth subparagraph of Article 4a(5b), the Commission shall, within 12 months from the date referred to in the first subparagraph of this paragraph, draw up and publish a report on the implementation of this Directive. The Commission shall evaluate the need for further strengthening the relevant provisions of this Directive and make any appropriate legislative proposals to that effect.';

(b) the following paragraph is inserted:

'1a. The Commission may adopt implementing acts concerning the information to be included in the report and the format of the report. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 9(2).';

(c) paragraphs 2 and 3 are replaced by the following:

¹². By 31 December 2013 the Commission shall submit a report to the European Parliament and to the Council which shall be accompanied, if appropriate, by legislative proposals. The Commission shall consider in its report the potential for reducing air pollution taking into account, inter alia: annual reports submitted in accordance with paragraphs 1 and 1a; observed air quality and acidification; fuel costs; potential economic impact and observed modal shift; and progress in reducing emissions from ships.

3. The Commission shall, in cooperation with Member States and stakeholders, by 31 December 2012, develop appropriate measures, including those identified in the Commission's staff working paper of 16 September 2011 entitled "Pollutant emission reduction from maritime transport and the sustainable waterborne transport toolbox" promoting compliance with the environmental standards of this Directive, and minimising the possible negative impacts.';

(d) paragraph 4 is replaced by the following:

'4. The Commission shall be empowered to adopt delegated acts in accordance with Article 9a concerning the adaptations of Article 2, points 1, 2, 3, 3a, 3b and 4, point (b) of Article 6(1a) and Article 6(2) to scientific and technical progress. Such adaptations shall not result in any direct changes to the scope of this Directive or to sulphur limits for fuels specified in this Directive.';

(11) Article 8 is deleted;

(12) Article 9 is replaced by the following:

'Article 9

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (*).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

(*) OJ L 55, 28.2.2011, p. 13.';

(13) the following Article is inserted:

'Article 9a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 4c(4) and Article 7(4) shall be conferred on the Commission for a period of five years from 17 December 2012. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 4c(4) and Article 7(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the powers specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 4c(4) and Article 7(4) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.';

(14) Article 11 is replaced by the following:

'Article 11

Penalties

1. Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive.

2. The penalties determined must be effective, proportionate and dissuasive and may include fines calculated in such a way as to ensure that the fines at least deprive those responsible of the economic benefits derived from their infringement and that those fines gradually increase for repeated infringements.';

(15) the Annex to Directive 1999/32/EC is replaced by the Annex to this Directive.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 18 June 2014. They shall forthwith communicate to the Commission the text of those provisions.

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. The methods of making such reference shall be laid down by Member States.

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

Entry into force

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

Article 4

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 21 November 2012.

For the European Parliament The President M. SCHULZ For the Council The President A. D. MAVROYIANNIS

ANNEX

'ANNEX I

EQUIVALENT EMISSION VALUES FOR EMISSION ABATEMENT METHODS AS REFERRED TO IN ARTICLE 4c(2)

Marine fuel sulphur limits referred to in Articles 4a and 4b and regulations 14.1 and 14.4 of Annex VI to MARPOL and corresponding emission values referred to in Article 4c(2):

Marine fuel Sulphur Content (% m/m)	Ratio Emission $SO_2(ppm)/CO_2(\% v/v)$			
3,50	151,7			
1,50	65,0			
1,00	43,3			
0,50	21,7			
0,10	4,3			

Note:

- The use of the Ratio Emissions limits is only applicable when using petroleum based Distillate or Residual Fuel Oils.

In justified cases where the CO₂ concentration is reduced by the exhaust gas cleaning (EGC) unit, the CO₂ concentration may be measured at the EGC unit inlet, provided that the correctness of such a methodology can be clearly demonstrated.

ANNEX II

CRITERIA FOR THE USE OF EMISSION ABATEMENT METHODS REFERRED TO IN ARTICLE 4c(3)

The emission abatement methods referred to in Article 4c shall comply at least with the criteria specified in the following instruments, as applicable:

Emission abatement method	Criteria for use			
Mixture of marine fuel and boil-off gas	Commission Decision 2010/769/EU of 13 December 2010 on the estab- lishment of criteria for the use by liquefied natural gas carriers of technological methods as an alternative to using low sulphur marine fuels meeting the requirements of Article 4b of Council Directive 1999/32/EC relating to a reduction in the sulphur content of certain liquid fuels as amended by Directive 2005/33/EC of the European Parliament and of the Council on the sulphur content of marine fuels (¹).			
Exhaust gas cleaning systems	Resolution MEPC.184(59) adopted on 17 July 2009			
	"Wash water resulting from exhaust gas cleaning systems which make use of chemicals, additives, preparations and relevant chemical created in situ", referred to in point 10.1.6.1 of Resolution MEPC.184(59), shall not be discharged into the sea, including enclosed ports, harbours and estuaries, unless it is demonstrated by the ship operator that such wash water discharge has no significant negative impacts on and do not pose risks to human health and the environment. If the chemical used is caustic soda it is sufficient that the washwater meets the criteria set out in Resolution MEPC.184(59) and its pH does not exceed 8,0.			
Biofuels	Use of biofuels as defined in Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources (²) that comply with the relevant CEN and ISO standards.			
	The mixtures of biofuels and marine fuels shall comply with the sulphur standards set out in Article 3a, Article $4a(1)$, $(1a)$ and (4) and Article 4b of this Directive.			
(¹) OJ L 328, 14.12.2010, p. 15. (²) OJ L 140, 5.6.2009, p. 16.'				

Π

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) No 1099/2012

of 26 November 2012

amending Regulation (EU) No 270/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Egypt

THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215(2) thereof,

Having regard to Council Decision 2011/172/CFSP of 21 March 2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Egypt (1),

Having regard to the joint proposal of the High Representative of the Union for Foreign Affairs and Security Policy and of the European Commission,

Whereas:

- Council Regulation (EU) No 270/2011 (2) gives effect to (1)the measures provided for in Decision 2011/172/CFSP.
- Council Decision 2012/723/CFSP (3) provides for an (2) amendment to Decision 2011/172/CFSP in order to permit the release of certain frozen funds or economic resources where they are required to satisfy a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in a Member State.
- Article 9 of Regulation (EU) No 270/2011 concerns (3) information to be supplied by persons, entities and bodies to the competent authorities of Member States, which has to be transmitted to the Commission, in order to facilitate compliance with that Regulation. In accordance with Article 9(2), any information provided or received is to be used only for the purposes for which it was provided or received. However, this should not prevent Member States from sharing such information, in accordance with their national law, with the relevant

authorities of Egypt and other Member States where necessary for the purpose of assisting the recovery of misappropriated assets.

Regulation (EU) No 270/2011 should therefore be (4)amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 270/2011 is hereby amended as follows:

(1) Article 5 is replaced by the following:

'Article 5

By way of derogation from Article 2, the competent 1. authorities in Member States, as indicated on the websites listed in Annex II, may authorise the release of certain frozen funds or economic resources, provided the following conditions are met:

- (a) the funds or economic resources are the subject of an arbitral decision rendered prior to the date on which the natural or legal person, entity or body referred to in Article 2 was listed in Annex I, or of a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in the Member State concerned, prior to or after that date;
- (b) the funds or economic resources will be used exclusively to satisfy claims secured by such a decision or recognised as valid in such a decision, within the limits set by applicable laws and regulations governing the rights of persons having such claims;
- (c) the decision is not for the benefit of a natural or legal person, entity or body listed in Annex I; and
- (d) recognising the decision is not contrary to public policy in the Member State concerned.

⁽¹⁾ OJ L 76, 22.3.2011, p. 63.

^{(&}lt;sup>2</sup>) OJ L 76, 22.3.2011, p. 4.
(³) See page 44 of this Official Journal.

