

Official Journal

of the European Union

L 69



English edition

Legislation

Volume 54

16 March 2011

Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

2011/160/EU:

- ★ **Council Decision of 7 March 2011 on the conclusion of an Agreement between the European Union, Iceland, Liechtenstein and Norway on an EEA Financial Mechanism 2009-2014, an Agreement between the European Union and Norway on a Norwegian Financial Mechanism for the period 2009-2014, an Additional Protocol to the Agreement between the European Economic Community and Iceland, concerning special provisions applicable to imports into the European Union of certain fish and fisheries products for the period 2009-2014, and an Additional Protocol to the Agreement between the European Economic Community and Norway, concerning special provisions applicable to imports into the European Union of certain fish and fisheries products for the period 2009-2014** 1

REGULATIONS

- ★ **Commission Regulation (EU) No 252/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex I⁽¹⁾** 3
- ★ **Commission Regulation (EU) No 253/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XIII⁽¹⁾** 7

Price: EUR 3

(Continued overleaf)

⁽¹⁾ Text with EEA relevance

EN

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

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

Commission Implementing Regulation (EU) No 254/2011 of 15 March 2011 establishing the standard import values for determining the entry price of certain fruit and vegetables	13
Commission Implementing Regulation (EU) No 255/2011 of 15 March 2011 amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EU) No 867/2010 for the 2010/11 marketing year	15
Commission Implementing Regulation (EU) No 256/2011 of 15 March 2011 fixing the import duties in the cereals sector applicable from 16 March 2011	17

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 7 March 2011

on the conclusion of an Agreement between the European Union, Iceland, Liechtenstein and Norway on an EEA Financial Mechanism 2009-2014, an Agreement between the European Union and Norway on a Norwegian Financial Mechanism for the period 2009-2014, an Additional Protocol to the Agreement between the European Economic Community and Iceland, concerning special provisions applicable to imports into the European Union of certain fish and fisheries products for the period 2009-2014, and an Additional Protocol to the Agreement between the European Economic Community and Norway, concerning special provisions applicable to imports into the European Union of certain fish and fisheries products for the period 2009-2014

(2011/160/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 217, in conjunction with Article 218(6)(a), thereof,

Having regard to the proposal from the Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) Pursuant to Council Decision 2010/674/EU ⁽¹⁾, the following agreements and protocols were signed, on behalf of the Union:

- Agreement between the European Union, Iceland, the Principality of Liechtenstein and the Kingdom of Norway on an EEA Financial Mechanism 2009-2014 and the Annex thereto,
- Agreement between the European Union and the Kingdom of Norway on a Norwegian Financial Mechanism for the period 2009-2014,
- Additional Protocol to the Agreement between the European Economic Community and the Republic of Iceland and the Annex thereto,
- Additional Protocol to the Agreement between the European Economic Community and the Kingdom of Norway and the Annex thereto.

(2) The replacement of the existing financial mechanisms by new mechanisms, which relate to different time periods,

different amounts of funds, and different implementing provisions, as well as the renewal and extension of the concessions relating to certain fish and fisheries products, taken as a whole, constitute an important development of the association with the EEA EFTA States, which justifies the recourse to Article 217 of the Treaty on the Functioning of the European Union.

(3) These agreements and protocols should be concluded,

HAS ADOPTED THIS DECISION:

Article 1

The following agreements and protocols are hereby approved on behalf of the Union:

- Agreement between the European Union, Iceland, the Principality of Liechtenstein and the Kingdom of Norway on an EEA Financial Mechanism 2009-2014 and the Annex thereto,
- Agreement between the European Union and the Kingdom of Norway on a Norwegian Financial Mechanism for the period 2009-2014,
- Additional Protocol to the Agreement between the European Economic Community and the Republic of Iceland and the Annex thereto,
- Additional Protocol to the Agreement between the European Economic Community and the Kingdom of Norway and the Annex thereto.

⁽¹⁾ OJ L 291, 9.11.2010, p. 1.

Article 2

The President of the Council is hereby authorised to designate the person empowered to deposit on behalf of the Union the act of approval provided for in each of the agreements and additional protocols, in order to express the consent of the Union to be bound.

Article 3

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

Done at Brussels, 7 March 2011.

For the Council
The President
CZOMBA S.

