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The AETL methodology as a potential solution to current challenges associated with the development and use of acute exposure levels in Seveso II applications

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Abstract

This paper analyses current trends in the development and use of acute exposure levels in Europe for the implementation of the Seveso II Directive [Council Directive 96/82/EC of December 9, 1996 on the control of major-accident hazards involving dangerous substances. Official Journal of the European Communities, vol. L 10, January 14, 1997, Luxembourg, pp. 13–33]. It also describes a new initiative to develop a European methodology for deriving acute exposure threshold levels that responds to emerging needs in this area. The need for acute exposure values to predict human health effects of potential accidents on exposed populations has burgeoned in recent years. As the driving legislation for managing industrial hazards in Europe, the Seveso II Directive has particularly influenced this trend. Yet at this time it is questionable whether the availability and range of acute exposure values for toxic substances has kept apace with the growing need. Results of a survey of Seveso II competent authorities in the EU-15 revealed that a variety of different types of acute exposure values (AEGLs, EPRGs, etc.) are used for Seveso II applications. Moreover, a comparison of these values indicates gaps in coverage of substances as well as inconsistencies in terms of how health effects and exposure periods are defined for each type. These findings highlight an opportunity for greater collaboration on scientific inputs to application of the Directive in Europe.

The ACUTEX project is an EU-funded research project aimed at furthering scientific exchange and collaboration in support of the development of acute exposure levels for toxic substances in Europe. Its goal is to develop a European methodology for deriving acute exposure threshold levels (AETLs). In particular, it provides the possibility for a common European platform for developing additional acute exposure values to meet emerging needs and cover more chemical substances. To maximise success, the work plan is designed to meet two very important challenges, the need to complement and add value to the existing array of acute exposure methodologies and the necessity of meeting requirements of a diverse range of European stakeholders. As such the project will draw on collaboration among European scientists and process of deliberation among stakeholders to deliver the following key results: (1) to facilitate wide acceptance of the methodology in Europe by both the scientific community and communities of different end-users; (2) to provide greater equivalence and transparency in implementation of the Seveso II Directive across the Member States, specifically through the development of common scientific bases for assessing risks and making risk management decisions related to toxic releases; (3) to produce a methodology that remains open to future collaboration on derivation of acute exposure levels on a European and a global basis.

Keywords: Acute exposure; Emergency response; Emergency planning; Land-use planning; Consequence assessment; Toxic release

1. Introduction

The need for acute exposure values has increased significantly in recent years due to the increasing reliance on various types of quantified risk assessments in the control of major-accident hazards. For example, estimates of acute effects from

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exposure to individual toxic substances are commonly used in risk assessments of hazardous installations in order to evaluate the potential consequences of particular accident scenarios, and more generally to support risk management decisions in relation to the application of appropriate preventive, mitigation and emergency management measures. Similarly, civil protection authorities at various levels of government are more and more seeking to base their emergency preparations, as well as actions in the field,[1] on quantified risk assessments, which also are dependent on estimates of the effects from acute exposure to particular substances.

Moreover, the Council Directive 96/82/EC of 9 December 1996 [1] on the control of major-accident hazards involving dangerous substances (the Seveso II Directive) incorporated a number of innovations directly dependent on the requirement that a full assessment is performed for a hazardous installation. The potential consequences of different scenarios, as estimated within the risk assessment, and in particular in terms of residual risk, are of primary importance in the implementation of provisions within the Directive related to land-use planning (Article 12) and emergency planning (various articles)[2].

The ACUTEX research project aims to develop a European-based methodology for deriving acute exposure threshold levels (AETLs) for use in implementation of the Seveso II Directive. A successful outcome of this project could lead to greater collaboration among various organisations and experts in the European Union for establishing acute exposure levels and developing supporting scientific information. In this way it would help to address concerns about increasing demand for more flexible exposure values, reduce the overall cost of providing this information, while at the same time offering greater consistency in information used across Europe to support risk management decisions.

