

Press Release 72/2009

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European chemicals policy

Federal Environment Agency recommends review of criteria for substances of very high concern

In advance of the 3rd Meeting of Competent Authorities for REACH and CLP (CARACAL) on October 12-13, 2009 in Brussels, the German Federal Environment Agency (UBA) calls for an amendment of Annex XIII of the REACH regulation which lists the criteria for the identification of PBT/vPvB substances. Several member state authorities are arguing that the criteria are out-of-date and do not reflect the current state of science, and that they jeopardise the effective protection of human health and the environment from hazardous substances. Currently, the European Commission is working on a new proposal to amend Annex XIII. The German Federal Environment Agency is concerned that the whole process might end without yielding the necessary amendments to update the legal text. In view of the particular importance of Annex XIII for the protection of human health and the environment, UBA urges the Commission to present a proposal taking into account current scientific knowledge.

Persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances pose a risk to human health and the environment that is not predictable in the long-term. Once released into the environment, adverse effects caused by these substances cannot be remediated. Consequently, strong precautionary measures are necessary to prevent the release of PBT/vPvB substances and ensure the "high level of protection of human health and the environment" that is laid down as aim of the REACH Regulation (Art. 1(1)).

REACH calls chemicals with PBT/vPvB-properties "substances of very high concern" (SVHC) and requires registrants to assess substances with respect to their PBT/vPvB properties as part of the chemical safety assessment. One important task of the Member States under REACH is to initiate regulatory measures, i.e. requiring authorisation for substances of very high concern. One precondition for the successful implementation of these measures is, however, that the PBT/vPvB assessment carried out by authorities and registrants is based on adequate PBT/vPvB criteria.

Art. 138(5) of REACH mandates the European Commission to review the current criteria in Annex XIII of REACH. The European Commission invited experts to discuss the review of Annex XIII in a Competent Authorities subgroup in two meetings in September and November 2008. The subgroup pointed out that the criteria do not reflect the current state of science and need to be

amended. In particular, the current criteria do not allow for the use of all available information. Furthermore, the current Annex XIII criteria do not correctly reflect the properties they are meant to describe. For instance, the term bioaccumulation refers to both the uptake of a chemical via the surrounding environmental medium (bioconcentration) and its uptake via the food chain (biomagnification). The REACH criterion for bioaccumulation, however, only refers to bioconcentration in aquatic species. It fails to identify substances that do not bioconcentrate in fish, but bioaccumulate in mammals via the food chain.

One of the goals in regulating PBT/vPvB substances is to protect pristine environments. Therefore, when assessing PBT/vPvB properties, the long-range transport of a substance should be taken into account in order to identify its potential to accumulate in remote areas. The current Annex XIII does not account for this property, whose inclusion is also necessary to comply with the requirements of the Stockholm Convention for persistent organic pollutants (POPs).

At the Meeting of the Competent Authorities in December 2008, the European Commission presented a draft proposal for an amendment of Annex XIII that left the criteria unchanged and only introduced minor improvements. The majority of Member State Competent Authorities expressed their serious concern that the proposed amendment is not adequate and called on the Commission to follow the recommendations of the expert subgroup.

As a result, the Commission stated that it would rework the draft and present a new proposal. Since then, no further information about the activities of the Commission to review Annex XIII have become available, though both Member State CAs and NGOs expressed their concern about the issue in letters to the Commission and asked the Commission to report about the progress.

Further information:

<http://www.reach-info.de/pbt.htm> (in German only)

http://ec.europa.eu/environment/chemicals/reach/reviews_en.htm#annex13

http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review-annexes/index_en.htm#h2-annex-xiii

Dessau-Roßlau, 09.10.2009
(4.749 Zeichen)