EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies

REVIEW OF REACH ANNEXES

Several reviews of REACH Annexes were specifically mandated by Article 138 or other provisions in REACH, or followed from the adoption of the CLP Regulation ... bg cs da de et el es fr ga hr it lv lt hu mt nl pl pt ro sk sl fi sv.

Reviews have been made or are currently ongoing of the following Annexes: Annex I, Annex II, Annex IV, Annex V, Annex XI, Annex XIII, Annex XVII

Stakeholder consultation

The Commission engaged Member States and other stakeholders on the reviews, in most cases in a sub-group of the REACH Competent Authorities (CA); the Competent Authority Sub Group for the review of the Annexes of REACH (CASG (Annexes)).

Annex I

Annex I of Regulation (EC) No. 1907/2006 (REACH) sets out the details of how to carry out a Chemical Safety Assessment and document it in a Chemical Safety Report. The Annex has been supplemented by a technical guidance document on Information Requirements and Chemical Safety Assessment.

Article 138(4) mandated the Commission to carry out a review of Annex I of REACH by 1 June 2008, with a view to proposing amendments, if appropriate. As an outcome of the review, the Commission services concluded that it was not appropriate to propose an amendment to the content of Annex I. The reasons for this conclusion are explained in a Commission Communication on Annexes I, IV and V.

The Commission has however adopted a Regulation ... bg cs da de et el es fr ga hr it lv lt hu mt nl pl pt ro sk sl fi sv to bring Annex I into line with the CLP Regulation (Regulation (EC) No 1272/2008) which was adopted in the meantime, and to ensure consistency throughout.

Annex II

Annex II of Regulation (EC) No 1907/2006 (REACH) describes what information should be included under each of the 16 headings of a safety data sheet (SDS).

SDSs are an important element of hazard communication and provide a mechanism for transmitting safety information on classified substances and mixtures, and certain non-classified substances and mixtures, including information from the relevant chemical safety report(s) down the supply chain to the immediate downstream user(s).

The Commission has adopted a Regulation amending the REACH Annexes relevant for SDS – Annex II and, to a lesser extent, Annex VI. The revision brings the SDS requirements into line with the Regulation on Classification, Labelling and Packaging (Regulation (EC) No 1272/2008) and with the guidance on the preparation of SDSs as laid down in the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) of the United Nations. A three column reference document compares Annex II as amended from 1 December 2010 onwards, with the relevant text of the GHS and with the original version of Annex II.

In order to facilitate the change-over for companies, the Regulation foresees a two-step transition, as presented in illustration1. The transition is built around two key dates of the CLP Regulation: 1 December 2010 and 1 June 2015, as presented in illustration2. The illustrations aim at facilitating the dissemination of information about the REACH and CLP Regulations, but do not intend to completely reflect the transitional arrangements in the legal text.

Special transitional rules provide extra flexibility for companies to adapt SDS already in use.

The Regulation replaces the entire Annex II of REACH with a new text, as of 1 December 2010 and again as of 1 June 2015. To help understanding the precise extent of the changes, two unofficial reference documents are available. The first document shows the differences, in "track changes", between the version of Annex II which has applied since 1 June 2007 and the version which will apply from 1 December 2010. Similarly, the second document shows the differences between that latter version and the version which will apply from 1 June 2015.

Only the text of the Regulation is authentic and the Commission accepts no responsibility or liability whatsoever with regard to the reference documents or the illustrations.

Annex IV

Annex IV of Regulation (EC) No. 1907/2006 (REACH) sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACH as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties.

Substances included in Annex IV are exempted from registration (as well as downstream user requirements and evaluation) for all their possible uses irrespective of the tonnage in which they are manufactured or imported (currently or in the future). Originally, Annex IV essentially reproduced the list of substances exempt from the obligation to report information under the repealed Existing Substances Regulation (Regulation (EEC) No. 793/93).

Article 138(4) mandated the Commission to carry out a review of Annex IV of REACH before 1 June 2008, with a view to proposing amendments, if appropriate. Recital 36 also required the review of Annex IV to take into account the application of Article 2(7)(a) and (b) and Annex XI to substances derived from mineralogical processes.

The Commission agreed with the Member States and stakeholders a process for submission of proposals for amendments to Annex IV, criteria against which the proposals for amendment can be judged, documentation that should be provided and a timetable for completing this work. As part of the review, a study was commissioned to assess existing entries and proposals for amendments against those criteria.

As an outcome of the review, the Commission adopted the amendment ... bg cs da de et el es fr ga hr it lv lt hu mt nl pl pt ro sk sl fi sv of Annex IV (as well as Annex V) on 8 October 2008. Further details of the review process on these annexes are explained in a Commission Communication on Annexes I, IV and V and a related Staff Working Document as well as in the Final Report (Report ; Appendix 1, 2 and 3) from a contractor that was engaged by the Commission for the purposes of the review.

