The EU ACUTEX Project and Substance Prioritisation for the Development of EU Acute Exposure Toxicity Thresholds

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Mary Trainor, HSL

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1. Summary

The aim of the EU ACUTEX project is to develop a methodology for establishing European Acute Exposure Threshold Levels (EU AETLs) for toxic substances. Their development is initially in the context of the Seveso II Directive. As part of this project, the Health and Safety Laboratory (HSL) is working with HSE to develop a methodology to prioritise the selection of substances for which toxicity thresholds will be developed. The views of CAP–EPLG members on substance prioritisation are invited. A copy of the paper has also been sent to the ACDS Major Hazards Sub-Committee members for comment.

2. The ACUTEX Project

The aim of the ACUTEX project is to develop a methodology for establishing European Acute Exposure Threshold Levels (EU AETLs) for toxic substances. At this stage, the development is in the context of the Control of Major Accident Hazards Involving Dangerous Substances Directive (96/82/EC) known as the Seveso II Directive[1]. However, extending this after the ACUTEX project to other activities such as pipelines and dangerous goods transportation has not been precluded. As part of the methodology development, AETLs will be produced for 21 substances as case studies.

AETLs will define the exposure conditions in terms of airborne concentration and exposure time that will produce a series of specified levels of harm to people for a number of toxic chemicals. The levels of harm have not yet been defined, but they are likely to range from transient discomfort at the lower end of the scale, to severe long-lasting adverse health effects and, at the upper end of the scale, life threatening effects or death.

It is considered that AETLs may potentially be used to aid decision making within EU Member States on emergency planning and land-use planning as appropriate in relation to Seveso II sites. The project does not, however, address how AETLs might be used in specific Member States as this is the responsibility of policy makers at Member State level. Rather it is intended that the ACUTEX project will:

- provide a broadly accepted, scientifically sound methodology for developing EU acute exposure thresholds which:

[1] In the UK, the Seveso II directive is implemented by the Control of Major Accident Hazards Regulations 1999 - the COMAH Regulations and, as regards land-use planning, through the 1999 amendments to the Planning (Hazardous Substances) Regulations 1992 – the Consents Regulations.

  - can be adapted, where appropriate, to the various national situations in land-use planning or emergency planning; and
  - will complement existing thresholds developed by Member States (or industry or other organisations); and
- through collaboration between toxicologists in the EU, and promotion of sharing data and expertise, reduce the overall cost of producing these thresholds.

A specific consideration at EU level has been the advantages or otherwise of joining the US programme for the development of Acute Exposure Guideline Levels (AEGLs)[2]. It was considered necessary to first form an EU team of experts, a need which has been met through the funding of ACUTEX. Additionally, technical queries have been raised on the appropriateness of AEGLs in an EU regulatory context. These queries include the possibly high (in this context) degree of precaution or conservatism used in their development[3]. It is intended that the AETL methodology will build on and refine the AEGL approach.

The ACUTEX project started on 1st December 02 and has a planned duration of 3 years. The project partners are drawn from 5 member states (France, Italy, Germany, Belgium and the UK) together with CEFIC (the association for the chemical industry in Europe), ECETOC (the European Chemical Industry Ecology and Toxicology Centre) and the European Commission's Joint Research Centre (JRC). Additionally, the work of the project is being monitored by a 'Critical Review Panel' which includes experts from major stakeholder groups.

HSE's Views on AETLs

HSE has a well established system for using toxicological information in the provision of advice to Local Authorities on their land-use planning decisions[4]. Given that UK

[2] To date, AEGLs have been published for 10 substances and a further 65 have reached the final consultation stage.
[3] The main source of uncertainty in the development of exposure threshold levels for humans is the paucity of toxicity data. In setting standards for safe levels of exposure to chemicals in, say, food or the workplace, a precautionary approach is used with `uncertainty factors' applied to address issues such as extrapolation from data on animal exposure. However, whilst a certain degree of precaution is appropriate in developing thresholds for use in emergency planning, overly cautious estimates can lead to, for example, inappropriate wide-scale evacuation and poor targeting of resources.
[4] HSE's general approach for determining the toxicological hazard posed by the release of a substance from a Major Hazard site in relation to land-use planning is described in `S. Fairhurst & R.M. Turner, Toxicological Assessments in Relation to Major Hazards, J. Haz. Mat. **33** 215-227

stakeholders are understood to be satisfied with this system, HSE's view is that AETLs are not needed in the UK for land-use planning.

However, in the UK, no acute toxicity thresholds have been developed for use in emergency planning. Additionally, none exist which are recognised at EU level.

Under the COMAH regulations, operators of top-tier establishments are required to prepare and keep up to date on-site emergency plans. They must also supply the necessary information to their local authority, which is required to prepare an off-site emergency plan. The operator's COMAH Safety Report[5] should form part of this supply of information. Both the operator and the local authority must produce written plans. Additionally, there are many activities which could present the risk of a major accident and which may require the preparation of arrangements for dealing with emergencies at either top-tier or lower-tier sites[6].

For toxic releases, operators estimate dispersion distances for various foreseeable events based on the toxicology of the material involved and the extent and severity of likely harm. At present, in order to predict the extent and severity of harm, operators can make use of a wide range of toxicological emergency threshold levels (including US `ERPG's, US `EAGL's and US `IDLH's) or make direct use of experimental toxicity data such as the LC_{50}[7] obtained from safety data sheets or toxicity literature searches. From this information, local authorities determine the area in which appropriate emergency measures might be needed. Inevitably, this leads to a lack of consistency in how emergency planning is dealt with for different sites and different substances.