2. The Member State concerned shall inform the other Member States and the Commission of any authorisation granted under this Article.';

(2) Article 6(1) is replaced by the following:

'1. Article 2(2) shall not apply to the addition to frozen accounts of:

- (a) interest or other earnings on those accounts; or
- (b) payments due under contracts, agreements or obligations that were concluded or arose before the date on which the natural or legal person, entity or body referred to in Article 2 has been listed in Annex I; or

(c) payments due under judicial, administrative or arbitral decisions rendered in the Union or enforceable in the Member State concerned,

provided that such interest, other earnings and payments are frozen in accordance with Article 2(1).';

(3) in Article 9, the following paragraph is added:

'3. Paragraph 2 shall not prevent Member States from sharing that information, in accordance with their national law, with the relevant authorities of Egypt and other Member States where necessary for the purpose of assisting the recovery of misappropriated assets.'

Article 2

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

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

Done at Brussels, 26 November 2012.

For the Council The President G. DEMOSTHENOUS L 327/16

EN

COUNCIL REGULATION (EU) No 1100/2012

of 26 November 2012

amending Regulation (EU) No 101/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Tunisia

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215(2) thereof,

Having regard to Council Decision 2011/72/CFSP of 31 January 2011 concerning restrictive measures directed against certain persons and entities in view of the situation in Tunisia (1),

Having regard to the joint proposal of the High Representative of the Union for Foreign Affairs and Security Policy and of the European Commission,

Whereas:

- Council Regulation (EU) No 101/2011 (2) gives effect to (1)the measures provided for in Decision 2011/72/CFSP.
- Council Decision 2012/724/CFSP (3) provides for an (2) amendment to Decision 2011/72/CFSP in order to permit the release of certain frozen funds or economic resources where they are required to satisfy a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in a Member State.
- Article 9 of Regulation (EU) No 101/2011 concerns (3) information to be supplied by persons, entities and bodies to the competent authorities of Member States, which has to be transmitted to the Commission, in order to facilitate compliance with that Regulation. In accordance with Article 9(2), any information provided or received is to be used only for the purposes for which it was provided or received. However, this should not prevent Member States from sharing such information, in accordance with their national law, with the relevant authorities of Tunisia and other Member States where necessary for the purpose of assisting the recovery of misappropriated assets.
- (4) Regulation (EU) No 101/2011 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 101/2011 is hereby amended as follows:

(1) Article 5 is replaced by the following:

'Article 5

1. By way of derogation from Article 2, the competent authorities in Member States, as indicated on the websites

(3) See page 45 of this Official Journal.

listed in Annex II, may authorise the release of certain frozen funds or economic resources, provided the following conditions are met:

- (a) the funds or economic resources are the subject of an arbitral decision rendered prior to the date on which the natural or legal person, entity or body referred to in Article 2 was listed in Annex I, or of a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in the Member State concerned, prior to or after that date;
- (b) the funds or economic resources will be used exclusively to satisfy claims secured by such a decision or recognised as valid in such a decision, within the limits set by applicable laws and regulations governing the rights of persons having such claims;
- (c) the decision is not for the benefit of a natural or legal person, entity or body listed in Annex I; and
- (d) recognising the decision is not contrary to public policy in the Member State concerned.

The Member State concerned shall inform the other 2. Member States and the Commission of any authorisation granted under this Article.';

(2) Article 6(1) is replaced by the following:

'1. Article 2(2) shall not apply to the addition to frozen accounts of:

- (a) interest or other earnings on those accounts; or
- (b) payments due under contracts, agreements or obligations that were concluded or arose before the date on which the natural or legal person, entity or body referred to in Article 2 has been listed in Annex I; or
- (c) payments due under judicial, administrative or arbitral decisions rendered in the Union or enforceable in the Member State concerned.

provided that such interest, other earnings and payments are frozen in accordance with Article 2(1).';

(3) in Article 9, the following paragraph is added:

Paragraph 2 shall not prevent Member States from sharing that information, in accordance with their national law, with the relevant authorities of Tunisia and other Member States where necessary for the purpose of assisting the recovery of misappropriated assets.'.

^{(&}lt;sup>1</sup>) OJ L 28, 2.2.2011, p. 62. (²) OJ L 31, 5.2.2011, p. 1.

Article 2

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

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

Done at Brussels, 26 November 2012.

For the Council The President G. DEMOSTHENOUS

COMMISSION IMPLEMENTING REGULATION (EU) No 1101/2012

of 26 November 2012

amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (¹), and in particular Article 247 thereof,

Whereas:

- (1) With the entry into force of Commission Regulation (EU) No 1006/2011 of 27 September 2011 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽²⁾, new CN codes apply to gas and fuel oils containing biodiesel. These changes may affect the mineral oil industry because certain mixing operations under the customs warehousing procedure and in free zones are not permitted anymore as 'usual forms of handling' because they result in a different eight-digit CN code.
- (2) A solution should be found to allow mixing of gas or fuel oils not containing biodiesel with gas or fuel oils containing biodiesel, classified in Chapter 27 of the CN, under the customs warehousing procedure and in free zones to continue as before the entry into force of Regulation (EU) No 1006/2011 on 1 January 2012.
- (3) Mixing gas or fuel oils with biodiesel should be allowed, so that separate storage of both types of goods is not

required. However, taking account of the Additional Note 2 in Chapter 27 of the Combined Nomenclature the mixture obtained should contain less than 0,5 %, by volume, of biodiesel or gas or fuel oils respectively.

- (4) Annex 72 to Commission Regulation (EEC) No 2454/93 (³) should therefore be amended accordingly.
- (5) The amendment should enter into force with retroactive effect in order to allow for extinguishing customs debts which were incurred since 1 January 2012 because of the introduction of the new CN codes.
- (6) 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 72 to Regulation (EEC) No 2454/93 is amended as set out in the Annex to this Regulation.

Article 2

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

It shall apply from 1 January 2012.

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

Done at Brussels, 26 November 2012.

For the Commission The President José Manuel BARROSO

^{(&}lt;sup>1</sup>) OJ L 302, 19.10.1992, p. 1.

⁽²⁾ OJ L 282, 28.10.2011, p. 1.

ANNEX

In the second paragraph of Annex 72, after point 14 the following points 14a and 14b are inserted:

- '14a. mixing of gas or fuel oils not containing biodiesel with gas or fuel oils containing biodiesel, classified in Chapter 27 of the CN, in order to obtain a constant quality or a quality which is requested by the customer, without changing the nature of the goods even if this results in a different eight-digit CN code;
- 14b. mixing of gas or fuel oils with biodiesel so that the mixture obtained contains less than 0,5 %, by volume, of biodiesel, and mixing of biodiesel with gas or fuel oils so that the mixture obtained contains less than 0,5 %, by volume, of gas or fuel oils;'.

COMMISSION IMPLEMENTING REGULATION (EU) No 1102/2012

of 26 November 2012

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

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

 Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the Official Journal of the European Union,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 26 November 2012.

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

^{(&}lt;sup>1</sup>) OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

(EUR/100 kg) CN code Third country code (1) Standard import value 0702 00 00 AL 44,1 MA 45,9 37,4 MK ΤN 73,5 TR 80,9 ZZ 56,4 0707 00 05 64,5 AL 141,4 MA MK 58,4 TR 117,0 ZZ 95,3 0709 93 10 MA 88,1 111,2 TR ZZ 99,7 0805 20 10 MA 138,7 138,7 ZZ 0805 20 30, 0805 20 50, 0805 20 70, CN 65,5 0805 20 90 HR 35,6 85,9 TR ΖZ 62,3 0805 50 10 AR 68,7 TR 85,4 ZA 49,1 ΖZ 67,7 0808 10 80 79,8 CN MK 33,9 NZ 138,3 US 125,6 137,2 ZA ZZ 103,0 0808 30 90 CN 56,6 TR 116,3 US 136,8 ZZ 103,2

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

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

COMMISSION IMPLEMENTING REGULATION (EU) No 1103/2012

of 26 November 2012

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Implementing Regulation (EU) No 892/2012 for the 2012/13 marketing year

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2012/13 marketing year are fixed by Commission Implementing Regulation (EU) No 892/2012 (³). Those prices and duties were last amended by Commission Implementing Regulation (EU) No 1092/2012 (⁴).

- (2) The data currently available to the Commission indicate that those amounts should be amended in accordance with Article 36 of Regulation (EC) No 951/2006.
- (3) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Implementing Regulation (EU) No 892/2012 for the 2012/13 marketing year, are hereby amended as set out in the Annex hereto.

