COUNCIL OF THE EUROPEAN UNION

Brussels, 12 October 2010

14860/10

LIMITE

COMPET 289
ENV 676
CHIMIE 36
MI 376
ENT 138

COVER NOTE

from:	European Commission
date of receipt:	6 October 2010
to:	General Secretariat of the Council
Subject:	Draft Commission Regulation (EU) No …/.. of 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

Delegations will find attached Commission document D010324/02.

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Encl.: D010324/02

EUROPEAN COMMISSION

Brussels, xxx
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Draft

COMMISSION REGULATION (EU) No …/..

of

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

Draft

COMMISSION REGULATION (EU) No …/..

of

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,

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,

Whereas:

(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 of that Regulation.

(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.

(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 account in the

[1] OJ L 396, 30.12.2006, p. 1. Regulation as corrected by OJ L 136, 29.5.2007, p.3..

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

(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 of 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.

(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.

(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.

(8) In cases where the technical dossier contains, for one or more endpoints, only limited information as required in Annexes VII and VIII of 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.

(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.

(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,

HAS ADOPTED THIS REGULATION:

Article 1

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

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 [date of entry into force] and shall comply with this Regulation from [2 years after date of entry into force].

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 [2 years after date of entry into force]. Article 22(5) of Regulation (EC) No 1907/2006 shall not apply to those updates.

Article 3

1. This Regulation shall enter into force on the third 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,

For the Commission
The President

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 bioacumulation 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.