Annex V

Annex V of Regulation (EC) No. 1907/2006 (REACH) sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACH because registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH.

Substances included in Annex V are exempted from registration (as well as downstream user requirements and evaluation) for all their possible uses irrespective of the tonnage at which they are manufactured or imported (currently or in the future). Annex V is mainly based on the reporting rules for the EINECS Inventory and reflects the experience in the operation of the Directive 67/548/EEC on classification, packing and labelling of dangerous substances, as collected in the Manual of Decisions (MoD) to this Directive. In addition, Annex V contains a number of changes made during the legislative procedure for the adoption of REACH.

Article 138(4) mandated the Commission to carry out a review of Annex V of REACH before 1 June 2008, with a view to proposing amendments, if appropriate. Recital 36 also required the review of Annex V to take into account the application of Article 2(7)(a) and (b) and Annex XI to substances derived from mineralogical processes.

The Commission undertook the review of Annex V, taking into account the comments received by Member States and stakeholders.

As an outcome of the review, the Commission adopted the amendments ... bg cs da de et el es fr ga hr it lv lt hu mt nl pl pt ro sk sl fi sv of Annex V (as well as Annex IV) on 8 October 2008. Further details of the review process on these annexes are explained in a Commission Communication on Annexes I, IV and V and a related Staff Working Document.

In addition, in 2009 the Commission services prepared a draft guidance on the interpretation of Annex V. The draft was handed over to the European Chemicals Agency for further development, in co-operation with Member States and relevant stakeholders and for subsequent insertion into the Guidance on registration. ECHA carried out its update and the final guidance document was made public in March 2010. In this context, also the Commission paper on vegetable oils derived from GMOs can be useful.

Annex XI

Annex XI sets out the general rules for adaptation of the standard testing regime (waiving) specified in the information Annexes. Part 3 of Annex XI deals with substance-tailored exposure-driven testing for sections 8.6 and 8.7 of Annex VIII, Annex IX and Annex X, where, on the basis of the exposure scenario(s) developed in the Chemical Safety Report, testing may be waived.

The Commission was given the task to adopt practical criteria defining what constitutes adequate justification for waiving tests. Recital 38 gives guidance that the criteria should be based on experience gained through RIPs.

In May 2008, ECHA published the technical guidance document on Information Requirements and Chemical Safety Assessment. On the basis of the experience reflected in this guidance document and after consultation of stakeholders, the Commission prepared an amendment of Annex XI ... bg cs da de et el es fr ga hr it lv lt hu mt nl pl pt ro sk sl fi sv, which was adopted on 16 February 2009.

Annex XIII

Annex XIII sets out the criteria for the identification of persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative (vPvB) substances; it does not apply to inorganic substances.

As mandated by Article 138(5), the Commission carried out a review of Annex XIII with a view to proposing an amendment to it, if appropriate. Recital 46 clarifies that the review was to take into account current and new experience in the identification of these substances.

The experience reflected in the technical guidance document on Information Requirements and Chemical Safety Assessment, from the PBT working group under Regulation (EC) No 793/93 and Directive 67/548/EEC and from the Regulation 850/2004 on Persistent Organic Pollutants, was taken into account in the review of Annex XIII. The conclusion of the review was that an adaptation of the criteria for the identification of PBT and vPvB substances was necessary.

As a result of this process Annex XIII has been amended in order to ensure that in the identification of PBT and vPvB substances all available information is considered, using a so-called "weight of evidence" approach. The new Annex XIII has been adopted by means of Commission Regulation (EU) No 253/2011 ... bg cs da de et el es fr ga hr it lv lt hu mt nl pl pt ro sk sl fi sv of 15 March 2011.

Annex XVII

Annex XVII sets out the list of restrictions on the manufacture, placing on the market and use of certain dangerous chemical substances, mixtures and articles. The Annex contains the restrictions of the marketing and use of dangerous substances adopted since 1976 in the framework of Directive 76/769/EEC (repealed), as well as subsequent restrictions adopted under REACH.

Title VIII and Annex XVII to REACH came into force on 1 June 2009.

In 2008 a review of Annex XVII was launched in consultation with all interested parties with the objective of harmonising the terminology, deleting obsolete provisions, adapting the provisions to the definitions under REACH and including some of the restrictions adopted under Directive 76/769/EEC. The revised Annex

XVII  ... bg cs da de et el es fr ga hr it lv lt hu mt nl pl pt ro sk sl fi sv was adopted on 22 June 2009.

/More on Authorisation and Restrictions/