2. Use of existing acute exposure values for Seveso implementation and types of values used in the EU-15

2.1. Ongoing pressure to increase the accuracy of risk assessments

Notably, risk assessments are used to predict the effects of an accident involving a toxic substance, and in particular, to identify and describe potential zones of impact within the installation and within the surrounding region. These predictions are naturally quite important to the decision-making process. For an installation, the resulting decisions can have a significant impact on the economy of a particular product or company. For land-use planners, such predictions may also have a profound impact on the economy of a particular region. For emergency responders, these decisions may be critical for saving lives and in general maintaining the health of responders and minimising impacts on the surrounding population. Therefore, there continues to be widespread support within the European Union for efforts that aim to improve the predictive capabilities of these analyses, including the underlying methodologies, data and parameters they use. Acute exposure values, represent one of these important parameters.[3]

With respect to acute exposure values, the desire for improved predictive capabilities is not only a question of having more data and improving interpolation methods; these challenges continue to be ongoing and important. However, for many competent authorities, it is also a question of having the possibility to match more precisely acute exposure values to particular accident scenarios and planning needs. For example, in a crisis involving a toxic release, emergency responders need to make decisions on a number of contingencies, including the concentration and duration of exposure to the substance or substances released. Estimates about the acute effects of exposure from release of a toxic chemical at a particular point in time can help to structure community evacuation plans, to ensure proper protective equipment, determine when to administer first aid, or when more serious medical attention will be required, and other actions in an emergency. As such, it has been argued that a variety of limits for each substance should be produced, covering effects ranging from odour to death, and time periods of less than 5 min to 2, 4, even 8 h. The call for a wider range of acute exposure values corresponding to a wider range of decision-making needs has been echoed by a number of competent authorities as well as the industry over the last several years [3–6].

2.2. Exposure values currently applied to support Seveso implementation within the Member States

In a recent survey conducted by the Major-Accident Hazards Bureau (MAHB), Member State competent authorities indicated that several "types" of acute exposure values are officially accepted for use in land-use and emergency planning to support regulatory requirements of the Seveso II Directive in their countries. Table 1 shows the variety of acute exposure limit regimes in use in Member States, according to this survey. The table represents the collective range of acute exposure levels used within the EU-15,[4] meaning that these Member States by and large use a subset of one or more of these types of values and no one of the EU-15 is using all nine of them. Various sources indicate that industry also uses a similar range of the exposure value types

[1] This paper uses the term "risk assessment" to include not only the formal methods of risk assessment that are in place for prevention, mitigation and land-use planning purposes, but also "rapid risk assessments" that support decisions that emergency responders are obliged to take on-the-spot in the event of a major incident.

[2] Several articles within the Directive contain emergency planning requirements, including Article 8 (domino effects), Article 10 (internal emergency planning in the context of safety reports) and Article 11 (external emergency plans).

[3] In a recent study, Tixier et al. [2] identified 62 different methodologies that have been applied over the past decade for performing risk analysis on an industrial plants, 16 of which required input regarding toxic properties.

[4] The EU-15 refers to the composition of the European Union prior to the enlargement of 1 May 2004. These countries are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom.

Table 1
Types of acute exposure values/methodologies currently in use in different EU competent authorities for land-use and emergency planning[a]

Acute exposure guideline levels (*AEGL*), developed by the U.S. National Advisory Committee on AEGLs (NAC/AEGLs), managed by the U.S. EPA. According to the Standard Operating Procedures for Developing Acute Exposure Guideline Levels (AEGLs) for Hazardous Chemicals, AEGLs are guideline levels for once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals [12]

Dangerous toxic load (*DTL*), developed by the U.K. Health and Safety Executive. The Dangerous Toxic Load (DTL) describes the exposure conditions, in terms of airborne concentration and duration of exposure, which would produce a particular level of toxicity in the general population HSE has defined SLOT (specified level of toxicity) DTLs and SLOD (significant likelihood of death) DTLs. No exposure duration period, but rather a probit function for a concentration for a specified time range and endpoint

Emergency Exposure Indices (*EEI*), developed by ECETOC. The EEE (t_1) is defined as "that airborne concentration for exposures lasting up to a specified exposure time (t_1) below which direct toxic effects are unlikely to lead to discomfort in the exposed population (including susceptible but excluding hypersusceptible groups) and above which, as the concentration increases, discomfort would become increasingly more common" and EEI (t_x) and EEI (t_e) for disability and death/permanent incapacity, respectively, are defined similarly [17]

