

To: Members of the MHSC/ACDS and CAP-EPLG

From: Dr Mary Trainor, Health and Safety Laboratory

Date: 26 January 2004

**FURTHER REQUEST FOR VIEWS OF UK STAKEHOLDERS ON
SUBSTANCE PRIORITISATION FOR THE DEVELOPMENT OF EU ACUTE EXPOSURE TOXICITY
THRESHOLDS (AETLs) IN THE CONTEXT OF THE EU ACUTEX PROJECT**

1. Recommendation

Members of the Major Hazards Sub-Committee of the HSC Advisory Committee on Dangerous Substances (MHSC/ACDS) and of the Chemical and Pipeline Emergency Planning Liaison Group (CAP-EPLG), are invited to note the contents of this memo and send views on UK priority substances to the contact below by 27 February 2004.

2. Stakeholder Feedback Received Following Initial Request for Views

In March 2003 the views of UK stakeholders were sought via the members of the MHSC/ACDS and the CAP-EPLG on substance prioritisation for the development of EU Acute Exposure Toxicity Thresholds (AETLs). The paper was labelled CAP-EPLG 4C 3 April 03 and ACOS/MHSC/INF1/03. A copy is attached. The paper gives the background to the EU ACUTEX project and the development of AETLs.

We received comments from emergency planners, industry and one academic; they are summarised in Annex 1 below. None of the comments suggested specific high priority substances. We are also grateful to SIESO for the opportunity to give a presentation at their summer conference¹.

3. Progress on Substance Prioritisation

We have now completed the prioritisation of 21 substances for use as case studies to develop the AETLs toxicological methodology. Additionally, as part of developing a substance prioritisation approach for any further AETLs development, we have carried out a UK Validation Exercise. In this exercise, priority and high priority substances were identified, subject to UK stakeholder consultation. The attached conference paper summarises this work.

¹ D.Bosworth and M.Trainor (2003) *The EU ACUTEX Project and Substance Prioritisation for the Development of EU Acute Exposure Toxicity Thresholds*, SIESO Conference on Aspects of COMAM 4/5 September 2003.

4. Request for Your Views on UK Priority Substances

The attached spreadsheet gives the list of UK priority and high priority substances subject to UK stakeholder consultation via this memo. The selection approach used is described in Annex 2. We stress that this selection has been made solely for the purposes of the Validation Exercise. In particular, it is in no way linked to the EU decision on whether or not a further AEGLs programme is appropriate, or the UK views on this. These decisions will be informed by the outcome of ACUTEX taking into account issues such as value for money.

5. Action

Please send your views on the priority and high priority substances to the contact below by 27 February 2004.

Contact:

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Annex 1: Summary of UK Stakeholder Feedback Following March 2003 Request.

1) There was a general interest in US AEGLs. We replied to a request for information from CAP-EPLG members and a specific request from emergency planners at one Local Authority.

2) K. Readman on behalf of SIESO

2a) At this stage, SIESO members have strong reservations about the advisability of funding a future AETLs programme. One reason is that there are significant uncertainties in calculating off-site risk for emergency planning purposes, (e.g. size of release, wind direction, dispersion characteristics) of which uncertainty in toxicity thresholds is but one contributor.

Comment: This is a point of fundamental importance. The potential value of a further AETLs programme following the ACUTEX project is being considered by the EU's Major Accidents Hazards Bureau (MAHB) at the Joint Research Centre in discussion with Member State Authorities and major EU stakeholders. An AETLs programme is by no means certain at this stage. Especially important in this decision will be the information the ACUTEX research provides on the appropriateness of US-AEGLs in an EU context.

2b) From an industry perspective, SIESO sees a possible benefit of EU recognised thresholds (whether or not these are AETLs) as potentially facilitating a more consistent approach in the use of toxicological data/thresholds for emergency planning across EU sites.

Comment: this is in line with views expressed by EU Member State Competent Authorities at the May 2001 Workshop on AEGLs hosted by the EU.