REGULATIONS

COMMISSION REGULATION (EU) No 252/2011

of 15 March 2011

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex I

(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC⁽¹⁾, and in particular Article 131 thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006⁽²⁾ harmonises the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the Community, taking into account the classification criteria and labelling rules of the Globally Harmonised System of Classification and Labelling of Chemicals.
- (2) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽³⁾ and Directive 1999/45/EC of the European Parliament and of the

Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations⁽⁴⁾ were amended several times. Directives 67/548/EEC and 1999/45/EC will be replaced over a transitional period according to which substances must be classified, labelled and packaged according to Regulation (EC) No 1272/2008 from 1 December 2010 and mixtures from 1 June 2015, although from 1 December 2010 until 1 June 2015 classification of substances according to both Directive 67/548/EEC and Regulation (EC) No 1272/2008 is required. Both Directives will be repealed in full by Regulation (EC) No 1272/2008 with effect from 1 June 2015.

- (3) Annex I to Regulation (EC) No 1907/2006 should be amended to adapt it to the criteria for classification and other relevant provisions laid down in Regulation (EC) No 1272/2008.
- (4) Article 58(1) of Regulation (EC) No 1272/2008 modifies Article 14(4) of Regulation (EC) No 1907/2006 to adapt it to the classification criteria in Regulation (EC) No 1272/2008. This also has consequences for Annex I to Regulation (EC) No 1907/2006, which was not amended by Regulation (EC) No 1272/2008. It is therefore necessary to adapt Annex I to Regulation (EC) No 1907/2006 to the new text in its Article 14(4).
- (5) Regulation (EC) No 1272/2008 introduces substantive changes in terminology compared to those used in Directive 67/548/EEC. Annex I to Regulation (EC) No 1907/2006 was not amended by Regulation (EC) No 1272/2008 and should be updated to reflect these changes and ensure consistency throughout.
- (6) Furthermore, references to Directive 67/548/EEC should be replaced by appropriate references to Regulation (EC) No 1272/2008.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ OJ L 353, 31.12.2008, p. 1.

⁽³⁾ OJ 196, 16.8.1967, p. 1.

⁽⁴⁾ OJ L 200, 30.7.1999, p. 1.

- (7) In accordance with Regulation (EC) No 1907/2006, registrations including chemical safety reports will have been submitted by the date of application of this Regulation. Changes in classification criteria and other relevant provisions resulting from Regulation (EC) No 1272/2008 apply to substances from 1 December 2010, in accordance with the second paragraph of Article 62 of that Regulation. In order to ensure a smooth transition for the updating of registrations, a transitional period should be provided.
- (8) Annex I to Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established pursuant to Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1907/2006 is amended as follows:

1. point 0.6 is replaced by the following:

‘0.6. Steps of a chemical safety assessment

0.6.1. A chemical safety assessment performed by a manufacturer or an importer for a substance shall include the following steps 1 to 4 in accordance with the respective sections of this Annex:

1. Human health hazard assessment.
2. Human health hazard assessment of physico-chemical properties.
3. Environmental hazard assessment.
4. PBT and vPvB assessment.

0.6.2. In the cases referred to in point 0.6.3 the chemical safety assessment shall also include the following steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:

5. Exposure assessment.
- 5.1. The generation of exposure scenario(s) (or the identification of relevant use and exposure categories, if appropriate).
- 5.2. Exposure estimation.
6. Risk characterisation.

0.6.3. Where as a result of steps 1 to 4 the manufacturer or importer concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 or is assessed to be a PBT or vPvB, the chemical safety assessment shall also include steps 5

and 6 in accordance with Sections 5 and 6 of this Annex:

- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, and 2.15 types A to F;
- (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9, and 3.10;
- (c) hazard class 4.1;
- (d) hazard class 5.1.

0.6.4. A summary of all the relevant information used in addressing the points above shall be presented under the relevant heading of the Chemical Safety Report (Section 7).’;

2. point 1.0.1 is replaced by the following:

‘1.0.1. The objectives of the human health hazard assessment shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008; and to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).’;

3. point 1.0.2 is replaced by the following:

‘1.0.2. The human health hazard assessment shall consider the toxicokinetic profile (i.e. absorption, metabolism, distribution and elimination) of the substance and the following groups of effects:

- (1) acute effects such as acute toxicity, irritation and corrosivity;
- (2) sensitisation;
- (3) repeated dose toxicity; and
- (4) CMR effects (carcinogenicity, germ cell mutagenicity and toxicity for reproduction).