Emergency response planning guidelines (*ERPG*), developed by the American Industrial Hygiene Association (AIHA). The emergency response planning guideline (EPRG) values are intended to provide estimates of concentration ranges above which one could reasonably anticipate observing adverse effects as defined according to the different threshold levels (EPRG-1, -2, and -3) [18]

Immediately dangerous to life and health (*IDLH*), developed by the U.S. National Institute of Occupational Safety and Health (NIOSH). These values represent a situation that poses a threat of exposure to airborne contaminants when that exposure is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from such an environment [19]

Intervention values for dangerous substances, developed by the Dutch Ministry of Housing, Spatial Planning and the Environment, are tiered thresholds representing concentrations of substances above which health effects can occur as defined in each tier, as follow the "instruction guidance value" (VRW), "alarm boundary values" (AGW) and "life threatening values" (LBW) [20]

SEI and SEL (*Threshold of Lethal Effects and Threshold of Irreversible Effects*), developed by the French Ministry of Environment, INERIS, INRS, IPSN, University Hospitals, and Industry. The "irreversible effects threshold" (SEI) and the "lethal effects threshold" (SEL) were developed to represent acute effect thresholds in the event of an accidental release into the atmosphere from an industrial site. These thresholds are used to calculate the distance over which effects occur and these distances are taken into account in controlling urban development around Seveso installations [21]

Temporary emergency exposure levels (*TEEL*), developed by the U.S. Department of Energy (DOE). Temporary emergency exposure limits (TEELs) were developed by the U.S. DOE to help with emergency planning at DOE sites when EPRGs are not available. Once an EPRG is assigned a chemical, the EPRG replaces the TEEL. The TEEL programme uses occupational exposure limits to derive TEELs [22]

Lethal concentration limits (LC_n). In common use in a number of different competent authorities and industry. The exposure concentration of a toxicant lethal to *n*% of a test population based on a dose–response curve

[a] The list represents values that have been specifically identified by Member State competent authorities (in Austria, Belgium, France, Germany, Italy, The Netherlands, Spain, and the United Kingdom) as values that they have applied within certain Seveso-related programme areas.

depicted in Table 1. (The private sector was not included in this survey.)

Some competent authorities have noted that they may use one type or types of values for certain policy decisions and another subset of values for other types of policy decisions. For emergency planning, the majority of Member States apply values that have already been produced by various methodologies, primarily of U.S. origin (AEGLs, EPRGs, IDLHs and TEELs). Some competent authorities, both at the national and regional level, have created their own methodologies and these can also be closely linked to methodologies described in Table 1.

In addition, many Member States use acute exposure values to support the decision-making process for implementing land-use planning requirements under Seveso II. As noted in [7], competent authorities may rely on a number of the existing threshold levels described in Table 1 or on thresholds derived directly from dose–response curves. On the other hand, France and the United Kingdom have developed their own methodologies for producing acute exposure values for use in land-use planning decisions associated with Seveso installations. These estimates of acute exposure effects are applied to define populations and areas of vulnerability in a way that helps determine particular land development scenarios and options around existing or future hazardous sites. In fact, these nationally-sponsored values are integral to current land-use planning policy in both France and the United Kingdom and are embedded in the decision-making process.

2.3. Challenges associated with use of existing acute exposure values in Seveso implementation

There are a large number of substances that have not been assigned any acute toxic threshold under any acute exposure value regime (except for perhaps TEEL). Whether there is a need for acute exposure levels for a substance depends very much on the quantity in use along with its potential for exposure. These factors can vary significantly among substances and the question

for Seveso end-users is whether acute exposure levels have been developed for the subset of substances that are of highest priority in Seveso applications. Nonetheless, there is some consensus that availability of acute exposure levels for the highest priority Seveso substances is far from complete [4].