3) Fire Service

3a) Ian Fentum.

Mixtures of substances are not in the scope of the ACUTEX project, but are very important for emergency planning.

Comment: An important point. Mixtures are out of scope because of the scientific limitations on what thresholds toxicologists can currently develop. The importance of

mixtures in terms of off-site risk due to the possibility of, for synergistic effects, is recognised.

3b) Dave Beverly.

For emergency responders, issues such as whether suitable PPE exists for the released substance, are particularly important in determining how effective a response can be mounted during an incident.

Comment: The scope of ACUTEX is likely to concentrate on developing thresholds for exposure of the public, not thresholds for emergency responders, although thresholds based on the onset of ill health would inform emergency responders about where to use PPE.

4. R Pullin on behalf of Health Protection Agency.

4a. Above all, it is essential to have a good knowledge of the nature and fate of chemical(s) that could be involved during incidents (local knowledge of chemical industry vital). This is more important than threshold values.

Comment: The Seveso II Directive, through its requirements for notification, safety reports, emergency planning arrangements etc. puts in place a framework for this knowledge. However, the scope of ACUTEX is restricted to development of thresholds.

4b. It is good to have values for guidance purposes, yet these are only really of worth provided that instantaneous data on the quantity of chemical(s) released is obtainable. Due to the nature of chemical incidents, initial data on the concentration(s)/quantity(ies) release is seldom known.

Comment: See 2a above.

4c. The document states that using current threshold values of safe non-harmful exposure to chemicals may result in greater population numbers being evacuated than needed and also poor targeting of resources. However, even though current threshold levels are calculated using uncertainty factors to ensure that a high level of precaution is built in, any new approach should **not** rule out the need for some level of caution.

Comment: Agreed. What is being considered within the ACUTEX project is what degree of precaution is appropriate. For example, issues currently being considered include reviewing the degree of precaution applied when: extrapolating animal data to humans; using Structure Activity Relationships for substances with very limited toxicological data; using chronic data where acute data does not exist; and susceptible individuals.

- 4d. The existence of a number of differing available toxicological data does not make it easy for writing emergency plans due to the inconsistencies in how levels/values have been determined and their inherent limitations. It is all very well in deciding to produce a new data set, yet prior to doing so the following need to be considered:
- (i) how unrealistic are the existing values/guidelines and what will the new guidelines offer in terms of added value (this is not at all clear),
 - (ii) there is already confusion over the difference between existing guidelines, so will a new system add to this or help to end the problem i.e. do not want to generate more data for the sake of it,
 - (iii) the document implies that the US AEGL approach is the best available for emergency planning, if this is the case can a simple correction factor be built in for the required purpose. AEGLs are well established and based upon sound scientific principles, and
 - (iv) surely the use of a new data set would have to be enforced through legislation.

Several hundred have now been determined and are endorsed by many countries. It is not at all clear what the ACUTEX scheme will contribute and we are in danger of duplication of effort and reinventing the wheel.

Comment (i), (ii), (iii) See 2 (a) above.

Comment (iv) Legislation is not being considered. Rather AETLs would be available for use, as appropriate, by Member States. This is essential because some Member States have already developed thresholds. For example the UK has SLOD/SLOTs for land-use planning purposes.

- 4e. The document mentions prioritising chemicals. This is an approach that the European Commission, through its Health Safety Advisory Group has shied away from on the grounds that the large numbers of chemicals used in industrialised countries (over 11 million chemicals have now been described), together with their ubiquitous presence in society, whether on industrial premises, on roads, rail, in air and at sea make the myriad of chemicals that the public might be exposed to almost endless, limiting the usefulness of such prioritised lists.

Comment: Prioritisation would be solely for the purpose of deciding which AETLs to develop first, if a AETLs programme goes ahead. In this respect, it parallels EU substance prioritisation for existing chemicals¹. Similarly, substances have been prioritised in relation to the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic², this convention has been signed by all EU Member States.