Based on all the available information, other effects shall be considered when necessary.’;

4. point 1.1.3 is replaced by the following:

‘1.1.3. All non-human information used to assess a particular effect on humans and to establish the dose (concentration) – response (effect) relationship, shall be briefly presented, if possible in the form of a table or tables, distinguishing between *in vitro*, *in vivo* and other information. The relevant test results (e.g. ATE, LD50, NO(A)EL or LO(A)EL) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.’;

5. points 1.3.1 and 1.3.2 are replaced by the following:

‘1.3.1. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified. Where applicable, Specific Concentration limits resulting from the application of Article 10 of Regulation (EC) No 1272/2008 and Articles 4 to 7 of Directive 1999/45/EC shall be presented and, if they are not included in Part 3 of Annex VI to Regulation (EC) No 1272/2008, justified.

The assessment should always include a statement as to whether the substance fulfils or does not fulfil the criteria given in Regulation (EC) No 1272/2008 for classification in the hazard class carcinogenicity category 1A or 1B, in the hazard class germ cell mutagenicity category 1A or 1B or in the hazard class reproductive toxicity category 1A or 1B.

1.3.2. If the information is inadequate to decide whether a substance should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.’;

6. the second sentence of point 1.4.1 is replaced by the following:

‘For some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established.’;

7. point 2.1 is replaced by the following:

‘2.1. The objective of the hazard assessment for physico-chemical properties shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008.’;

8. point 2.2 is replaced by the following:

‘2.2. As a minimum, the potential effects to human health shall be assessed for the following physicochemical properties:

- explosivity,
- flammability,
- oxidising potential.

If the information is inadequate to decide whether a substance should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.’;

9. point 2.5 is replaced by the following:

‘2.5. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified.’;

10. point 3.0.1 is replaced by the following:

‘3.0.1. The objective of the environmental hazard assessment shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008 and to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC).’;

11. points 3.2.1 and 3.2.2 are replaced by the following:

‘3.2.1. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified. Any M-factor resulting from the application of Article 10 of Regulation (EC) No 1272/2008 shall be presented and, if it is not included in Part 3 of Annex VI to Regulation (EC) No 1272/2008, justified.

3.2.2. If the information is inadequate to decide whether a substance should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.’;

12. points 4.1 and 4.2 are replaced by the following:

‘4.1. Step 1: Comparison with the criteria

This part of the PBT and vPvB assessment shall entail the comparison of the available information with the criteria given in Section 1 of Annex XIII and a statement of whether the substance fulfils or does not fulfil the criteria. The assessment shall be conducted in accordance with the provisions laid down in the introductory part of Annex XIII as well as Sections 2 and 3 of that Annex.

4.2. Step 2: Emission Characterisation

If the substance fulfils the criteria or it is considered as if it is a PBT or vPvB in the registration dossier an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance.’;

13. Part B of the table in Section 7 is amended as follows:

- (a) points 5.3.1, 5.3.2 and 5.3.3 are deleted;
- (b) points 5.5.1 and 5.5.2 are deleted;

(c) point 5.7 is replaced by the following:

‘5.7. Germ cell mutagenicity’;

(d) points 5.9.1 and 5.9.2 are deleted.

Article 2

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

It shall apply from 5 May 2011.

However, for registrations submitted prior to 5 May 2011, the chemical safety report shall be updated in accordance with this Regulation by 30 November 2012 at the latest. Article 22(5) of Regulation (EC) No 1907/2006 shall not apply to those updates.

This Article is without prejudice to Articles 2 and 3 of Commission Regulation (EU) No 253/2011 ⁽¹⁾, with regard to Article 1(12) of this Regulation.

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

Done at Brussels, 15 March 2011.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ See page 7 of this Official Journal.

COMMISSION REGULATION (EU) No 253/2011**of 15 March 2011****amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XIII****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

account in the review of Annex XIII with a view to ensuring a high level of protection for human health and the environment.

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

Having regard to Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC⁽¹⁾, and in particular Article 131 thereof,

(4) The review carried out by the Commission pursuant to Article 138(5) of Regulation No 1907/2006 has revealed that there is a need to amend Annex XIII to that Regulation.

