[X1 ANNEX I

GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 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 (Official Journal of the European Union L 396 of 30 December 2006).

6. RISK CHARACTERISATION

6.1. The risk characterisation shall be carried out for each exposure scenario and shall be presented under the relevant heading of the Chemical Safety Report.

6.2. The risk characterisation shall consider the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonably foreseeable, under the assumption that the risk management measures described in the exposure scenarios in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

6.3. The risk characterisation consists of:

— a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL,

— a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs, and

— an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

6.4. For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

— the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, and,

— the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in Section 2 is negligible.

6.5. For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.

For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.**]**

Status:
Point in time view as at 27/12/2015.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, Division 6..