In addition, where values do exist for particular substances, competent authorities are increasingly concerned about the use of different values for different risk assessments, that is, according to whatever kind of value (e.g., TEEL, EPRG) is available for the substance in question. This practice naturally leads to inconsistencies because of the inherent differences between the way different types of values are defined and structured. It brings into question the reliability and consistency of results produced by risk assessments associated with potential toxic releases as well as the decisions in which their results are used. Table 2 illustrates the breadth of inconsistency that exists between the different exposure level regimes identified in Table 1 in terms of exposure periods and health effects that are targeted by each value. For example, TEELs or IDLHs are often used as parameters in risk assessments when an AEGL or an EPRG are not available for a particular substance. TEELs, IDLHs and EPRGS each offer only one exposure period, each of which is calculated on the basis of a different duration (15, 30 and 60 min, respectively). Concentrations producing specific effects can be much higher at short intervals than longer intervals and using threshold values for different exposure periods of the same chemical will produce substantially different outcomes in terms of estimating the size of a potential impact zone. Moreover, it is difficult to be certain whether procedures for deriving different types of values, for example, EPRGs versus AEGLs, would have reached the same conclusions concerning classification of specific health effects and interpretation of data. Other important distinctions between different methodologies, such as representative populations, data sources, and uncertainty factors, are not shown here but these have equal influence in creating disparities between the different types of values and the level of certainty with which they can be applied in particular situations.

For land-use planning these factors are further complicated by the political and financial costs that the land-use planning requirement of the Seveso II Directive could impose on particular hazardous establishments or local communities. In fact, the disparity in approaches and methodologies across Member States to support land-use planning decisions under Seveso II has been a central topic of discussion within the European Union for some time. These differences are perceived as hindering efforts to make land-use planning around Seveso plants a transparent and understandable process to stakeholders. While it is understood that land-use policy, land-use decision-making processes and their outcomes should be at the discretion of individual competent authorities, and that these differences should necessarily remain, there has been growing support for efforts to reduce disparities in the technical underpinnings of land-use planning decisions (reference scenarios, accident frequency and consequence estimates, treatment of uncertainties, and other data sources and parameters). Already some European-funded projects had been funded in the Fifth Framework Programme to support greater harmonisation in underlying principles (such as

Table 2
Health effects and exposure durations targeted by threshold levels[a] of acute exposure levels used in the EU

Health effect/duration of exposure	1 min	10 min	15 min	20 min	30 min	1 h	4 h	8 h	Probit
No appreciable risk of health effects, not likely to suffer discomfort			EEI-1, TEEL-0		EEI-1	EEI-1			
Objectionable odour			TEEL-1			EPRG-1, VRW			
Mild effects, discomfort, irritation		AEGL-1	EEI-2, TEEL-1		AEGL-1, EEI-2	AEGL-1, EPRG-1, EEI-2, VRW	AEGL-1	AEGL-1	
Likely to suffer severe distress									SLOD
Medical attention required									SLOD
Impairment of an individual's ability to take protective action or escape		AEGL-2	TEEL-2		IDLH, AEGL-2	AEGL-2, EPRG-2	AEGL-2	AEGL-2	
Serious health effects, serious injury requiring prolonged treatment		AEGL-2	TEEL-2		AEGL-2	AEGL-2, EPRG-2, AGW	AEGL-2	AEGL-2	SLOD
Permanent incapacity		EEI-3			EEI-3	EEI-3			
Immediate or delayed permanent adverse health effects, irreversible health effects	SEI	SEI, AEGL-2	TEEL-2	SEI	SEI, AEGL-2	SEI, AEGL-2, EPRG-2, AGW	AEGL-2	AEGL-2	
Life-threatening effects		AEGL-3	TEEL-3		AEGL-3	AEGL-3, EPRG-3, LBW	AEGL-3	AEGL-3	
Likely to cause death, lethal effects	SEL	SEL, EEI-3		SEL	IDLH, SEL, EEI-3	SEL, EEI-3, LBW			SLOT

[a] Threshold levels represent, in some cases (EEIs), the concentration below which (EEIs) the health effect is not expected to occur and in other cases (e.g., EPRGs, AEGLs, SEIs, SELs) they represent the concentration above which the health effects in question may be experienced.

