ANNEX XV

DOSSIERS

I. INTRODUCTION AND GENERAL PROVISIONS

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

— harmonised classification and labelling of CMRs, respiratory sensitisers and other effects,

— the identification of PBTs, vPvBs, or a substance of equivalent concern,

— restrictions of the manufacture, placing on the market or use of a substance within the Community.

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 to the Agency, a robust study summary shall be included in the dossier.

II. CONTENT OF DOSSIERS

1. **Dossier for harmonised classification and labelling for CMRs, respiratory sensitisers and other effects**

Proposal

The proposal shall include the identity of the substance(s) concerned and the harmonised classification and labelling proposed.

Justification

A comparison of the available information with the criteria for CMRs, respiratory sensitisers and other effects on a case by case basis in Directive 67/548/EEC according to the relevant parts of Section 1 of Annex I shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I.

Justification for other effects at Community Level

Justification shall be provided that there is a need for action demonstrated at Community Level.

2. **Dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern according to Article 59**

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 57(a), (b) or (c), a PBT according to Article 57(d), a vPvB according to Article 57(e), or a substance of equivalent concern according to Article 57(f).

Justification

A comparison of the available information with the criteria in Annex XIII for PBT according to Article 57(d), and vPvBs according to Article 57(e), or an assessment of the hazards and a comparison with Article 57(f), 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.

3. **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 10 to 14) 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 at Community Level

Justification shall be provided that:

— action is required on a Community-wide basis,

— a restriction is the most appropriate Community wide 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.