(5) Experience shows that, for the adequate identification of PBT and vPvB substances, all relevant information should be used in an integrated manner and applying a weight-of-evidence approach by comparing the information to the criteria set out in Section 1 of Annex XIII.

Whereas:

(6) A weight-of-evidence determination is particularly relevant in cases where the application of the criteria set out in Section 1 of Annex XIII to the available information is not straightforward.

(1) Regulation (EC) No 1907/2006 provides that substances which are persistent, bioaccumulative and toxic (PBT) as well as substances which are very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII may be included in Annex XIV in accordance with the procedure laid down in Article 58. Furthermore, Regulation (EC) No 1907/2006 establishes registration obligations of Union manufacturers or importers of substances on their own, in mixtures or articles, where, as part of the chemical safety assessment in accordance with Annex I, registrants have to do a PBT and vPvB assessment comprising, as a first step, a comparison with the criteria in Annex XIII to that Regulation.

(7) Accordingly, for the PBT and vPvB assessment of a substance in the framework of registration, registrants should consider all the information that is contained in the technical dossier.

(2) Article 138(5) of Regulation No 1907/2006 requires the Commission to review Annex XIII by 1 December 2008, in order to assess the adequacy of the criteria for identifying substances which are PBT or vPvB, with a view to proposing an amendment to it, if appropriate.

(8) In cases where the technical dossier contains, for one or more endpoints, only limited information as required in Annexes VII and VIII to Regulation (EC) No 1907/2006, the available data may not allow to reach a definitive conclusion on the PBT or vPvB properties. In such cases, the relevant information available in the technical dossier should be used for screening for P, B, or T properties.

(3) Experience at international level shows that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern. For that reason, the Commission has taken existing experience in the identification of these substances into

(9) In order to avoid unnecessary studies, only in cases where the screening assessment indicates a possible P, B, or T property, or a vP or vB property, the registrant should develop additional information or propose additional testing to conclude its PBT and vPvB assessment, unless the registrant implements or recommends sufficient risk management measures or operational conditions. For the same reason, registrants should not be required to develop additional information or propose additional testing if there is no indication of the P or B properties from the screening.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

- (10) Since substances can have one or more constituents with PBT or vPvB properties, or can transform or degrade into products with such properties, the identification should also take account of the PBT/vPvB-properties of such constituents and transformation and/or degradation products.
- (11) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

Article 2

1. Registrations of substances under Regulation (EC) No 1907/2006 and updates pursuant to Article 22 of that Regulation may be submitted in accordance with the Annex to this Regulation as from 19 March 2011 and shall comply with this Regulation from 19 March 2013.

2. Registrations of substances under Regulation (EC) No 1907/2006 that are not in accordance with the Annex to this Regulation shall be updated in order to comply with this Regulation no later than 19 March 2013. Article 22(5) of Regulation (EC) No 1907/2006 shall not apply to those updates.

HAS ADOPTED THIS REGULATION:

Article 1

Annex XIII to Regulation (EC) No 1907/2006 is replaced by the text set out in the Annex to this Regulation.

Article 3

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

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

Done at Brussels, 15 March 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

‘ANNEX XIII

CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES

This Annex lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance.

For the identification of PBT substances and vPvB substances a weight-of-evidence determination using expert judgement shall be applied, by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1. This shall be applied in particular where the criteria set out in Section 1 cannot be applied directly to the available information.

A weight-of-evidence determination means that all available information bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination.

The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.

The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.

This Annex shall apply to all organic substances, including organo-metals.

1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES**1.1. PBT Substances**

A substance that fulfils the persistence, bioaccumulation and toxicity criteria of Sections 1.1.1, 1.1.2 and 1.1.3 shall be considered to be a PBT substance.

1.1.1. Persistence

A substance fulfils the persistence criterion (P) in any of the following situations:

- (a) the degradation half-life in marine water is higher than 60 days;
- (b) the degradation half-life in fresh or estuarine water is higher than 40 days;
- (c) the degradation half-life in marine sediment is higher than 180 days;
- (d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;
- (e) the degradation half-life in soil is higher than 120 days.

1.1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2 000.

1.1.3. Toxicity

A substance fulfils the toxicity criterion (T) in any of the following situations:

- (a) the long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms is less than 0,01 mg/l;
- (b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to Regulation EC No 1272/2008;
- (c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008.