LUPACS [8]) and scientific bases (e.g., ASSURANCE [9]) for land-use planning decisions under Seveso.

3. Development of new acute exposure levels and the ACUTEX project

3.1. Roots of European efforts to develop acute exposure levels

Up until recently, efforts to produce new methodologies and launch new initiatives to produce acute exposure levels within the Member States, where they exist, have been fragmented. Individual Member States (France, The Netherlands and the United Kingdom, for example) have produced their own methodologies, as indicated in Table 1. The research consortium of the European chemical industry, ECETOC, also has produced a methodology. However, producing one's own acute exposure values requires a significant commitment of resources, starting with the process of developing an accepted methodology, followed by the expense and time required for developing acute exposure limits for each substance.

Since the late 1990s, the growing pressure to have more flexible levels covering more substances has gradually increased support within Europe for collaborative actions in regard to the development of acute exposure levels. One benefit of collaboration would be the pooling of resources that could potentially increase the number of substances that could be assigned acute exposure limits in a shorter period of time. At the same time, such collaboration could contribute to overall consistency and transparency concerning the types of acute exposure levels being used, at least among collaborating partners.

As it happened, a U.S. initiative served as a catalyst to concrete discussions about the European collaboration on development of acute exposure levels, which eventually resulted in the launching of the ACUTEX project. During the period that support for collaboration was increasing in Europe, U.S. policymakers introduced an initiative to "internationalise" its AEGLs programme in the context of OECD. The AEGLs programme was originally conceived to address concerns of U.S. competent authorities and other stakeholders about the availability, reliability and range of acute exposure levels for use in making risk management decisions for emergency planning [10,11], concerns that closely mirrored those of their European counterparts. Established in 1995, the programme was designed to produce a broader range of exposure limits for each substance than any other existing methodology, envisioning three health-effect endpoints and five exposure periods extending from 10 min to 8 h.[5] Moreover, the programme takes advantage of broad-based stakeholder involvement to gains access to the widest possible set of relevant data and improve the acceptability of the end values by a broad-based scientific community.[6]

At a workshop held at the European Commission's Joint Research Centre in Ispra, Italy in 2001, in response to this initiative, participants confirmed that European Member States had a common interest in and commitment to promoting greater access and availability of acute exposure levels. For the first time, the possibility of European collaboration on the production of acute exposure levels was introduced. The consensus was largely driven by the two over-riding perceptions described previously in this paper: (a) that current exposure levels were inadequate to cope with the expanded scope of risk management decisions related to hazardous installations (e.g., due to limited coverage of substances and health effects in relation to duration of exposure) and (b) that inconsistencies in data sets and methodologies used to produce acute exposure values contributed to the inconsistency and uncertainty surrounding results of risk assessments.

However, at the same time, it became clear that, prior to any EU-level decision to participate in an international effort to produce acute exposure levels, European collaboration and information exchange on acute exposure levels would need to be more actively promoted and strengthened. In particular, the workshop highlighted strong differences in priorities and perspectives between European end-users, as defined by Member States as well as by different types of end-users (e.g., emergency planners, land-use planners, industrial safety experts). Therefore, any strengthening of European collaboration in this area would have to include, as a key process element, consensus-building among a broad range of end-users in regard to the definition and derivation of acute exposure values and substances that should be targeted. The achievements of the AEGLs project were also acknowledged as widely respected within the EU and it was understood that they should be taken into account in future collaborations.

In late 2001 efforts to harmonise land-use planning along technical lines gained added importance. Following the catastrophic incident on 21 September 2001 at the Grande Paroisse site in Toulouse, France, enhanced technical harmonisation in the field of industrial risk assessment was identified by stakeholders as a high priority.[7] Acute exposure threshold levels for

[5] The AEGLs methodology, incorporating both scientific and consensus processes for producing the exposure levels, is described comprehensively within the Standard Operating Procedures developed by the U.S. National Research Council (NRC) and approved by the NAC/AEGL committee [12].