- 4f. It is important that the transportation of dangerous chemicals, whether by pipeline, road, rail, sea or air (limited), is not ignored as many incidents requiring the assistance of emergency services occur during such processes. COMAH sites, although potentially extremely dangerous contribute very few chemical incidents per year. Quantitatively, smaller non-regulated sites, such as small factories, commercial premises and agricultural land contribute proportionately far greater incidents, morbidity and mortality. Any useful scheme relating exposure to environmental chemicals to human health effects will therefore need to address chemicals commonly involved in such incidents, such as chlorine, hydrocarbons, mercury etc (National Focus for Chemical Incidents surveillance data, 1997-2003). It is also surprising that in the present climate there is no mention of chemical warfare agents or toxic industrial chemicals (TICs) that could be used in such a capacity.

Comment: Funding for the ACUTEX research project is in the context of the Seveso II directive only. A broader scope for an EU AETL's programme (if there is one) has not been ruled out.

5. R. Mountain, Disaster Management School, Coventry University

Odourless substances may pose specific issues for off-site emergency planning and management.

Comment: Specific suggestions for how to incorporate this in prioritisation would be welcome.

¹ See: van Haelst, A.G. and Hansen, B.G. (2000) *Priority setting for Existing Chemicals: Automated Data Selection Route*. Environ. Tox. And Chem. **19**, 2372-2377.

² See: Provisional Instruction Manual for the Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC). OSPAR Commission 2002.

Annex 2: HSE's Selection of Priority and High Priority Substances Subject to Stakeholder Consultation.

1. The Priority Substances

Within the Validation Exercise for the prioritisation of substances for any further AETLs programme, HSE has proposed a total of 154 priority substances subject to stakeholder consultation. These are all the toxic¹ substances for which HSE has been asked to give advice on land-use planning in the vicinity of Seveso sites. In other words, these are all substances which pose (or have posed) a sufficiently significant off-site risk to have needed consideration when giving land-use planning advice. The list of substances has been taken directly from the list at <http://www.hse.gov.uk/hid/haztox.htm>. This is a publicly available list which gives HSE's land-use planning toxicity threshold (the SLOD/SLOT). These 154 priority substances are given in the attached spreadsheet.

2. The High Priority Substances

Out of these 154 substances HSE has also identified 29 substances which are judged to be of high priority. The high priority substances are listed as P1 on the spreadsheet while the remaining priority substances are listed as P2.

Four of the high priority substances are proposed because they are used in the UK as "exemplar" substances, see table 1. The exemplars are basically "worst case" substances in terms of their toxicity, within the coverage of classification given in table 1.

Substance			Coverage of classification
Name	Formula	CAS No.	
Methyl Chloroformate	C ₂ H ₃ ClO ₂	79-22-1	<i>Very Toxic</i> worst case
Methyl Iodide	CH ₃ I	74-88-4	<i>Toxic</i> high volatility range, worst case
Propionitrile	C ₃ H ₅ N	107-12-0	<i>Toxic</i> medium volatility range, worst case
Ethylene Dibromide	C ₂ H ₄ Br ₂	106-93-4	<i>Toxic</i> low volatility range, worst case

Table 1: The 4 High Priority "Exemplars"

The other 25 high priority substances are those which, in the UK, are considered to be most significant in terms of their potential for off-site harm. This takes into account issues such as population near sites, tonnage and storage type. They were identified on the basis of expert judgement by specialist Major Hazards inspectors. For 24 of the 25 substances this was informed by quantitative studies which HSE had previously carried out for other purposes.

¹ Toxic substances are those within the scope of the Seveso II Directive; that is to say they have "ASL" classification, or self classification as Toxic or Very Toxic. (In a small number of cases self classification has been used where HSE considers that the "ASL" classification is no longer up to date.) Additionally the Named Carcinogens listed in the Directive are within scope.

We also note that in some cases the high priority substances are reaction products of precursor substances. Consideration of the potential for release of these precursors and the number of top tier sites at which they are held, was an important consideration in selecting the high priority substances.