



Helpdesk

EU NEWS ON IMPLEMENTATION OF “ACQUIS COMMUNAUTAIRE”

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Chemical products

Commission review of Annexes I, IV, V, XI and XIII of REACH



Within the first 18 months after the entry into force of REACH (Regulation (EC) No. 1907/2006), the Commission has been tasked to carry out a number of reviews of the following Annexes of the Regulation:

- [Annex I](#)
- [Annex IV](#)
- [Annex V](#)
- [Annex XI, and](#)
- [Annex XIII](#)

The Commission will involve Member States and other stakeholders on the reviews in a sub-group of the REACH Competent Authorities.

Following the reviews, and if appropriate, the Commission will prepare amendments to the relevant Annexes to take into account the results of the reviews.

Stakeholder consultation

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

The Commission asked for nominations by CA members and observers to enable consultation covering all the reviews. The following Member States: AT, BE, DE, DK, EE, ES, FI, FR, GR, IE, IT, LT, IT, NL, SE, UK, and observers: Norway, CEFIC, REACH Alliance, CONCAWE, WWF and ETUC, were nominated and selected.

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 have concluded that it is currently not appropriate to propose an amendment to Annex I. The Commission plans to publish a Communication explaining the reasons for this conclusion.

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 register 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.

On the basis of these criteria, 294 proposals for amendment by Member States and stakeholders were received and evaluated by a consultant. Moreover, the consultant also reviewed the existing entries in the Regulation as published in OJ L 136 of 29 May 2007 against these criteria. The final report by the consultant will be made available on this website.

As an outcome of the review, the Commission adopted the amendment ([OJ L268 of 9 October 2008](#)) of Annex IV (as well as Annex V) on 8 October 2008. The Commission also plans to publish a Communication and a Staff Working Paper explaining further details of the review process on these annexes.

Comment:

Added to the list are certain vegetable oils, animal fats and waxes, as well as glass and ceramic frits. On the other hand, three other substances – vitamin A, carbon and graphite – have been removed from the list of exemptions and added to the list of products subject to registration.

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 amendment ([OJ L268 of 9 October 2008](#)) of Annex V (as well as Annex IV) on 8 October 2008. The Commission also plans to publish a Communication and a Staff Working Paper explaining further details of the review process on these annexes.

In addition, the Commission services have prepared [draft guidance](#) on the interpretation of Annex V. This draft guidance represents at the current stage the views of the Commission services only. It 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. However, as this draft document might be helpful to stakeholders in relation to registration and pre-registration, we decided to already make it available on this website.

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 by 1 December 2008 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, the Commission services will elaborate an amendment of Annex XI to be adopted by 1 December 2008.

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.

Article 138(5) mandates the Commission to carry out a review of Annex XIII by 1 December 2008. Recital 76 requires the criteria in Annex XIII to be reviewed taking into account current and new experience in the identification of these substances and if appropriate amended with a view to ensuring a high level of protection of human health and the environment.

The experience reflected in the [technical guidance document on Information Requirements and Chemical Safety Assessment](#) (link to document at <http://reach.jrc.it>), 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 will be reflected in the review of Annex XIII.

Stakeholder's comments concerning the review of Annex XIII should preferably be co-ordinated and channelled through the members and observers of the CASG Annexes (see above) with a copy to the Commission services (ENV-REACH-annexes@ec.europa.eu, ENTR-REACH-Annexes@ec.europa.eu).