[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).

5. EXPOSURE ASSESSMENT

5.0. Introduction

The objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4. The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report:

Step 1	:	Generation of exposure scenario(s) or the generation of relevant use and exposure categories.
Step 2	:	Exposure Estimation.

Where required and in accordance with Article 31, the exposure scenario shall also be included in an annex to the Safety Data Sheet.

5.1. Step 1: Development of exposure scenarios

5.1.1. Exposure scenarios as described in Sections 0.7 and 0.8 shall be generated. Exposure scenarios are the core of the process to carry out a chemical safety assessment. The chemical safety assessment process may be iterative. The first assessment will be based on the required minimum and all available hazard information and on the exposure estimation that corresponds to the initial assumptions about the operating conditions and risk management measures (an initial exposure scenario). If the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control. The refinement of hazard assessment may require generation of additional hazard information. The refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures in the exposure scenario or more precise exposure estimation. The exposure scenario, resulting from the final iteration (a final exposure scenario), shall be included in the chemical safety report and attached to the safety data sheet in accordance with Article 31.

The final exposure scenario shall be presented under the relevant heading of the chemical safety report, and included in an annex to the safety data sheet, using an appropriate short title giving a brief general description of the use, consistent with those given in Section 3.5 of Annex VI. Exposure scenarios shall cover any manufacture in the Community and all identified uses.

In particular, an exposure scenario includes, where relevant, a description of:

Operational conditions

— the processes involved, including the physical form in which the substance is manufactured, processed and/or used,

— the activities of workers related to the processes and the duration and frequency of their exposure to the substance,

— the activities of consumers and the duration and frequency of their exposure to the substance,

— the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment.

Risk management measures

— the risk management measures to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and the different environmental compartments to the substance,

— the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.

5.1.2. Where a manufacturer, importer or downstream user applies for an application for an authorisation for a specific use, exposure scenarios need only be developed for that use and the subsequent life-cycle steps.

5.2. Step 2: Exposure Estimation

5.2.1. The exposure shall be estimated for each exposure scenario developed and shall be presented under the relevant heading of the Chemical Safety Report and where required and in accordance with Article 31, summarised in an annex to the safety data sheet. The exposure estimation entails three elements: (1) emission estimation; (2) assessment of chemical fate and pathways; and (3) estimation of exposure levels.

5.2.2. The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage. The emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented.

5.2.3. A characterisation of possible degradation, transformation, or reaction processes and an estimation of environmental distribution and fate shall be performed.

5.2.4. An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern. In particular, the exposure estimation shall take account of:

— adequately measured, representative exposure data,

— any major impurities and additives in the substance,

— the quantity in which the substance is produced and/or imported,

— the quantity for each identified use,

— implemented or recommended risk management, including the degree of containment,
— duration and frequency of exposure according to the operational conditions,
— the activities of workers related to the processes and the duration and frequency of their exposure to the substance,
— the activities of consumers and the duration and frequency of their exposure to the substance,
— the duration and frequency of emissions of the substance to the different environmental compartments and the dilution in the receiving environmental compartment,
— the physicochemical properties of the substance,
— transformation and/or degradation products,
— the likely routes of exposure of and potential for absorption in humans,
— the likely pathways to the environment and environmental distribution and degradation and/or transformation (see also Section 3 Step 1),
— scale (geographical) of exposure,
— matrix dependent release/migration of the substance.

5.2.5. Where adequately measured representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties can also be considered.**]**

Status:
Point in time view as at 12/10/2008.

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 5..