[6] This pooling of resources was also intended to help accelerate the pace of values development, thereby allowing coverage of more substances over a shorter time frame. It was expected that the programme would be regularly producing final AEGL values for approximately 40 chemicals each year starting in 2003. The programme established an initial goal of developing acute exposure levels for approximately 400–500 acutely hazardous substances over the ensuing 10 years. The committee's first efforts focused on AEGLs development for a little over 100 chemicals, and selection of additional chemicals for study was nearing completion in 2003. As of August 2005, AEGLs for 24 substances have already been finalised and published, with several more in the final stages of the process [13].

[7] The European Expert Group on Land-Use Planning under Seveso II identified five objectives for achieving a common platform for implementing Article 12 of the Directive, including the development of a common technical database of scenarios and data for use in risk/hazard assessment approaches underlying land-use planning decisions [16].

toxic substances were considered an important risk-related measure in this context.

3.2. The ACUTEX project: development of a methodology for European acute exposure threshold levels (AETLs)

Against this background the European-funded research project, ACUTEX, was conceived. It was primarily considered that such a project could strengthen European collaboration in derivation of acute exposure levels and, if successful, could entail significant benefits to the scientific and regulatory communities in Europe and internationally. The ACUTEX project, a 3-year project finishing at the end of 2005, aims to develop a methodology for establishing European Acute Exposure Threshold Levels (AETLs) [14]. The project represents a collaboration of nine scientific partners from government, industry and academia in Europe and results will also be critiqued by a Critical Review Panel of additional stakeholder representatives. The end result is intended to be a technical guidance document that will describe a methodology that may be used to derive acute exposure levels for European applications.

The project is charged with weaving together a number of important expectations for the methodology. The collaboration between European toxicologists of varying backgrounds and nationality supports the expectation that the methodology is a step forward towards establishment of a uniform and accepted basis for evaluating data for acute exposure levels in Europe. The methodology is also expected to take advantage of best practices established in existing methodologies, while incorporating new techniques for chemical risk assessment. A number of innovations are targeted to address particular needs of European end-users as well as enhance transparency of the scientific process.

Notably, the methodology will aim to meet the needs of end-users in the scientific community, responsible for implementing the methodology to develop new levels, and also the needs of end-users within the competent authorities and industrial installations, who may apply the AETLs in decisions concerning industrial risk. The project incorporates a Critical Review Panel, consisting of representatives from both policy and research organisations within government, industry and academia, to review project developments and interim deliverables. In this way, the project allows early and frequent exchange of perspectives and information from relevant stakeholders to facilitate the necessary consensus building on the scientific bases and larger policy objectives of the methodology.

Innovative elements of the AETL methodology will include an expanded range of threshold values and a number of measures intended to make application of the methodology, such as how supporting data are evaluated and applied, more consistent and transparent. For example, the methodology introduces a matrix approach for identifying and categorising health effects. Making use of both kinetic and dynamic properties of toxic substances, the matrix will enable more precise definition of the degree of susceptibility that is to be expected in special subpopulations. Rules for addressing data uncertainties and for applying threshold levels to sensitive sub-populations will also be recommended. These measures have been conceived as a means to make the technical work behind the development of specific values more accessible to other interested scientists and acute exposure programmes, providing a means of data exchange and also maintaining a potential opening for future collaboration.

Another important project deliverable is a priority-setting procedure that would assist stakeholders collaborating on the development of AETLs in future to prioritise and select substances to undergo the AETLs process. Completed in the first half of this project, the results of this effort are already available and described in [15].

The project will validate and improve the new approaches by cases studies, with contributions from end-users and stakeholders. To achieve this objective, the methodology will be applied to 21 different substances, termed “case studies, which have been specifically selected to represent a diversity of characteristics, e.g., causing different kinds of health effects, or effecting exposure through different pathways. (The selection process and substances selected are also described in [15].) In this way, the case studies will be designed to challenge the methodology in order to identify where certain aspects needed to be strengthened and to observe particular sensitivities that should be taken into account in subsequent applications of the methodology. The results of these case studies will then be used to confirm the functionality of the methodology and to refine certain aspects as necessary. For further validation and improvement these results will be discussed with end-users taking part in the Critical Review Panel and also within stakeholder workshops to be held over the course of the project.