Our understanding is that the lack of recognised UK or EU acute toxicity thresholds for emergency planning has been an issue for the UK chemical industry. For example, as regards HF Alkylation Units, industry has highlighted to HSE the discrepancy between the availability of an accepted threshold for emergency planning in relation to the environment, and the lack of one in relation to potential harm to people.

(1993)'. The system is also described in the HSE web-site article: http:/www.hse.gov.uk/hid/haztox.htm

[5] For details see `Preparing Safety Reports', HSG190, HSE Books, 1999.

[6] For details of emergency planning under COMAH and other legislation which may apply see `Emergency Planning for Major Accidents', HSG191, HSE Books, 1999.

[7] The LC_{50} for a particular species is the airborne concentration for a specified exposure period that will kill 50% of the exposed population.

Additionally, HSE has a specific role in defining the `Public Information Zone'. This is the area where people are liable to be affected by a major accident. The operator is required to provide appropriate information to people within it. At present the 'Public Information Zone' is taken by HSE to be the `Consultation Zone' (also called the `Outer Zone') determined for land-use planning purposes. HSE has adopted this approach as a pragmatic one in the absence of suitable thresholds for emergency planning. This has the advantages of consistency across different sites and substances and transparency in how it is derived. However, the weaknesses of this approach are recognised.

Again, HF Alkylation Units have been a specific issue, in this context raised by local authority emergency planners regarding a particular UK site. For this site, it has been debated whether setting the public information zone in this way may significantly underestimate the area which should be considered.

HSE therefore considers that EU AETLs could potentially be valuable in the context of emergency planning by:

- improving the quality of the toxicological information upon which it is based; and
- providing toxicity threshold levels which are specifically relevant to the EU and hence UK regulatory framework.

Based on this, specific benefits are that AETLs could potentially:

- provide a basis for a more meaningful Public Information Zone;
- provide toxicity and exposure levels at which harm to off-site populations can be determined relevant to predicted emergencies; and
- promote greater consistency and transparency in how emergency planning is carried out for sites within the UK.

Within the ACUTEX project, HSE is therefore strongly recommending the development of a series of toxicity thresholds for emergency planning covering an appropriate range of exposure times and degree of harm, and developed with a degree of precaution which would be appropriate in a UK (and EU) context.

3. Substance Prioritisation for AETLs Development

As part of the ACUTEX project, the Health and Safety Laboratory (HSL) is working with HSE to develop a methodology and criteria to be used by decision makers to prioritise the selection of substances for which AETLs will be developed following the ACUTEX project[8]. HSL is an agency of HSE.

Whilst this work is at an early stage, we envisage that the methodology is likely to take the form of:

- risk based decisions at Member State Level (including stakeholder consultation as considered appropriate within Member States) to produce prioritised lists; followed by
- decisions at EU level (including stakeholder consultation at EU level as considered appropriate) to produce a final list.

The aim is not to dictate the outcome of these decisions. Rather, it is intended that the methodology should facilitate both the decision making process and its transparency by providing a common, agreed framework.

Additionally, we will be proposing a methodology for selection of the 21 substances for the ACUTEX case studies. The selection itself is to be made by decision makers drawn from the ACUTEX project (including the JRC). The basis will be lists of 10 priority substances (the `Top 10') submitted by Member State Competent Authorities in response to a request by the JRC in November 02. HSE's list has been sent to JRC and is at Annex 1.

3.1 Factors of Importance for Substance Prioritisation

As the first stage of development of the substance prioritisation methodology, HSL is compiling information on 'factors of importance'. Views have been invited from Member State Competent Authorities and major EU stakeholders via the ACUTEX Critical Review Panel. Notably, CEFIC has held a workshop on ACUTEX during which a number of factors of importance were proposed. Our preliminary list of factors is at Annex 2.

[8] This presupposes that an AETLs programme will follow ACUTEX which is not necessarily the case. However, in the event of the EU joining the AEGLs programme, the substance prioritisation methodology could potentially be used for decisions on which substances the EU proposes for inclusion in the programme.

3.2 Development and Validation of Substance Prioritisation Methodology

The methodology development will take into account both the factors of importance and existing approaches to substance prioritisation in other contexts (for example, for EU environmental 'Regulatory Assessment Levels' for Major Hazards).

The draft methodology will be submitted to the ACUTEX Critical Review Panel for comment. In September 03 a validation exercise will be carried out working with three Member State Competent Authorities including HSE. This will take the form of producing prioritised lists for the three Competent Authorities and discussion with JRC (as representing the interests of decision making at EU level).

The work is due for completion in May 04.

4. Views of UK Stakeholders on Substance Prioritisation

The views of UK stakeholders on substance prioritisation are being sought via the Chemical and Pipeline Emergency Planning Liaison Group and the Major Hazards Sub-Committee of the HSC Advisory Committee on Dangerous Substances. It would be particularly helpful to have your views and input at this early stage of the project.

For example:

- do any additional "factors of importance" need to be included;
- what factors are of importance to emergency planners and industry;
- are there any specific substances you consider should be of high priority and if so why.

As part of the validation exercise which begins in September 03, we plan to invite further views from UK stakeholders on the result of the prioritisation of UK substances.

Please send your comments by 1st May 03, or any requests for further information to:

Dr Mary Trainor
Risk Assessment Section
Health and Safety Laboratory,
Broad Lane, Sheffield, S3 7ZL
Email, mary.trainor@hsl.gov.uk

or phone 0114 - 2892909.