ANNEX XV

DOSSIERS

1. INTRODUCTION AND GENERAL PROVISIONS

This Annex lays down general principles for preparing dossiers to propose and jusify:

- the identification of CMRs, PBTs, vPvBs, or a substance of equivalent concern in accordance with Article 49,

- restrictions of the manufacture, placing on the market or use of a substance

The relevant parts of Annex I shall be used for the methodology and format of any dossier according to this Annex.

For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted, a robust study summary shall be included in the dossier.

2. CONTENT OF DOSSIERS

2.1. Dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern according to Article 49

Proposal

The proposal shall include the identity of substance(s) concerned and whether it is proposed to be identified as a CMR according to Article 47(1)(a), (b) or (c), a PBT according to Article 47(1)(ç), a vPvB according to Article 47(1)(d), or a substance of equivalent concern according to Article 47(1)(e).

Justification

A comparison of the available information with the criteria in Annex XIII for PBT according to Article 47(1)(ç), and vPvBs according to Article 47(1)(d), or an assessment of the hazards and a comparison with Article 47(1)(e), according to the relevant parts of Sections 1 to 4 of Annex I shall be completed. This shall be documented in the format set out in Part B of the Chemical Safety Report in Annex I.

Information on exposures, alternative substances and risks

The available use and exposure information and information on alternative substances and techniques shall be provided.

2.2. Dossiers for restrictions proposal

Proposal

The proposal shall include the identity of the substance and the restriction(s) proposed for the manufacture, placing on the market or use(s) and a summary of the justification.

Information on hazard and risk

The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report.

Evidence shall be provided that implemented risk management measures (including those identified in registrations under Articles 11 to 15 to this By-law) are not sufficient.

Information on alternatives

Available information on alternative substances and techniques shall be provided, including:

— information on the risks to human health and the environment related to the manufacture or use of the alternatives,

— availability, including the time scale,

— technical and economical feasibility.

Justification for Restrictions

Justification shall be provided that:

— action is required,

— a restriction is the most appropriate measure which shall be assessed using the following criteria:

(i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;

(ii) practicality: the restriction must be implementable, enforceable and manageable;

(iii) monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

Socio-economic assessment

The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

Information on stakeholder consultation

Information on any consultation of stakeholders and how their views have been taken into account shall be included in the dossier.