Article 2

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

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

Done at Brussels, 26 November 2012.

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

 $^{(^1)\,}$ OJ L 299, 16.11.2007, p. 1.

^{(&}lt;sup>2</sup>) OJ L 178, 1.7.2006, p. 24.

^{(&}lt;sup>3</sup>) OJ L 263, 28.9.2012, p. 37.

^{(&}lt;sup>4</sup>) OJ L 323, 22.11.2012, p. 15.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 27 November 2012

		(EUR)		
CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned		
1701 12 10 (¹)	34,63	0,76		
1701 12 90 (1)	34,63	4,22		
1701 13 10 (1)	34,63	0,90		
1701 13 90 (1)	34,63	4,52		
1701 14 10 (1)	34,63	0,90		
1701 14 90 (1)	34,63	4,52		
1701 91 00 (²)	39,67	5,57		
1701 99 10 (²)	39,67	2,44		
1701 99 90 (2)	39,67	2,44		
1702 90 95 (3)	0,40	0,28		

 $(^1)$ For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007. $(^2)$ For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.

(3) Per 1 % sucrose content.

DIRECTIVES

COMMISSION DIRECTIVE 2012/39/EU

of 26 November 2012

amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (¹), and in particular point (e) of the Article 28 thereof,

Whereas:

- (1) Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (²) requires that HTLV-I antibody testing must be performed for donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas. This testing is required both for donors of reproductive cells, in accordance with Annex III to Directive 2006/17/EC, and for other donors, in accordance with Annex II thereof.
- (2) Recent scientific evidence provided by the European Centre for Disease Prevention and Control (ECDC) and field practice experience showed that it is very difficult, in the current state of scientific knowledge, to determine what is an HTLV-I high-incidence area. This testing requirement is thus not implemented in a uniform manner.
- (3) 'Incidence' measures the rate of occurrence of new cases of a disease or condition, while 'prevalence' is the proportion of a population that is affected by a particular disease at a specific time. In practice, data for prevalence are more available than data on incidence. In addition, prevalence is a more relevant measure than incidence when assessing the impact of a chronic disease within a community and to assess the subsequent needs. It is therefore appropriate to replace references to highincidence by references to high-prevalence in order to

ensure a more consistent implementation of the HTLV-I testing requirements across the Member States.

- (4) Point 4.2 of Annex III to Directive 2006/17/EC requires that blood samples must be obtained at the time of each donation both, for partner donation (not for direct use) and for non-partner donation of reproductive cells.
- (5) As far as partner donation of reproductive cells is concerned, recent scientific evidence has demonstrated that requiring testing at fixed time intervals up to a maximum of 24 months would not diminish the level of safety of the cells concerned as long as appropriate safety and quality systems are in place in tissue establishments using Assisted Reproductive Technology, in accordance with Article 16 of Directive 2004/23/EC. During these time intervals, the results of the previous test carried out on the same donor can be relied upon.
- (6) Whereas testing at the time of each donation does not improve the safety of reproductive cells donated between partners, field practice experience shows that this requirement is costly and cumbersome for both, patients and healthcare systems. In order to act in a more proportionate manner to the safety objective pursued, it is therefore appropriate to allow the Member States to require testing at fixed time intervals which they may determine up to a maximum of 24 months instead of at the time of each donation.
- (7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 29 of Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II and III to Directive 2006/17/EC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 June 2014 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

^{(&}lt;sup>1</sup>) OJ L 102, 7.4.2004, p. 48.

⁽²⁾ OJ L 38, 9.2.2006, p. 40.

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 twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2012.

For the Commission The President José Manuel BARROSO

ANNEX

Annexes II and III to Directive 2006/17/EC are amended as follows:

- (1) in Annex II, point 1.2 is replaced by the following:
 - '1.2. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas';
- (2) Annex III is amended as follows:
 - (a) point 2.4 is replaced by the following:
 - '2.4. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas';
 - (b) point 3.3 is replaced by the following:
 - '3.3. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas';
 - (c) point 4.2 is replaced by the following:
 - '4.2. For donations other than by partners, blood samples must be obtained at the time of each donation.

For donation by partners (not for direct use), blood samples must be obtained within three months before the first donation. For further partner donations by the same donor, further blood samples must be obtained according to national legislation, but no later than 24 months from the previous sampling.'

COMMISSION DIRECTIVE 2012/40/EU

of 26 November 2012

correcting Annex I to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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 bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 2013 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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 twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2012.

For the Commission The President José Manuel BARROSO

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 Directive 2009/91/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium tetraborate as an active substance in Annex I thereto (²) defines disodium tetraborate by three CAS numbers for three different forms of the substance. The CAS numbers are based on a report submitted to the Commission by the Netherlands on 7 July 2006 and endorsed by the Standing Committee on Biocidal Products on 20 February 2009.
- (2) The Netherlands have informed the Commission that the CAS number for the pentahydrate form in the original report was incorrect, and submitted a revised report to the Commission according to which the correct CAS number for this form is 12179-04-3. The revised report was endorsed by the Standing Committee on Biocidal Products on 25 May 2012.
- (3) Annex I to Directive 98/8/EC should therefore be corrected accordingly.
- (4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 201, 1.8.2009, p. 39.

ANNEX

In Annex I to Directive 98/8/EC, the third column of entry No 24 is replaced by the following:

	IUPAC name Identification numbers
ʻdisodium tetraborate	
EC No: 215-540-4	
CAS No (anhydrous): 1330-43-4	
CAS No (pentahydrate): 12179-04-3	
CAS No (decahydrate): 1303-96-4'	

COMMISSION DIRECTIVE 2012/41/EU

of 26 November 2012

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 nonanoic acid to product type 2

(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:

- 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 nonanoic acid.
- (2) Commission Directive 2011/13/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include nonanoic acid as an active substance in Annex I thereto (³) included nonanoic acid as an active substance in Annex I to Directive 98/8/EC for use in product type 19, repellents and attractants, as defined in Annex V to Directive 98/8/EC.
- (3) Pursuant to Regulation (EC) No 1451/2007, nonanoic acid has now been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product type 2, private area and public health area disinfectants and other biocidal products, as defined in Annex V to that Directive.
- (4) Austria was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 6 August 2010 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 25 May 2012, in an assessment report.
- (6) It appears from the evaluations that biocidal products used as private area and public health area disinfectants

and other biocidal products as defined in Annex V to Directive 98/8/EC and containing nonanoic acid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to extend the inclusion of nonanoic acid in Annex I to that Directive to product type 2.

- (7) Not all potential uses have been evaluated at Union level. It is therefore appropriate to require that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments 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.
- (8) In view of the irritant properties of the substance, it is appropriate to require that exposure during non-professional use is minimised through the design of the packaging, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.
- (9) The provisions of this Directive should be applied simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products of product type 2 containing the active substance nonanoic acid 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 to Directive 98/8/EC, in order to permit Member States and 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.
- (12) Directive 98/8/EC should therefore be amended accordingly.
- (13) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011 (⁴), Member States have undertaken to accompany, in justified cases, the

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

⁽³⁾ OJ L 34, 9.2.2011, p. 52.

⁽⁴⁾ OJ C 369, 17.12.2011, p. 14.

notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(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 30 September 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2014.

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 twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2012.

For the Commission The President José Manuel BARROSO

L 327/30

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ANNEX

The following is added to entry 'No 41' 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 (*)
				'1 October 2014	30 September 2016	30 September 2024	2	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.'

(*) 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 2012/42/EU

of 26 November 2012

amending Directive 98/8/EC of the European Parliament and of the Council to include hydrogen cyanide 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:

- 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 hydrogen cyanide.
- (2) Pursuant to Regulation (EC) No 1451/2007, hydrogen cyanide has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in the following product types, as defined in Annex V to that Directive: product type 8, wood preservatives, product type 14, rodenticides, and product type 18, insecticides, acaricides and products to control other arthropods.
- (3) The Czech Republic was designated as Rapporteur Member State and submitted three competent authority reports, including recommendations, to the Commission on 24 January 2008 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (4) The competent authority reports were 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 25 May 2012, in three assessment reports.
- (5) It appears from the evaluations that biocidal products used as wood preservatives, rodenticides, insecticides, acaricides and products to control other arthropods and containing hydrogen cyanide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include hydrogen cyanide in Annex I to that Directive.