1.2. vPvB Substances

A substance that fulfils the persistence and bioaccumulation criteria of Sections 1.2.1 and 1.2.2 shall be considered to be a vPvB substance.

1.2.1. Persistence

A substance fulfils the “very persistent” criterion (vP) in any of the following situations:

- (a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days;
- (b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days;
- (c) the degradation half-life in soil is higher than 180 days.

1.2.2. Bioaccumulation

A substance fulfils the “very bioaccumulative” criterion (vB) when the bioconcentration factor in aquatic species is higher than 5 000.

2. SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES

2.1. Registration

For the identification of PBT and vPvB substances in the registration dossier, the registrant shall consider the information as described in Annex I and in Section 3 of this Annex.

If the technical dossier contains for one or more endpoints only information as required in Annexes VII and VIII, the registrant shall consider information relevant for screening for P, B, or T properties in accordance with Section 3.1 of this Annex. If the result from the screening tests or other information indicate that the substance may have PBT or vPvB properties, the registrant shall generate relevant additional information as set out in Section 3.2 of this Annex. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant shall submit a testing proposal. Where the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI the additional information may be omitted, and subsequently the substance is considered as if it is a PBT or vPvB in the registration dossier. No additional information needs to be generated for the assessment of PBT/vPvB properties if there is no indication of P or B properties following the result from the screening test or other information.

2.2. Authorisation

For dossiers for the purposes of identifying substances referred to in Article 57(d) and Article 57(e), relevant information from the registration dossiers and other available information as described in Section 3 shall be considered.

3. INFORMATION RELEVANT FOR THE SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES

3.1. Screening Information

The following information shall be considered for screening for P, vP, B, vB and T properties in the cases referred to in the second paragraph of Section 2.1 and may be considered for screening for P, vP, B, vB and T properties in the context of Section 2.2.

3.1.1. Indication of P and vP properties

- (a) Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII;
- (b) Results from other screening tests (e.g. enhanced ready test, tests on inherent biodegradability);
- (c) Results obtained from biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI;
- (d) Other information provided that its suitability and reliability can be reasonably demonstrated.

3.1.2. Indication of B and vB properties

- (a) Octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII or estimated by (Q)SAR models in accordance with Section 1.3 of Annex XI;
- (b) Other information provided that its suitability and reliability can be reasonably demonstrated.

3.1.3. Indication of T properties

- (a) Short-term aquatic toxicity in accordance with Section 9.1 of Annex VII and Section 9.1.3 of Annex VIII;
- (b) Other information provided that its suitability and reliability can be reasonably demonstrated.

3.2. Assessment Information

The following information shall be considered for the assessment of P, vP, B, vB and T properties, using a weight-of-evidence approach.

3.2.1. Assessment of P or vP properties

- (a) Results from simulation testing on degradation in surface water;
- (b) Results from simulation testing on degradation in soil;
- (c) Results from simulation testing on degradation in sediment;
- (d) Other information, such as information from field studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

3.2.2. Assessment of B or vB properties

- (a) Results from a bioconcentration or bioaccumulation study in aquatic species;
- (b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:
 - Results from a bioaccumulation study in terrestrial species;
 - Data from scientific analysis of human body fluids or tissues, such as blood, milk, or fat;
 - Detection of elevated levels in biota, in particular in endangered species or in vulnerable populations, compared to levels in their surrounding environment;
 - Results from a chronic toxicity study on animals;
 - Assessment of the toxicokinetic behaviour of the substance;
- (c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.

3.2.3. Assessment of T properties

- (a) Results from long-term toxicity testing on invertebrates as set out in Section 9.1.5 of Annex IX;
- (b) Results from long-term toxicity testing on fish as set out in Section 9.1.6 of Annex IX;

- (c) Results from growth inhibition study on aquatic plants as set out in in Section 9.1.2 of Annex VII;
 - (d) The substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard phrases: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard phrase: H340), toxic for reproduction in Category 1A, 1B and/or 2 (assigned hazard phrases: H360, H360F, H360D, H360FD, H360Fd, H360fD, H361, H361f, H361d or H361fd), specific target organ toxic after repeated dose in Category 1 or 2 (assigned hazard phrase: H372 or H373), according to Regulation EC No 1272/2008;
 - (e) Results from long-term or reproductive toxicity testing with birds as set out in Section 9.6.1 of Annex X;
 - (f) Other information provided that its suitability and reliability can be reasonably demonstrated.'
-

COMMISSION IMPLEMENTING REGULATION (EU) No 254/2011**of 15 March 2011****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 16 March 2011.

