

**Question for written answer P-9135/2010
to the Commission
Rule 117
Anja Weisgerber (PPE)**

Subject: Annex XIII to Regulation (EC) No 1907/2006 (REACH) - criteria for PBT and vPvB substances

The draft Commission regulation to amend Annex XIII to Regulation (EC) No 1907/2006 (REACH) does not change the criteria for the identification of persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances, but takes into account the results of new research into the environmental impact of these substances. Analysis of the environmental impact of a substance entails taking into account all available information on the identification of PBT and vPvB substances.

The draft states that, for the purposes of identifying PBT and vPvB substances, expert reports must be used to determine environmental impact.

Due consideration of environmental impact would therefore contribute to identifying PBT and vPvB substances even when the criteria used in screening tests for the identification of PBT and vPvB substances are not fulfilled. In other words, the changes would make it easier to identify substances for which a false negative result has been obtained.

For reasons of consistency, environmental impact should also be taken into account in the event of a false positive.

In future, will all information on environmental impact be taken into account if the identification criteria used in screening tests are fulfilled?

The purpose of the criteria for PBT and vPvB substances is to predict the environmental impact of a substance. However, there may be cases where actual measurements disprove the predictions. These cases would be false positive cases.

Will the revised Annex XIII also take such cases into account?

Can the Commission ensure that substances which fulfil the identification criteria are not identified as PBT or vPvB substances if the available information taken as a whole shows that they do not have the characteristics of a PBT or vPvB substance despite fulfilling the criteria?