4. Challenges faced by the ACUTEX project in meeting end-user needs

4.1. Defining values that are compatible with science and the diverse needs of end users

In its landmark research, the U.S. NRC defined the art of setting exposure levels as “protecting the integrity of the [chemical] risk assessment, while building more productive linkages to make [chemical] risk assessment more accurate and relevant to risk management” [11]. Early in the project the ACUTEX partners, supported by a majority of stakeholders, rejected an approach that targeted specific policy decisions, in particular, land-use and emergency planning. The ACUTEX partners sustained that, from the scientist’s perspective, technically sound values can only be derived on the basis of clear scientific parameters, for example, specific health effects or dose–response relationships, rather than particular decision-making scenarios. Given the variety of approaches to managing risk in Europe, the strict assignment of particular values to particular types of decisions could limit the use of such values in risk management policy decisions. Nonetheless, it was recognised that the methodology needed to address the practical decision-making needs in some manner to ensure the production of genuinely useful values for real-world Seveso applications. Therefore, the project envisions a methodology in which individual acute exposure thresholds are defined in

the context of a range of policy needs, rather than any one specific scenario or group of scenarios. Moreover, the project will consider that the inclusion of precise and transparent information on health effects of each substance could also assist end-users in appropriate application of the values for particular situations.

4.2. Working towards European and then global harmonisation

The ACUTEX project originated with the proposal that the member countries of OECD could join forces with the U. S. in the production of acute exposure values in these regions. There were compelling arguments both for and against participating in the U.S. AEGLs programme, or using the AEGLs methodology, and debate in Europe over this question is ongoing. However, while harmonisation with the U.S. AEGLs programme may offer some desirable outcomes for Europe, it seems apparent that Europe must first achieve an internal agreement within its own borders concerning methods for developing acute exposure values.

Moreover, if ACUTEX were to be reasonably successful in obtaining acceptance for the AETL methodology in Europe, then what might be the future of harmonisation in this area? Given the diversity of opinion that such a consensus would need to satisfy in Europe, it is perhaps unrealistic to expect the methodology could develop into an exact replica of the AEGLs methodology, or into an exact replica of any other methodology applied in Europe, such as SEIs/SELs, EEIs, EPRGs or TEELs. Nonetheless, the project will take into consideration the key elements of the dominant methodologies applied in Europe. In the event that resolution of important differences is not possible within the project, it will aim to leave the door as wide open as possible for future resolution.

If, in the end there are differences between AETLs and other methodologies, the real question concerns whether these differences will pose an obstacle to the interchangeability of values between different development programmes in Europe and the U.S., to the exchange of data and analysis, or to multi-national collaboration on values development. It is hoped that transparency in the development of the AETLs methodology will enable scientists and end-users, both in Europe and abroad, to understand and overcome any obstacle of this type. If such an open attitude is sustained, there is a real possibility that the values will become broadly useful within the global community of end-users. In this way, they would represent a significant net contribution to the existing pool of values already available.

In any event, it has often been stated that long-term international co-operation in scientific research related to policy matters is most often achieved progressively. There is reason to hope that the mutual exchange and open dialogue on acute exposure levels within ACUTEX project could encourage some bilateral or multilateral activity among European Member States in this area, and perhaps some day pave the way for convergence of acute exposure values and stronger collaboration on their development in an international context.

5. Conclusion

The selection and use of acute exposure values for Seveso II implementation varies widely within Europe and implies that there is an opportunity for future collaboration to produce more values for more substances and improve consistency in parameters used in generating risk assessments of major industrial hazards. The ACUTEX project is designed to develop an advanced approach to defining acute toxic levels for use in risk assessments conducted in the context of the Directive, particularly in regard to emergency planning and land-use planning. Specifically, the methodology will allow creation of scientific findings and exposure threshold levels that is intended to be useful to a broad range of European scientists and policymakers engaged in work where definition of the acute effects of toxic substances is required. Moreover, the methodology is intended to serve as a platform for collaborative efforts in producing acute exposure levels for chemicals among European organisations as well as on an international basis. In fulfilling these goals, it is hoped that the project will play an important role in improving the science behind development of acute exposure levels and in the technical harmonisation of industrial risk assessment in Europe and beyond.

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