- (6) Not all potential uses have been evaluated at Union level. It is therefore appropriate to require that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments 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 view of the highly toxic and flammable properties of (7) the active substance and the assumptions made during the risk assessment, it is appropriate to require that products are only authorised for use by professionals adequately trained to use them and that safe operational procedures during fumigation and venting are established for operators and bystanders, including the following requirements: products shall be used with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing; re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and bystanders by ventilation; exposure during and after ventilation shall be prevented from exceeding safe levels for operators and bystanders by the establishment of a supervised exclusion zone; prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to be fumigated shall be protected against accidental ignition.
- (8) The provisions of this Directive should be applied simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products of product types 8, 14 and 18 containing the active substance hydrogen cyanide and also 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 to Directive 98/8/EC, in order to permit Member States and 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.

^{(&}lt;sup>1</sup>) OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

L 327/32

EN

- (11) Directive 98/8/EC should therefore be amended accordingly.
- (12) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011 (¹), Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.
- (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 30 September 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2014.

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 twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2012.

For the Commission The President José Manuel BARROSO

^{(&}lt;sup>1</sup>) OJ C 369, 17.12.2011, p. 14.

27.11.2012

In Annex I to Directive 98/8/EC, the following entry is added:

		11	,					
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 (*)
·60	hydrogen cyanide	hydrogen cyanide EC No: 200-821-6 CAS No: 74-90-8	976 g/kg	1 October 2014	30 September 2016	30 September 2024	8, 14 and 18	 When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations of products for use as a fumigant are subject to the following conditions: (1) product shall only be supplied to and used by professionals adequately trained to use them; (2) safe operational procedures during fumigation and venting shall be established for operators and bystanders; (3) products shall be used with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing; (4) re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and bystanders by ventilation; (5) exposure during and after ventilation shall be prevented from exceeding safe levels for operators and bystanders by the establishment of a supervised exclusion zone; (6) prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to be fumigated shall be protected against accidental ignition.'

(*) 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 2012/43/EU

of 26 November 2012

amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council

(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 Articles 11(4) and 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) provides detailed rules for the evaluations of existing active substances. Article 15(2) of the Regulation provides for peer reviews by experts from the Member States prior to the Commission decisions on inclusion in Annex I.
- (2) Pursuant to Article 10(2)(i) of Directive 98/8/EC, inclusion of an active substance in Annex I shall, where appropriate, be subject to requirements on the minimum degree of purity and the nature and maximum content of certain impurities.
- (3) The first inclusion in Annex I was decided in Commission Directive 2006/140/EC of 20 December 2006 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (³). That Directive defined the headings of Annex I to Directive 98/8/EC. Those headings include 'Minimum purity of the active substance in the biocidal product as placed on the market'.
- (4) In the context of the peer reviews provided for by Article 15(2) of Regulation (EC) No 1451/2007, Member States experts have developed a method for establishing the similarity of the chemical compositions and the hazard profiles, known as 'technical equivalence', of substances falling within the same definition but being produced from different sources or manufacturing processes. For this establishment, the degree of purity is
- (1) OJ L 123, 24.4.1998, p. 1.

only one of the factors that can be decisive. Furthermore, lower purity of an active substance does not necessarily compromise its hazard profile.

- (5) It is therefore appropriate to replace the existing reference to minimum purity in the headings of Annex I to Directive 98/8/EC by a reference to the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11 of the Directive, and indicate that, in the product placed on the market, the active substance may be of a different purity provided that it has been proven technically equivalent with the evaluated substance.
- (6) The first row of Annex I to Directive 98/8/EC established by Commission Directive 2006/140/EC also contains the heading '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)'.
- According to Article 4(1) of Directive 98/8/EC, a (7)Member State receiving an application for mutual recognition of an existing authorisation has a period of 120 days to authorise the product through mutual recognition. However, if the first authorisation of a product is granted less than 120 days before the deadline for compliance with Article 16(3) of the Directive for that product, a Member State receiving a complete application for mutual recognition of that authorisation cannot comply with the deadline for compliance with Article 16(3) of the Directive if it uses the 120-day period provided for by Article 4(1) of the Directive, even if the complete application for mutual recognition was submitted without delay after the granting of the first authorisation.
- (8) For products for which the first authorisation is granted later than 120 days before the original deadline for compliance with Article 16(3) of Directive 98/8/EC, it is therefore appropriate to extend Member States' deadline for complying with Article 16(3) of the Directive by mutually recognising the first authorisation to 120 days after the submission of the complete application for mutual recognition, provided that the complete application for mutual recognition has been submitted within 60 days of the granting of the first authorisation.
- (9) Furthermore, in a situation where a Member State proposes, within the deadline for compliance with Article 16(3) of Directive 98/8/EC, to derogate from mutual recognition of an authorisation in accordance with Article 4(4) of the Directive, that Member State's

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

^{(&}lt;sup>3</sup>) OJ L 414, 30.12.2006, p. 78.

compliance with Article 16(3) of the Directive within that deadline can be impossible, and will depend on the date when the Commission decision on the matter is adopted in accordance with the second subparagraph of Article 4(4) of the Directive. In such cases, the deadline should therefore be suspended until a reasonable period after the Commission decision has been adopted.

- (10) For products for which one or more Member States have proposed to derogate from mutual recognition in accordance with Article 4(4) of Directive 98/8/EC, it is therefore appropriate to extend Member States' deadline for complying with Article 16(3) of the Directive by mutually recognising the first authorisation to 30 days after the adoption of the Commission decision.
- (11) 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 bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive by 31 March 2013 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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 twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2012.

For the Commission The President José Manuel BARROSO

L 327/36

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In Annex I to Directive 98/8/EC, the first row, which contains the headings to all entries, shall read as follows:

'No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)		Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
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(*) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.

(**) For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).

(***) 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 IMPLEMENTING DIRECTIVE 2012/44/EU

of 26 November 2012

amending Directives 2003/90/EC and 2003/91/EC setting out implementing measures for the purposes of Article 7 of Council Directives 2002/53/EC and 2002/55/EC respectively, as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species and vegetable species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (¹), and in particular Article 7(2)(a) and (b) thereof,

Having regard to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (²), and in particular Article 7(2)(a) and (b) thereof,

Whereas:

- (1) Commission Directives 2003/90/EC (3) and 2003/91/EC (4) were adopted to ensure that the varieties the Member States include in their national catalogues comply with the guidelines established by the Community Plant Variety Office (CPVO) as regards the characteristics to be covered as a minimum by the examination of the various species and the minimum conditions for examining the varieties, as far as such guidelines had been established. For other varieties those Directives provide that guidelines of the International Union for Protection of new Varieties of Plants (UPOV) are to apply.
- (2) The CPVO and UPOV have since established further guidelines for one other species and have updated existing ones.
- (3) Directives 2003/90/EC and 2003/91/EC should therefore be amended accordingly.
- (4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I and II to Directive 2003/90/EC are replaced by the text in Part A of the Annex to this Directive.

Article 2

The Annexes to Directive 2003/91/EC are replaced by the text in Part B of the Annex to this Directive.

Article 3

For examinations started before 1 January 2014 Member States may apply Directives 2003/90/EC and 2003/91/EC in the version applying before their amendment by this Directive.

Article 4

Member States shall adopt and publish, by 31 December 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 January 2014.

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

Article 5

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

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2012.

For the Commission The President José Manuel BARROSO

(⁴) OJ L 254, 8.10.2003, p. 7. (⁴) OJ L 254, 8.10.2003, p. 11.

 $^{(^1)~}OJ~L~193,~20.7.2002,~p.~1.$

 ⁽²⁾ OJ L 193, 20.7.2002, p. 33.
 (3) OJ L 254, 8.10.2003, p. 7.

^{) 0)} L 234, 8.10.2003, p. 11.

ANNEX

PART A 'ANNEX I

List of species referred to in Article 1(2)(a) which are to comply with CPVO test protocols

Scientific name	Common name	CPVO protocol
Festuca filiformis Pourr.	Fine-leaved sheep's fescue	TP 67/1 of 23.6.2011
Festuca ovina L.	Sheep's fescue	TP 67/1 of 23.6.2011
Festuca rubra L.	Red fescue	TP 67/1 of 23.6.2011
Festuca trachyphylla (Hack.) Krajina	Hard fescue	TP 67/1 of 23.6.2011
Lolium multiflorum Lam.	Italian ryegrass	TP 4/1 of 23.6.2011
Lolium perenne L.	Perennial ryegrass	TP 4/1 of 23.6.2011
Lolium x boucheanum Kunth	Hybrid ryegrass	TP 4/1 of 23.6.2011
Pisum sativum L.	Field pea	TP 7/2 of 11.3.2010
Brassica napus L.	Swede rape	TP 36/2 of 16.11.2011
Helianthus annuus L.	Sunflower	TP 81/1 of 31.10.2002
Linum usitatissimum L.	Flax/Linseed	TP 57/1 of 21.3.2007
Avena nuda L.	Small naked oat, Hulless oat	TP 20/1 of 6.11.2003
Avena sativa L. (includes A. byzantina K. Koch)	Oats and Red oat	TP 20/1 of 6.11.2003
Hordeum vulgare L.	Barley	TP 19/3 of 21.3.2012
Oryza sativa L.	Rice	TP 16/2 of 21.3.2012
Secale cereale L.	Rye	TP 58/1 of 31.10.2002
xTriticosecale Wittm. ex A. Camus	Hybrids resulting from the crossing of a species of the genus <i>Triticum</i> and a species of the genus <i>Secale</i>	TP 121/2 rev. 1 of 16.2.2011
Triticum aestivum L.	Wheat	TP 3/4 rev. 2 of 16.2.2011
Triticum durum Desf.	Durum wheat	TP 120/2 of 6.11.2003
Zea mays L.	Maize	TP 2/3 of 11.3.2010
Solanum tuberosum L.	Potato	TP 23/2 of 1.12.2005
The text of these protocols can be found on	the CPVO web site (www.cpvo.europa.eu).	•

List of species referred to in Article 1(2)(b) which are to comply with UPOV test guidelines

Scientific name	Common name	UPOV guideline
Beta vulgaris L.	Fodder beet	TG/150/3 of 4.11.1994
Agrostis canina L.	Velvet bent	TG/30/6 of 12.10.1990
Agrostis gigantea Roth.	Red top	TG/30/6 of 12.10.1990
Agrostis stolonifera L.	Creeping bent	TG/30/6 of 12.10.1990
Agrostis capillaris L.	Brown top	TG/30/6 of 12.10.1990
Bromus catharticus Vahl	Rescue grass	TG/180/3 of 4.4.2001
Bromus sitchensis Trin.	Alaska brome grass	TG/180/3 of 4.4.2001
Dactylis glomerata L.	Cocksfoot	TG/31/8 of 17.4.2002
Festuca arundinacea Schreber	Tall fescue	TG/39/8 of 17.4.2002
Festuca pratensis Huds.	Meadow fescue	TG/39/8 of 17.4.2002
xFestulolium Asch. et Graebn.	Hybrids resulting from the crossing of a species of the genus <i>Festuca</i> with a species of the genus <i>Lolium</i>	TG/243/1 of 9.4.2008
Phleum nodosum L.	Small timothy	TG/34/6 of 7.11.1984
Phleum pratense L.	Timothy	TG/34/6 of 7.11.1984
Poa pratensis L.	Smooth-stalked meadow grass	TG/33/6 of 12.10.1990
Lupinus albus L.	White lupin	TG/66/4 of 31.3.2004
Lupinus angustifolius L.	Narrow-leaved lupin	TG/66/4 of 31.3.2004
Lupinus luteus L.	Yellow lupin	TG/66/4 of 31.3.2004
Medicago sativa L.	Lucerne	TG/6/5 of 6.4.2005
Medicago x varia T. Martyn	Sand lucerne	TG/6/5 of 6.4.2005
Trifolium pratense L.	Red clover	TG/5/7 of 4.4.2001
Trifolium repens L.	White clover	TG/38/7 of 9.4.2003
Vicia faba L.	Field bean	TG/8/6 of 17.4.2002
Vicia sativa L.	Common vetch	TG/32/6 of 21.10.1988
Brassica napus L. var. napobrassica (L.) Rchb.	Swede	TG/89/6 rev. of 4.4.2001 + 1.4.2009
Raphanus sativus L. var. oleiformis Pers.	Fodder radish	TG/178/3 of 4.4.2001
Arachis hypogea L.	Groundnut/Peanut	TG/93/3 of 13.11.1985
Brassica rapa L. var. silvestris (Lam.) Briggs	Turnip rape	TG/185/3 of 17.4.2002

Common name	UPOV guideline
Hemp	TG/276/1 of 28.3.2012
Safflower	TG/134/3 of 12.10.1990
Cotton	TG/88/6 of 4.4.2001
Рорру	TG/166/3 of 24.3.1999
White mustard	TG/179/3 of 4.4.2001
Soya bean	TG/80/6 of 1.4.1998
Sorghum	TG/122/3 of 6.10.1989
	Hemp Safflower Cotton Poppy White mustard Soya bean

The text of these guidelines can be found on the UPOV web site (www.upov.int).'

PART B 'ANNEX I

List of species referred to in Article 1(2)(a) which are to comply with CPVO test protocols

Scientific name	Common name	CPVO protocol
Allium cepa L. (Cepa group)	Onion and Echalion	TP 46/2 of 1.4.2009
Allium cepa L. (Aggregatum group)	Shallot	TP 46/2 of 1.4.2009
Allium fistulosum L.	Japanese bunching onion or Welsh onion	TP 161/1 of 11.3.2010
Allium porrum L.	Leek	TP 85/2 of 1.4.2009
Allium sativum L.	Garlic	TP 162/1 of 25.3.2004
Allium schoenoprasum L.	Chives	TP 198/1 of 1.4.2009
Apium graveolens L.	Celery	TP 82/1 of 13.3.2008
Apium graveolens L.	Celeriac	TP 74/1 of 13.3.2008
Asparagus officinalis L.	Asparagus	TP 130/2 of 16.2.2011
Beta vulgaris L.	Beetroot including Cheltenham beet	TP 60/1 of 1.4.2009
Brassica oleracea L.	Curly kale	TP 90/1 of 16.2.2011
Brassica oleracea L.	Cauliflower	TP 45/2 of 11.3.2010
Brassica oleracea L.	Sprouting broccoli or Calabrese	TP 151/2 of 21.3.2007
Brassica oleracea L.	Brussels sprouts	TP 54/2 of 1.12.2005
Brassica oleracea L.	Kohlrabi	TP 65/1 of 25.3.2004
Brassica oleracea L.	Savoy cabbage, White cabbage and Red cabbage	TP 48/3 of 16.2.2011
Brassica rapa L.	Chinese cabbage	TP 105/1 of 13.3.2008
Capsicum annuum L.	Chilli or Pepper	TP 76/2 of 21.3.2007
Cichorium endivia L.	Curled-leaved endive and Plain-leaved endive	TP 118/2 of 1.12.2005
Cichorium intybus L.	Industrial chicory	TP 172/2 of 1.12.2005
Cichorium intybus L.	Witloof chicory	TP 173/1 of 25.3.2004
<i>Citrullus lanatus</i> (Thumb.) Matsum. et Nakai	Watermelon	TP 142/1 of 21.3.2007
Cucumis melo L.	Melon	TP 104/2 of 21.3.2007
Cucumis sativus L.	Cucumber and Gherkin	TP 61/2 of 13.3.2008
Cucurbita pepo L.	Marrow or Courgette	TP 119/1 of 25.3.2004
Cynara cardunculus L.	Globe artichoke and Cardoon	TP 184/1 of 25.3.2004
Daucus carota L.	Carrot and Fodder carrot	TP 49/3 of 13.3.2008

Scientific name	Common name	CPVO protocol
Foeniculum vulgare Mill.	Fennel	TP 183/1 of 25.3.2004
Lactuca sativa L.	Lettuce	TP 13/5 of 16.2.2011
Lycopersicon esculentum Mill.	Tomato	TP 44/4 of 21.3.2012
Petroselinum crispum (Mill.) Nyman ex A. W. Hill	Parsley	TP 136/1 of 21.3.2007
Phaseolus coccineus L.	Runner bean	TP 9/1 of 21.3.2007
Phaseolus vulgaris L.	Dwarf French bean and Climbing French bean	TP 12/3 of 1.4.2009
Pisum sativum L. (partim)	Wrinkled pea, Round pea and Sugar pea	TP 7/2 of 11.3.2010
Raphanus sativus L.	Radish	TP 64/1 of 27.3.2002
Solanum melongena L.	Aubergine or Egg plant	TP 117/1 of 13.3.2008
Spinacia oleracea L.	Spinach	TP 55/4 of 21.3.2012
Valerianella locusta (L.) Laterr.	Corn salad or Lamb's lettuce	TP 75/2 of 21.3.2007
Vicia faba L. (partim)	Broad bean	TP Broadbean/1 of 25.3.2004
Zea mays L. (partim)	Sweet corn and Pop corn	TP 2/3 of 11.3.2010
The text of these protocols can be found on	the CPVO web site (www.cpvo.europa.eu).	1

List of species referred to in Article 1(2)(b) which are to comply with UPOV test guidelines

TG/106/4 of 31.3.2004			
TG/37/10 of 4.4.2001			
hicory TG/154/3 of 18.10.1996			
TG/155/4 rev. of 28.3.2007 + 1.4.2009			
TG/63/7 of 28.3.2012			
TG/62/6 of 24.3.1999			
TG/116/4 of 24.3.2010			

DECISIONS

COUNCIL DECISION 2012/723/CFSP

of 26 November 2012

amending Decision 2011/172/CFSP concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Egypt

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Whereas:

- (1) On 21 March 2011, the Council adopted Decision 2011/172/CFSP (¹).
- (2) To facilitate the return of misappropriated funds to the Egyptian State, the derogations under Decision 2011/172/CFSP should be amended to permit the release of certain frozen funds or economic resources where they are required to satisfy a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in a Member State, prior to or after the date of designation of the natural or legal persons, entities and bodies concerned.
- (3) Decision 2011/172/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2011/172/CFSP is hereby amended as follows:

(1) Article 1(4) is replaced by the following:

'4. By way of derogation from paragraph 1, the competent authorities of a Member State may authorise the release of certain frozen funds or economic resources, provided the following conditions are met:

- (a) the funds or economic resources are the subject of an arbitral decision rendered prior to the date on which the natural or legal person, entity or body referred to in paragraph 1 was listed in the Annex or of a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in the Member State concerned, prior to or after that date;
- (b) the funds or economic resources will be used exclusively to satisfy claims secured by such a decision or

recognised as valid in such a decision, within the limits set by applicable laws and regulations governing the rights of persons having such claims;

- (c) the decision is not for the benefit of a natural or legal person, entity or body listed in the Annex; and
- (d) recognising the decision is not contrary to public policy in the Member State concerned.

The Member State concerned shall inform the other Member States and the Commission of any authorisation granted under this paragraph.';

(2) Article 1(6) is replaced by the following:

'6. Paragraph 2 shall not apply to the addition to frozen accounts of:

- (a) interest or other earnings on those accounts; or
- (b) payments due under contracts, agreements or obligations that were concluded or arose prior to the date on which those accounts became subject to the measures provided for in paragraphs 1 and 2; or
- (c) payments due under judicial, administrative or arbitral decisions rendered in the Union or enforceable in the Member State concerned,

provided that any such interest, other earnings and payments remain subject to the measures provided for in paragraph 1.'.

Article 2

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

Done at Brussels, 26 November 2012.

For the Council The President G. DEMOSTHENOUS

 $^{(^1)~}OJ~L~76,~22.3.2011,~p.~63.$

27.11.2012 EN

COUNCIL DECISION 2012/724/CFSP

of 26 November 2012

amending Decision 2011/72/CFSP concerning restrictive measures directed against certain persons and entities in view of the situation in Tunisia

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Whereas:

- (1) On 31 January 2011, the Council adopted Decision 2011/72/CFSP (¹).
- (2) To facilitate the return of misappropriated funds to the Tunisian State, the derogations under Decision 2011/72/CFSP should be amended to permit the release of certain frozen funds or economic resources where they are required to satisfy a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in a Member State, prior to or after the date of designation of the natural or legal persons, entities and bodies concerned.
- (3) Decision 2011/72/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2011/72/CFSP is hereby amended as follows:

(1) Article 1(4) is replaced by the following:

'4. By way of derogation from paragraph 1, the competent authorities of a Member State, may authorise the release of certain frozen funds or economic resources, provided the following conditions are met:

- (a) the funds or economic resources are the subject of an arbitral decision rendered prior to the date on which the natural or legal person, entity or body referred to in paragraph 1 was listed in the Annex or of a judicial or administrative decision rendered in the Union, or a judicial decision enforceable in the Member State concerned, prior to or after that date;
- (b) the funds or economic resources will be used exclusively to satisfy claims secured by such a decision or

recognised as valid in such a decision, within the limits set by applicable laws and regulations governing the rights of persons having such claims;

- (c) the decision is not for the benefit of a natural or legal person, entity or body listed in the Annex; and
- (d) recognising the decision is not contrary to public policy in the Member State concerned.

The Member State concerned shall inform the other Member States and the Commission of any authorisation granted under this paragraph.';

(2) Article 1(5) is replaced by the following:

^{'5.} Paragraph 2 shall not apply to the addition to frozen accounts of:

- (a) interest or other earnings on those accounts; or
- (b) payments due under contracts, agreements or obligations that were concluded or arose prior to the date on which those accounts became subject to this Decision; or
- (c) payments due under judicial, administrative or arbitral decisions rendered in the Union or enforceable in the Member State concerned,

provided that any such interest, other earnings and payments remain subject to the measures provided for in paragraph 1.'.

Article 2

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

Done at Brussels, 26 November 2012.

For the Council The President G. DEMOSTHENOUS EN

COMMISSION IMPLEMENTING DECISION

of 22 November 2012

authorising the placing on the market of bovine lactoferrin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (Morinaga)

(notified under document C(2012) 8390)

(Only the English text is authentic)

(2012/725/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (¹), and in particular Article 7 thereof,

Whereas:

- (1) On 2 March 2011 the company Morinaga Milk Industry Co. Ltd made a request to the competent authorities of Ireland to place bovine lactoferrin on the market as novel food ingredient. Bovine lactoferrin is an iron binding protein from milk to be added to foods.
- (2) On 22 June 2011 the competent food assessment body of Ireland issued its initial assessment report. In this report they recommended that instead of carrying out an initial assessment an additional assessment was required, because another application concerning bovine lactoferrin was already referred to EFSA.
- (3) The Commission forwarded the initial assessment report to all Member States on 20 July 2011.
- (4) The European Food Safety Authority (EFSA) was consulted on 22 August 2011.
- (5) On 28 June 2012 in their 'Scientific opinion on bovine lactoferrin' (²) EFSA came to the conclusion that bovine lactoferrin is safe under the proposed uses and use levels.

- (6) On 27 April 2012 in another 'Scientific opinion on bovine lactoferrin' (³) EFSA already came to the conclusion that lactoferrin was safe under the proposed uses and use levels. Therefore it appears appropriate to authorise the same uses for both applications.
- (7) Bovine lactoferrin complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) 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

Bovine lactoferrin as specified in Annex I may be placed on the market as a novel food ingredient for the uses defined and at the maximum levels established in Annex II, and without prejudice to the provisions of Regulation (EC) No 1925/2006 of the European Parliament and of the Council (⁴) and Directive 2009/39/EC of the European Parliament and of the Council (⁵).

Article 2

The designation of bovine lactoferrin authorised by this Decision on the labelling of the foodstuffs containing it shall be 'Lactoferrin from cow's milk'.

Article 3

This Decision is addressed to Morinaga Milk Industry Co., Ltd, 33-1, Shiba 3-chome, Minato-ku, Tokyo 108-8384, Japan.

Done at Brussels, 22 November 2012.

For the Commission Maroš ŠEFČOVIČ Vice-President

^{(&}lt;sup>1</sup>) OJ L 43, 14.2.1997, p. 1.

^{(&}lt;sup>2</sup>) EFSA Journal 2012; 10(7): 2811.

⁽³⁾ EFSA Journal 2012; 10(5): 2701.

^{(&}lt;sup>4</sup>) OJ L 404, 30.12.2006, p. 26.

⁽⁵⁾ OJ L 124, 20.5.2009, p. 21.

SPECIFICATIONS OF BOVINE LACTOFERRIN

Definition

Bovine lactoferrin (bLF) is a protein that occurs naturally in cow's milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids.

bLF is isolated from skimmed milk via ion exchange and subsequent ultra-filtration steps. Finally it is dried by spraying and large particles are sieved out.

Description: Virtually odorless, light pinkish powder

Physical-chemical properties of bovine lactoferrin

Moisture	less than 4,5 %
Ash	less than 1,5 %
Arsenic	less than 2 mg/kg
Iron	less than 350 mg/kg
Protein	more than 93,0 %
of which bovine lactoferrin	more than 95,0 %
of which other proteins	less than 5,0 %
pH (2 % solution, 20 °C)	5,2 to 7,2
Solubility (2 % solution, 20 °C)	complete

USES OF BOVINE LACTOFERRIN (bLF)

Maximum use levels of bLF
100 mg/100 ml
200 mg/100 g
670 mg/100 g
pending on the needs of the individual up to 3 g/day
200 mg/100 g
330 mg/100 g
50 mg/100 g
120 mg/100 g
80 mg/100 g
2 000 mg/100 g
130 mg/100 g
1 000 mg/100 g
750 mg/100 g
3 000 mg/100 g

COMMISSION IMPLEMENTING DECISION

of 22 November 2012

authorising the placing on the market of dihydrocapsiate as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2012) 8391)

(Only the English text is authentic)

(2012/726/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (¹), and in particular Article 7 thereof,

Whereas:

- On 6 August 2010 the company Ajinomoto Co. Inc., Japan made a request to the competent authorities of the United Kingdom to place dihydrocapsiate on the market as novel food ingredient.
- (2) On 10 March 2011 the competent food assessment body of the United Kingdom issued its initial assessment report. In this report it came to the conclusion that dihydrocapsiate will not present a health risk to consumers.
- (3) The Commission forwarded the initial assessment report to all Member States on 13 April 2011.
- (4) Within the 60 day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections were raised in accordance with that provision.
- (5) Therefore the European Food Safety Authority (EFSA) was consulted on 9 November 2011.
- (6) On 28 June 2012 in their 'Scientific opinion on dihydrocapsiate' (²) EFSA came to the conclusion that dihydrocapsiate is safe under the proposed uses and use levels.
- (7) Dihydrocapsiate complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) 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

Dihydrocapsiate as specified in the Annex I may be placed on the market as a novel food ingredient for the uses defined and at the maximum levels established in Annex II, and without prejudice to the provisions of Regulation (EC) No 1925/2006of the European Parliament and of the Council (³), Directive 2009/39/EC of the European Parliament and of the Council (⁴) and Directive 2009/54/EC of the European Parliament and of the Council (⁵).

Article 2

The designation of dihydrocapsiate authorised by this Decision on the labelling of the foodstuffs containing it shall be 'Dihydrocapsiate'.

Article 3

This Decision is addressed to Ajinomoto Co. Inc., 15-1, Kyobashi, Chuo-ku, 1-choume, 104-8315, Tokyo, Japan.

Done at Brussels, 22 November 2012.

For the Commission Maroš ŠEFČOVIČ Vice-President

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ EFSA Journal 2012; 10(7):2812.

^{(&}lt;sup>3</sup>) OJ L 404, 30.12.2006, p. 26.

^{(&}lt;sup>4</sup>) OJ L 124, 20.5.2009, p. 21.

⁽⁵⁾ OJ L 164, 26.6.2009, p. 45.

EN

ANNEX I

SPECIFICATIONS OF DIHYDROCAPSIATE

Definition

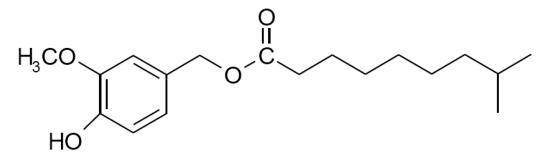
Dihydrocapsiate is synthesised by enzyme-catalysed esterification of vanillyl alcohol and 8-methylnonanoic acid. Following the esterification dihydrocapsiate is extracted with n-hexane.

The enzyme Lipozyme 435 was approved by the Danish Veterinary and Food Administration.

Description: Viscous colourless to yellow liquid

Chemical formula: C₁₈H₂₈O₄

Structural formula:



CAS No: 205687-03-2

Physical-chemical properties of dihydrocapsiate

Dihydrocapsiate	more than 94 %
8-Methylnonanoic acid	less than 6 %
Vanillyl acohol	less than 1 %
Synthesis related substances	less than 2 %

USES OF DIHYDROCAPSIATE

Food category	Maximum use levels
Cereal bars	9 mg/100 g
Biscuits, cookies and crackers	9 mg/100 g
Rice based snacks	12 mg/100 g
Carbonated drinks, dilutable drinks, fruit juice based drinks	1,5 mg/100 ml
Vegetable drinks	2 mg/100 ml
Coffee based drinks, tea based drinks	1,5 mg/100 ml
Flavoured water — still	1 mg/100 ml
Precooked oatmeal cereal	2,5 mg/100 g
Other cereals	4,5 mg/100 g
Ice cream, dairy desserts	4 mg/100 g
Pudding mixes (ready to eat)	2 mg/100 g
Products based on yoghurt	2 mg/100 g
Chocolate confectionery	7,5 mg/100 g
Hard candy	27 mg/100 g
Sugar-free gum	115 mg/100 g
Whitener/creamer	40 mg/100 g
Sweeteners	200 mg/100 g
Soup (ready to eat)	1,1 mg/100 g
Salad dressing	16 mg/100 g
Vegetable protein	5 mg/100 g
Ready to eat meals Replacement meals	3 mg/meal
Meal replacement drinks	1 mg/100 ml

EN

COMMISSION IMPLEMENTING DECISION

of 22 November 2012

authorising the placing on the market of bovine lactoferrin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (FrieslandCampina)

(notified under document C(2012) 8404)

(Only the Dutch text is authentic)

(2012/727/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (¹), and in particular Article 7 thereof,

Whereas:

- (1) On 2 March 2009 the company FrieslandCampina (formerly DMV International) made a request to the competent authorities of the Netherlands to place lactoferrin on the market as novel food ingredient. Lactoferrin is an iron-binding protein from milk to be added to foods.
- (2) On 31 March 2010 the competent food assessment body of the Netherlands issued its initial assessment report. In this report it came to the conclusion that there was no reason for concern thus lactoferrin may be placed on the market as a novel food ingredient.
- (3) The Commission forwarded the initial assessment report to all Member States on 13 April 2010.
- (4) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections were raised in accordance with that provision.
- (5) Therefore the European Food Safety Authority (EFSA) was consulted on 9 November 2010.
- (6) On 27 April 2012 in their 'Scientific opinion on bovine lactoferrin' (²) EFSA came to the conclusion that bovine lactoferrin is safe under the proposed uses and use levels.
- (7) On 28 June 2012 in another 'Scientific opinion on bovine lactoferrin' (³) EFSA also came to the conclusion

that bovine lactoferrin is safe under the proposed uses and use levels. Therefore it appears appropriate to authorise the same uses for both applications.

- (8) Bovine lactoferrin complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Bovine lactoferrin as specified in Annex I may be placed on the market as a novel food ingredient for the uses defined and at the maximum levels established in Annex II, and without prejudice to the provisions of Regulation (EC) No 1925/2006 of the European Parliament and of the Council (⁴) and Directive 2009/39/EC of the European Parliament and of the Council (⁵).

Article 2

The designation of bovine lactoferrin authorised by this Decision on the labelling of the foodstuffs containing it shall be 'Lactoferrin from cows' milk'.

Article 3

This Decision is addressed to FrieslandCampina, Nieuwe Kanaal 7R, 6709 PA Wageningen, The Netherlands.

Done at Brussels, 22 November 2012.

For the Commission Maroš ŠEFČOVIČ Vice-President

^{(&}lt;sup>1</sup>) OJ L 43, 14.2.1997, p. 1.

⁽²⁾ EFSA Journal 2012;(5):2701.

⁽³⁾ EFSA Journal 2012;10(7):2811.

^{(&}lt;sup>4</sup>) OJ L 404, 30.12.2006, p. 26.

⁽⁵⁾ OJ L 124, 20.5.2009, p. 21.

SPECIFICATIONS OF BOVINE LACTOFERRIN

Definition

Bovine lactoferrin (bLF) is a protein that occurs naturally in cows' milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids.

bLF is isolated from skimmed milk via ion exchange and subsequent ultra-filtration steps. Finally it is dried by spraying and large particles are sieved out.

Description: Virtually odourless, light pinkish powder.

Physical-chemical properties of bovine lactoferrin

less than 4,5 %
less than 1,5 %
less than 2 mg/kg
ess than 350 mg/kg
more than 93 %
more than 95 %
less than 5 %
5,2 to 7,2
complete
•

USES OF BOVINE LACTOFERRIN (bLF)

Food category	Maximum use levels of bLF	
Infant formulae and follow-on formulae (ready to drink)	100 mg/100 ml	
Foods on dairy basis intended for young children (ready to eat/drink)	200 mg/100 g	
Processed cereal food (solid)	670 mg/100 g	
Foods for special medical purposes	Depending on the needs of the individual up to 3 g/day	
Beverages based on milk	200 mg/100 g	
Powdered drink mixes based on milk (ready to drink)	330 mg/100 g	
Beverages based on fermented milk (including yoghurt drinks)	50 mg/100 g	
Non-alcoholic drinks	120 mg/100 g	
Products based on yoghurt	80 mg/100 g	
Products based on cheese	2 000 mg/100 g	
Ice cream	130 mg/100 g	
Cakes and pastries	1 000 mg/100 g	
Candies	750 mg/100 g	
Chewing gum	3 000 mg/100 g	

27.11.2012 EN

COMMISSION DECISION

of 23 November 2012

concerning the non-inclusion of bifenthrin for product type 18 in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

(notified under document C(2012) 8442)

(Text with EEA relevance)

(2012/728/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 the second subparagraph of Article 16(2) thereof,

Whereas:

- 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 bifenthrin.
- (2) Pursuant to Regulation (EC) No 1451/2007, bifenthrin has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive.
- (3) France was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 2 November 2009 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 25 May 2012 in an assessment report.
- (5) The assessment has demonstrated that biocidal products used as insecticides, acaricides and products to control other arthropods and containing bifenthrin cannot be expected to satisfy the requirements laid down in

Article 5 of Directive 98/8/EC. The scenarios evaluated in the environmental risk assessment showed an unacceptable risk for the aquatic compartment. It is therefore not appropriate to include bifenthrin for use in product type 18 in Annex I, IA or IB to Directive 98/8/EC.

- (6) In the interest of legal certainty, the date as of which biocidal products of product type 18 containing bifenthrin should no longer be placed on the market should be specified, taking into account both the unacceptable effects of those products and the legitimate expectations of manufacturers of those products.
- (7) 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

Bifenthrin (CAS No 82657-04-3) shall not be included in Annex I, IA or IB to Directive 98/8/EC for product type 18.

Article 2

For the purposes of Article 4(2) of Regulation (EC) No 1451/2007, biocidal products of product type 18 containing bifenthrin (CAS Nr 82657-04-3) shall no longer be placed on the market with effect from 1 May 2013.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 23 November 2012.

For the Commission Janez POTOČNIK Member of the Commission

^{(&}lt;sup>1</sup>) OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

EN

COMMISSION IMPLEMENTING DECISION

of 23 November 2012

amending Decision 2008/866/EC, on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption, as regards its period of application

(notified under document C(2012) 8459)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1)Regulation (EC) No 178/2002 lays down the general principles governing food and feed in general, and food and feed safety in particular, at Union and national level. It provides for emergency measures where there is evidence that food or feed imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned.
- Commission Decision 2008/866/EC of 12 November (2) 2008 on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption (2) was adopted following an outbreak of hepatitis A in humans related to the consumption of bivalve molluscs imported from Peru contaminated with hepatitis A virus (HAV). That Decision initially applied until 31 March 2009 but this period of application was extended until 30 November 2012 by Commission Implementing Decision 2011/723/EU (3).
- A Commission audit was carried out in June 2011. The (3) inspectors concluded that a well implemented control

system and monitoring plan are in place and improvements have been noted since the former inspection visit in 2009.

- The Peruvian competent authority presented an action (4)plan in response to the recommendations included in the final report of the abovementioned audit. However, the monitoring system for virus detection in live bivalve molluscs is not fully implemented yet, hence the possible contamination of live bivalve mollusc with Hepatitis A virus could not be excluded. In addition, the testing method for HAV is still under validation.
- The limit of application of Decision 2008/866/EC should (5) therefore be amended accordingly.
- The measures provided for in this Decision are in (6) accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

In Article 5 of Decision 2008/866/EC, the date '30 November 2012' is replaced by the date '30 November 2013'.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 23 November 2012.

For the Commission Maroš ŠEFČOVIČ Vice-President

^{(&}lt;sup>1</sup>) OJ L 31, 1.2.2002, p. 1. (²) OJ L 307, 18.11.2008, p. 9. (³) OJ L 288, 5.11.2011, p. 26.

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) No 1095/2012 of 22 November 2012 amending Regulation (EC) No 1484/95 as regards representative prices in the poultrymeat and egg sectors and for egg albumin

(Official Journal of the European Union L 325 of 23 November 2012)

On page 12, the Annex is replaced by the following text:

'ANNEX

'ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security pursuant to Article 3(3) (EUR/100 kg)	Origin (1)
0207 12 10	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as "70 % chickens", frozen	126,4	0	AR
		119,7	0	BR
0207 12 90	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as "65 % chickens", frozen	123,7	0	AR
		130,4	0	BR
0207 14 10	Fowls of the species Gallus domesticus, boneless cuts, frozen	259,0	12	AR
		211,0	27	BR
		335,9	0	CL
		223,2	23	TH
0207 25 10	Turkeys, not cut in pieces, presented as "80 % turkeys", frozen	193,1	0	BR
0207 27 10	Turkeys, boneless cuts, frozen	307,8	0	BR
		302,7	0	CL
0408 91 80	Eggs, not in shell, dried	468,8	0	AR
1602 32 11	Preparations of fowls of the species Gallus domesticus, uncooked	262,5	7	BR
	uomesutus, uncooked	312,6	0	CL
3502 11 90	Egg albumin, dried	594,9	0	AR

(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"...

2012/725/EU:

★ Commission Implementing Decision of 22 November 2012 authorising the placing on the market of bovine lactoferrin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (Morinaga) (notified under document C(2012) 8390) 46

2012/726/EU:

2012/727/EU:

2012/728/EU:

2012/729/EU:

★ Commission Implementing Decision of 23 November 2012 amending Decision 2008/866/EC, on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption, as regards its period of application (notified under document C(2012) 8459) (1) 56

Corrigenda

Corrigendum to Commission Implementing Regulation (EU) No 1095/2012 of 22 November 2012	
amending Regulation (EC) No 1484/95 as regards representative prices in the poultrymeat and egg	
sectors and for egg albumin (OJ L 325, 23.11.2012)	57



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