ANNEX 2

SUBSTANCE PRIORITISATION FOR THE EU ACUTEX PROJECT

HSL'S PRELIMINARY OVERVIEW OF FACTORS OF IMPORTANCE

A. FOR SELECTION OF 21 ACUTEX CASE STUDY SUBSTANCES FROM COMPETENT AUTHORITIES's `TOP 10' LISTS

A.1 ACUTEX Scope

- Substances within the scope to be agreed by the ACUTEX Critical Review Panel (under discussion is inclusion of Seveso II named substances including carcinogens[1], and substances in the toxic and very toxic generic categories).

A.2 Needs of Toxicologists for Development of AETLs Methodology

- Some substances with a good, medium and poor toxicological database.
- Substances giving good range of toxic effects (e.g. avoid over-representation of, say, respiratory tract irritants).

A.3 Comparison with US AEGLs

- Include some substances with AEGLs to allow scientific comparison with AETLs (e.g. do different approaches to degree of conservatism significantly affect the thresholds produced?) This is to inform the decision following completion of ACUTEX, on whether or not the EU would wish to participate in the AEGLs programme[2].

A.4 Representative Substances for SEVESO II

- Substances which can be used as examples of common types of Major Hazard sites/incident potential.
- Substances which can be used as surrogates for the "Toxic" & "Very toxic", categories and named carcinogens under Seveso II (e.g. choice of worst case toxicity)[3].

[1] The named carcinogens are the so-called `one-shot' carcinogens for which a single exposure can lead to cancer. For most carcinogens it is considered that cancers will only occur after repeated exposure over a long period of time, they are outside the scope under discussion.
[2] The decision itself includes a number of policy considerations. We note that at present both Germany and the Netherlands are part of the AEGLs programme.
[3] Subject to the ACUTEX scope to be agreed.

B. FOR POST-ACUTEX SUBSTANCE PRIORITISATION ONLY

B.1 Post-ACUTEX Scope

- Substances within an agreed scope. (This scope would be defined following ACUTEX. It may be broader than that agreed for ACUTEX itself and might, for example, include corrosive and irritant substances.)

B.2 Issues of Off-Site Risk from Inhalation

These issues could form the basis of a risk-ranking scheme for substance prioritisation at Member State level.

B.2a Technical/Scientific

- Number of sites.
- Hazard/risk potential:
  - tonnage per site[4];
  - toxicity;
  - dispersion characteristics[5];
  - likelihood of release;
  - other site-specific risk factors[6].
- Population distribution.

B.2b Policy

- Societal concerns – e.g. following an incident.
- Stakeholder priorities (industry, emergency planners etc.)[7].

B.3 Flexible Methodology which can be Adapted to Changing Needs

- E.g. substance prioritisation currently restricted to context of Seveso II but dangerous goods transportation and pipelines may be a future consideration.
- E.g. AETLs development currently restricted to toxicity of individual substances but effects of combinations of substances might be considered at a future date.

B.4 Interface with US AEGLs Programme

- Policy issue: include some substances with no AEGLs so that explicitly complement AEGLs programme (assumes similar toxicological dataset can be used)?
- Policy issue: if AEGLs & AETLs differ significantly, should existence of AEGL affect prioritisation?

[4] One consideration may be that in implementing SEVESO II some Member States have used lower `threshold quantities' than those specified in the directive.

[5] To be considered together with release mechanism: e.g. use vapour pressure for pressure liquefied toxic gases, or potential for spread in fire plume for substances such as the low volatility paraquat dichloride.

[6] For example: geography (slopes etc.), storage conditions & type (e.g. pressurised, moveable containers, warehouses), loading & off-loading operations.

[7] For example: priorities for emergency planners might include the relative difficulties of managing an incident (e.g. odourless toxic substances may be an issue), the risk to their personnel, and the frequency with which emergency planners' assistance is required.

C. FOR BOTH POST-ACUTEX SUBSTANCE PRIORITISATION & SELECTION OF 21 ACUTEX CASE STUDY SUBSTANCES

C.1 Degree of Uncertainty Related to Existing Toxicity Thresholds

- Lack of, or limitations in, any existing toxicity thresholds may lead to degree of uncertainty on off-site risks which (whilst not necessarily quantifiable) leads to substance being of high priority for AETL development[8]. It should be stressed that this is not a solely `scientific' question since it may be the assumptions used in existing thresholds (such as the degree of precaution used) which dictates whether a particular threshold is deemed appropriate for use in the context of the EU or a particular Member State.

C.2 Representation of Member States Interests

- Equity amongst Member States: for example, include 1 high priority substance per member state.
- Give higher weighting to substances which are of priority for several Member States.

C.3 Synergy with other SEVESO II Programmes/Projects

- Where practicable, draw on, or complement methodologies, criteria, and information collected from member states through other Seveso II programmes/projects.

C.4 Data Availability

- Base methodologies on data which is readily available
- Any data required from Member States should be readily available to them. (For instance in a risk ranking scheme, tonnage per site could be requested in categories such as small, medium, large).

C.6 Degree of Detail for Methodologies/ Data

- Methodologies & data requests should be of level of detail appropriate to task.

NOTE
The aim of WP2A is to produce a methodologies and criteria for substance prioritisation. The aim is not to dictate the outcome of the decisions - rather the methodology should facilitate both the decision making process & it's transparency.

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[8] It is possible that some substances deemed of high priority for the EU will not have toxicological datasets. These cannot be considered for ACUTEX case studies. This could be interpreted as signalling, post-ACUTEX, the need to consider developing a toxicological dataset for these substances. However, in practice, toxicity testing might not be conducted. Any such decisions necessarily have a strong ethical dimension. For instance, in the UK, authorisation of animal testing is subject to an extremely high level of scrutiny. In the UK, it might not be considered appropriate to carry out animal tests solely to provide information on the potential adverse health effects from a hypothetical release at a Major Hazard site given the strong regulatory measures in force regarding safety at these sites.