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

Done at Brussels, 15 March 2011.

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

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

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

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	MA	53,2
	TN	109,4
	TR	83,7
	ZZ	82,1
0707 00 05	JO	158,2
	TR	151,8
	ZZ	155,0
0709 90 70	MA	40,0
	TR	127,1
	ZZ	83,6
0805 10 20	EG	55,3
	IL	75,7
	JM	51,6
	MA	47,8
	TN	46,2
	TR	72,9
	ZZ	58,3
0805 50 10	EG	67,3
	TR	55,1
	ZZ	61,2
0808 10 80	AR	96,2
	BR	91,4
	CA	91,4
	CL	114,1
	CN	89,0
	MK	50,2
	US	130,2
	ZA	67,5
0808 20 50	ZZ	91,3
	AR	93,9
	CL	71,8
	CN	65,4
	US	79,9
	ZA	90,5
	ZZ	80,3

⁽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 255/2011**of 15 March 2011****amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EU) No 867/2010 for the 2010/11 marketing year**

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

- (1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups

for the 2010/11 marketing year are fixed by Commission Regulation (EU) No 867/2010 ⁽³⁾. These prices and duties have been last amended by Commission Regulation (EU) No 251/2011 ⁽⁴⁾.

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 16 March 2011.

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

Done at Brussels, 15 March 2011.

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

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 178, 1.7.2006, p. 24.

⁽³⁾ OJ L 259, 1.10.2010, p. 3.

⁽⁴⁾ OJ L 67, 15.3.2011, p. 24.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 16 March 2011

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 11 10 ⁽¹⁾	55,06	0,00
1701 11 90 ⁽¹⁾	55,06	0,00
1701 12 10 ⁽¹⁾	55,06	0,00
1701 12 90 ⁽¹⁾	55,06	0,00
1701 91 00 ⁽²⁾	50,68	2,27
1701 99 10 ⁽²⁾	50,68	0,00
1701 99 90 ⁽²⁾	50,68	0,00
1702 90 95 ⁽³⁾	0,51	0,21

⁽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.

COMMISSION IMPLEMENTING REGULATION (EU) No 256/2011**of 15 March 2011****fixing the import duties in the cereals sector applicable from 16 March 2011**

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 (EU) No 642/2010 of 20 July 2010 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of import duties in the cereals sector ⁽²⁾, and in particular Article 2(1) thereof,

Whereas:

- (1) Article 136(1) of Regulation (EC) No 1234/2007 states that the import duty on products falling within CN codes 1001 10 00, 1001 90 91, ex 1001 90 99 (high quality common wheat), 1002, ex 1005 other than hybrid seed, and ex 1007 other than hybrids for sowing, is to be equal to the intervention price valid for such products on importation increased by 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.

- (2) Article 136(2) of Regulation (EC) No 1234/2007 lays down that, for the purposes of calculating the import duty referred to in paragraph 1 of that Article, representative cif import prices are to be established on a regular basis for the products in question.

- (3) Pursuant to Article 2(2) of Regulation (EU) No 642/2010, the price to be used for the calculation of the import duty on products of CN codes 1001 10 00, 1001 90 91, ex 1001 90 99 (high quality common wheat), 1002 00, 1005 10 90, 1005 90 00 and 1007 00 90 is the daily cif representative import price determined as specified in Article 5 of that Regulation.

- (4) Import duties should be fixed for the period from 16 March 2011 and should apply until new import duties are fixed and enter into force,

HAS ADOPTED THIS REGULATION:

Article 1

From 16 March 2011, the import duties in the cereals sector referred to in Article 136(1) of Regulation (EC) No 1234/2007 shall be those fixed in Annex I to this Regulation on the basis of the information contained in Annex II.

Article 2

This Regulation shall enter into force on 16 March 2011.

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

Done at Brussels, 15 March 2011.

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

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 187, 21.7.2010, p. 5.

ANNEX I

Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 16 March 2011

CN code	Description	Import duties ⁽¹⁾ (EUR/t)
1001 10 00	Durum wheat, high quality	0,00
	medium quality	0,00
	low quality	0,00
1001 90 91	Common wheat seed	0,00
ex 1001 90 99	High quality common wheat, other than for sowing	0,00
1002 00 00	Rye	0,00
1005 10 90	Maize seed, other than hybrid	0,00
1005 90 00	Maize, other than seed ⁽²⁾	0,00
1007 00 90	Grain sorghum, other than hybrids for sowing	0,00

⁽¹⁾ For goods arriving in the Union via the Atlantic Ocean or via the Suez Canal the importer may benefit, pursuant to Article 2(4) of Regulation (EU) No 642/2010, from a reduction in the duty of:

- 3 EUR/t, where the port of unloading is on the Mediterranean Sea, or on the Black Sea,
- 2 EUR/t, where the port of unloading is in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom, or on the Atlantic coast of the Iberian peninsula.

⁽²⁾ The importer may benefit from a flatrate reduction of EUR 24 per tonne where the conditions laid down in Article 3 of Regulation (EU) No 642/2010 are met.

ANNEX II

Factors for calculating the duties laid down in Annex I

1.3.2011-14.3.2011

1. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

(EUR/t)

	Common wheat ⁽¹⁾	Maize	Durum wheat, high quality	Durum wheat, medium quality ⁽²⁾	Durum wheat, low quality ⁽³⁾	Barley
Exchange	Minneapolis	Chicago	—	—	—	—
Quotation	256,33	200,16	—	—	—	—
Fob price USA	—	—	304,48	294,48	274,48	173,42
Gulf of Mexico premium	102,15	14,27	—	—	—	—
Great Lakes premium	—	—	—	—	—	—

⁽¹⁾ Premium of 14 EUR/t incorporated (Article 5(3) of Regulation (EU) No 642/2010).⁽²⁾ Discount of 10 EUR/t (Article 5(3) of Regulation (EU) No 642/2010).⁽³⁾ Discount of 30 EUR/t (Article 5(3) of Regulation (EU) No 642/2010).

2. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

Freight costs: Gulf of Mexico–Rotterdam: 18,59 EUR/t

Freight costs: Great Lakes–Rotterdam: — EUR/t

2011 SUBSCRIPTION PRICES (excluding VAT, including normal transport charges)

EU Official Journal, L + C series, paper edition only	22 official EU languages	EUR 1 100 per year
EU Official Journal, L + C series, paper + annual DVD	22 official EU languages	EUR 1 200 per year
EU Official Journal, L series, paper edition only	22 official EU languages	EUR 770 per year
EU Official Journal, L + C series, monthly DVD (cumulative)	22 official EU languages	EUR 400 per year
Supplement to the Official Journal (S series), tendering procedures for public contracts, DVD, one edition per week	multilingual: 23 official EU languages	EUR 300 per year
EU Official Journal, C series — recruitment competitions	Language(s) according to competition(s)	EUR 50 per year

Subscriptions to the *Official Journal of the European Union*, which is published in the official languages of the European Union, are available for 22 language versions. The Official Journal comprises two series, L (Legislation) and C (Information and Notices).

A separate subscription must be taken out for each language version.

In accordance with Council Regulation (EC) No 920/2005, published in Official Journal L 156 of 18 June 2005, the institutions of the European Union are temporarily not bound by the obligation to draft all acts in Irish and publish them in that language. Irish editions of the Official Journal are therefore sold separately.

Subscriptions to the Supplement to the Official Journal (S Series — tendering procedures for public contracts) cover all 23 official language versions on a single multilingual DVD.

On request, subscribers to the *Official Journal of the European Union* can receive the various Annexes to the Official Journal. Subscribers are informed of the publication of Annexes by notices inserted in the *Official Journal of the European Union*.

Sales and subscriptions

Subscriptions to various priced periodicals, such as the subscription to the *Official Journal of the European Union*, are available from our sales agents. The list of sales agents is available at:

http://publications.europa.eu/others/agents/index_en.htm

EUR-Lex (<http://eur-lex.europa.eu>) offers direct access to European Union legislation free of charge. The *Official Journal of the European Union* can be consulted on this website, as can the Treaties, legislation, case-law and preparatory acts.

For further information on the European Union, see: <http://europa.eu>



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN