



Survey on methodologies in the risk assessment of chemical exposures in emergency response situations in Europe

Milla Heinälä^a, Ursula Gundert-Remy^b, Maureen Heraty Wood^c, Marc Ruijten^d, Peter M.J. Bos^e, Antti Zitting^a, Sarah Bull^f, David Russell^f, Elsa Nielsen^g, Gudrun Cassel^h, Per Leffler^h, Sylvie Tissotⁱ, Jean-Martin Vincentⁱ, Tiina Santonen^{a,*}

^a Finnish Institute of Occupational Health (FIOH), Topeliuksenkatu 41aA, 00250 Helsinki, Finland

^b Bundesinstitut für Risikobewertungen (BfR), Thielallee 88-92, 14195 Berlin, Germany

^c Commission of the European Communities-Directorate General Joint Research Centre, Rue de la Loi 200, 1049 Brussels, Belgium

^d CrisisTox Consult, Albrechtsveld 106, 2804 WG Gouda, The Netherlands

^e National Institute for Public Health and the Environment (RIVM), Antonie van Leeuwenhoeklaan 9, 3721 MA Bilthoven, The Netherlands

^f UK Health Protection Agency (UK HPA), Centre for Radiation Chemical and Environmental Hazards, OX11 0RQ Chilton, Near Didcot, UK

^g Technical University of Denmark (DTU), Anker Engeldsvej 101A, DK-2800 Kgs. Lyngby, Denmark

^h Swedish Defence Research Agency (FOI), Cementvägen 20, S-90182, Umeå, Sweden

ⁱ Institut National de l'Environnement Industriel et des Risques (INERIS), Parc ALATA, 60550 Verneuil-an-Halatte, France

HIGHLIGHTS

- ▶ There is variation in risk assessment practice of acute chemical releases in Europe.
- ▶ Training especially on the application of acute exposure reference values is needed.
- ▶ Release of toxic and irritating/corrosive chemicals are perceived as a serious risk.
- ▶ Globalisation and high productivity demands are potential future risk drivers.

ARTICLE INFO

Article history:

Received 1 August 2012

Received in revised form 19 October 2012

Accepted 20 October 2012

Available online 5 November 2012

Keywords:

Chemical incidents

Health risk assessment

Acute exposure reference values

Survey

ABSTRACT

A scientifically sound assessment of the risk to human health resulting from acute chemical releases is the cornerstone for chemical incident prevention, preparedness and response. Although the general methodology to identify acute toxicity of chemicals has not substantially changed in the last decades, there is ongoing debate on the current approaches for human health risk assessment in scenarios involving acute chemical releases.

A survey was conducted to identify: (1) the most important present and potential future chemical incident scenarios and anticipated changes in chemical incidents or their management; (2) information, tools and guidance used in different countries to assess health risks from acute chemical releases; and (3) needs for new information, tools, guidance and expertise to enable the valid and rapid health risk assessment of acute chemical exposures.

According to the results, there is an obvious variability in risk assessment practices within Europe. The multiplicity of acute exposure reference values appears to result in variable practices. There is a need for training especially on the practical application of acute exposure reference values. Although acutely toxic and irritating/corrosive chemicals will remain serious risks also in future the development of plausible scenarios for potential emerging risks is also needed. This includes risks from new mixtures and chemicals (e.g. nanoparticles).

© 2012 Elsevier B.V. All rights reserved.

Abbreviations: ACUTEX, ACUTE Exposure (an EU project in 2002–2005); AEGL, acute exposure guideline level; AERV, acute exposure reference value; AETL, acute exposure threshold levels; CLP, regulation on classification, labelling and packing of substances and mixtures; ERPG, emergency response planning guideline; IDLH, immediately dangerous to life and health limit; QSAR, quantitative structure–activity relationship; REACH, regulation on registration, evaluation, authorisation and restriction of chemicals; SCAPA, subcommittee on consequence assessment and protective actions; STEL, short term occupational exposure limit value for 15 min; TEEL, temporary emergency exposure limit.

* Corresponding author. Tel.: +358 304742666; fax: +358 30472110.

E-mail address: tiina.santonen@ttl.fi (T. Santonen).

1. Introduction

Public health management of acute chemical incidents is based on the knowledge of health risks arising from short term, high level exposure, which enables the assessment of public health consequences and the needs for evacuation and other protective measures. This is a special situation that is not covered in most other existing risk assessment schemes such as Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [1] or, for example, the approval of new pesticides or biocides for access to the market. These schemes are focused on the risks of chemicals from their normal use and handling and do not take into account short term high level exposures due to, for example, accidents or incorrect use. Therefore the related methodologies are mostly focused on subacute to chronic exposure and are aimed to identify the levels at which no harm is likely to result from exposure.

The methodology to identify acute toxicity of chemicals has not substantially changed in the last decades. However, there is ongoing debate regarding the current approaches for human health risk assessment in scenarios involving acute chemical releases. One question concerns identification of the most relevant substances that should be considered in acute chemical incident scenarios. Secondly, there is an issue concerning the types of health effects that should be included in such an assessment. As individual assessments performed by different authorities or organisations may result in different conclusions (that can all be scientifically justified) there may be a need for further co-operation and harmonisation of approaches for risk assessment of acute chemical releases and for deriving chemical specific guidance values applicable for acute chemical release scenarios. A harmonized and consistent response is especially important in case of transboundary incidents to mitigate consequences.

In addition to the concern over accidental chemical releases, there is growing awareness about potential deliberate exposure stemming from the release of a dangerous substance through an intentional act of violence, terrorism or sabotage. In addition to classical chemical weapons, commonly used industrial chemicals have been suggested as possible threats in scenarios involving deliberate releases of chemicals [2,3]. As another new area of concern, potential acute health effects due to chemical releases associated with new technologies, for example, nanotechnology and current or future trends engendered by nature or society, such as climate change and globalisation, are issues that also should be considered.

Acutely toxic or corrosive chemicals, such as hydrogen cyanide, chlorine or hydrogen sulphide, are usually well recognised in acute exposure risk assessment schemes. However, concerns have been raised about other toxic effects, for example, carcinogenic or reprotoxic effects of chemicals after single, incidental exposure (e.g. “one-shot carcinogenicity” [4]). Carcinogenic and reprotoxic effects are typically studied in repeated dose toxicity studies and there is, at present, no clear methodology for the extrapolation from those studies to single, peak exposures lasting only days or even hours. However, since the risk cannot be excluded, there should be a method to assess, for instance, the cancer risk caused by a single, peak exposure to a carcinogenic substance [4,5].

Acute exposure reference values (AERVs) are used to express the likelihood of adverse health effects following the exposure to a particular substance. During chemical incidents these values are applied to models, e.g. atmospheric dispersion models, to predict consequences in a certain area or to estimate evacuation distances to enable rapid decision making in such emergency situations.

Reference values applied for food, consumer products or to the workplace define exposure levels at which no harm is likely to result from exposure i.e. are protective values. In contrast,

AERVs, define predictive exposure levels for different degrees of health impairment, on a continuum from exposure levels without an expected health effect to those with an anticipated degree of harm or where lethal effects are to be expected. There are at present several AERVs in use in Europe [6]. The two most frequently used values are *Acute Exposure Guideline Levels (AEGL)* [7–9] developed by the U.S. National Advisory Committee for the Development of Acute Exposure Guideline Levels for Hazardous Substances (AEGLC Committee), which is managed by U.S. Environmental Protection Agency (U.S. EPA), and *Emergency Response Planning Guidelines (ERPG)* [10] developed by the American Industrial Hygiene Association (AIHA). Other values include *Temporary Emergency Exposure Limit (TEEL)* [11–13] values developed by Subcommittee on Consequence Assessment and Protective Actions (SCAPA) and *Immediately Dangerous to Life and Health limit (IDLH)* [14] values defined by the U.S. National Institute of Occupational Safety and Health (NIOSH). In addition, there are national values available in some European countries, for example in the Netherlands (*Intervention Values for Dangerous Substances*) [15] and France (*SEI and SEL; Threshold of Lethal Effects and Threshold of Irreversible Effects*) [16].

In recent years, there have been some efforts to promote greater co-operation and harmonisation within Europe. EU-funded ACUTEX project (2002–2005) aimed to develop an European methodology for producing Acute Exposure Threshold Levels (AETL) [6]. The project took advantage of best practices established in existing methodologies, and incorporated new techniques to address particular needs of European end-users. This project was beneficial in moving Europe closer towards adopting some common principles for developing exposure levels, but full co-operation and harmonisation of procedures for the development of AERVs is still an unmet need in Europe.

For these reasons, a study was launched to explore the current practices, needs and developments of the risk assessment of acute chemical releases in EU. The specific aims of the study were to identify:

- 1) the most important present and potential future chemical incident scenarios and anticipated changes in chemical incidents or their management;
- 2) information, tools and guidance used in different countries to assess health risks from acute chemical releases; and
- 3) needs for new information, tools, guidance and expertise to enable the valid and rapid health risk assessment of acute chemical exposures.

This study was conducted as a part of the EU FP7 funded project iNTeg-Risk (Early Recognition, Monitoring and Integrated Management of Emerging, New Technology related, Risks).

2. Methods

2.1. Questionnaire design

A web-based questionnaire was chosen as being the most efficient method to conduct the study. The draft questionnaire was developed by the Finnish Institute of Occupational Health in collaboration with eight other institutes from seven different European countries. The survey consisted of 37 questions that included both open and multiple choice questions, many with scaled answers. The same scales were used on each question as far as possible, and an ‘I don’t know’ option was included in most questions. Respondents also had the opportunity to add additional comments for each question.

The first section was composed of six questions and aimed to provide information on the most important chemical incident scenarios and the anticipated changes in chemical incidents or their management. This section focused on the identification of substances considered to pose the most serious risk due to accidental or deliberate releases, on the influence of recent developments such as nanotechnology, globalisation or climate change or terrorism on the risk of chemical incidents, and on the influence of certain legislative actions (for example REACH) on the management of acute chemical incidents.

The second section consisted of eleven questions related to current risk assessment practises presently in use in different countries. More specifically, they included questions on the use of different AERVs, the importance of these values, their ease of use, appropriateness of the available time frames, and appropriateness of the health effects addressed. Questions also related to additional information sources, air dispersion modelling and the use of portable measuring devices in health risk assessment during acute chemical incidents were included.

The last section focused on the needs for additional guidance e.g. on the assessment of the risk of different long term health effects or risks caused by chemical mixtures, new modelling tools e.g. atmospheric dispersion modelling, read-across, dose-response modelling or training.

2.2. Target population

The target population consisted of professionals working in chemical risk assessment and emergency prevention, planning, preparedness and response at different levels of responsibility, i.e. policy makers involved in developing policies and regulations governing the safe use of chemicals and incident prevention, planning and response, scientists involved in the development of tools, practices or guidelines for risk assessment of chemical incidents and end-users of these tools, practices or guidelines.

As we aimed at gathering pan-European information, professionals from as many European countries as possible were invited to participate. The survey was disseminated in 24 countries including Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, The Netherlands, and UK. In addition to national institutes in the respective countries, questionnaires were sent to intergovernmental organisations such as the World Health Organisation (WHO).

2.3. Survey dissemination

Currently, the responsible bodies and institutes for chemical incident management vary greatly in the different European countries. This made it difficult to identify the relevant contact persons to target for the survey. Project partners are most familiar with the structure and contacts within their own country, and often also with that of their neighbouring country or otherwise related country. Therefore, each project partner provided contact data for professionals in each of the three defined target groups (policy makers, scientists, end-users) for their own country, as well as for their neighbouring or otherwise assigned country.

A survey tool designed for the iNTeg-Risk project was used to construct the survey. To disseminate the survey, a link to the survey was sent via e-mail with a covering letter. A total of 210 surveys were sent to persons in 23 countries. The number of surveys disseminated does not include Germany, where a different strategy was utilised. In Germany, the data protection law precludes exchange of mailing lists. Therefore the survey was sent to institutions involved in chemical incident management, which forwarded

the invitation according to their mailing lists. Hence, the exact number of questionnaires distributed in Germany is not exactly known but as 15 institutions have been approached the number of questionnaires distributed is likely to be more than 30. The survey was disseminated in December 2009. The last responses were received in summer 2010.

2.4. Analysis of the responses

Descriptive analyses were carried out on the data collected. The survey was originally intended to provide a detailed analysis per target group, in addition to responses as a whole. However this objective proved difficult to achieve since the survey responses demonstrated that the groups are not mutually exclusive. In particular, some respondents had more than one role and acted both as (for instance) end-user and policy maker, or scientist and end-user. Hence, it was not possible to identify from which point of view these respondents completed the survey. For this reason, the results are expressed in terms of the whole group of respondents. The “*n*” used in percentage calculations, refers to the total number of respondents of each individual question. Since not all respondents answered all questions, the total number of respondents varies per question.

3. Results

3.1. Analysis of responses

Out of the 210 questionnaires sent out (Germany excluded), 67 responses were received, giving a response rate of 32%. Because the exact number of surveys disseminated in Germany is not exactly known, the response rate cannot be calculated for the whole group. Total number of responses (Germany included) was 86.

The survey was distributed in 24 countries. Responses were received from 18 countries. Most responses were received from Germany (19 responses, 22%), Finland (10 responses, 12%) and the Netherlands (10 responses, 12%). Five responses were received from Belgium, France, Italy, Romania and Sweden. Two to four responses were received from Austria, Czech Republic, Denmark, Estonia, Ireland, Slovenia, and UK, and only one from Norway, Portugal, and Slovakia. There were no responses from Bulgaria, Hungary, Latvia, Lithuania, Poland, and Spain. The main reason for the lack of responses from some countries was the difficulty in the identification of the appropriate institutions or persons involved in public health preparedness.

When the respondents categorised the work of their organisation in the field of chemical emergencies, the most common category was toxicological risk assessment (43%). Legislation, air dispersion modelling, poison centre activity, medical profession (excluding poison centres), rescue service, fire service, environmental health, toxicological laboratory and industry were each represented by 14–27% of respondents (Table 1). Only five responses were from the police or the military.

3.2. Identification of important chemical incident scenarios

A majority of respondents indicated that irritating/corrosive substances, acutely toxic substances, combustion gases and pulmonary toxicants were the most important chemical groups when considering the seriousness of the health risks related to the incidental release of different types of chemicals (Fig. 1a). According to respondents, nanoparticles/nanomaterials, chemical weapons, reprotoxic chemicals and pesticides were considered less serious risks. Notably, carcinogenic substances were not highly prioritised. For the category nanoparticles/nanomaterials 41% of respondents did not express an opinion.

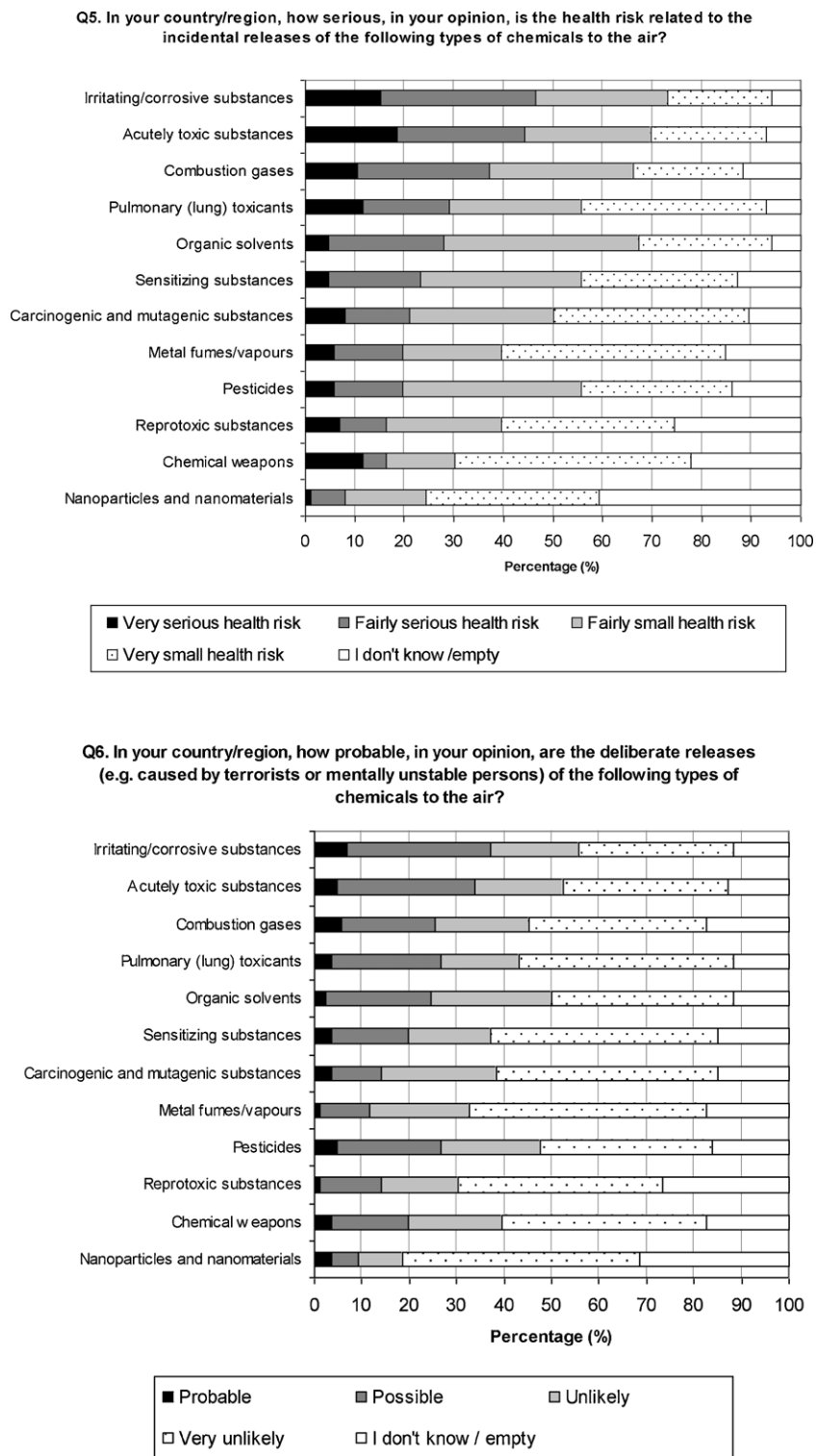


Fig. 1. (a) Health risk related to the incidental chemical releases to the air anticipated by respondents. (b) Probability of deliberate chemical releases anticipated by respondents ($n = 86$).

According to the respondents, the chemical groups most likely to be involved in deliberate releases were irritating/corrosive substances and acutely toxic substances, followed by pulmonary toxicants, pesticides, combustion gases, and organic solvents (Fig. 1b). Deliberate release of nanoparticles/nanomaterials, metal fumes/vapours, carcinogenic and mutagenic substances and reprotoxic substances was considered to be unlikely or very unlikely, although 27% and 31% of respondents (23 and 27 out of 86) were

unable to give an answer for reprotoxic substances and nanoparticles/nanomaterials, respectively. The probability for deliberate release of chemical weapons was considered to be rather low as well.

When asked about the effects of current or future trends possibly affecting the risk of chemical incidents, developments in nanotechnology were perceived as a potential risk driver in the future; 33% (28 out of 86) of respondents anticipated a significant

Q7. In what way might the following factors influence the risk of acute health hazards caused by chemicals in the next 5–10 years?

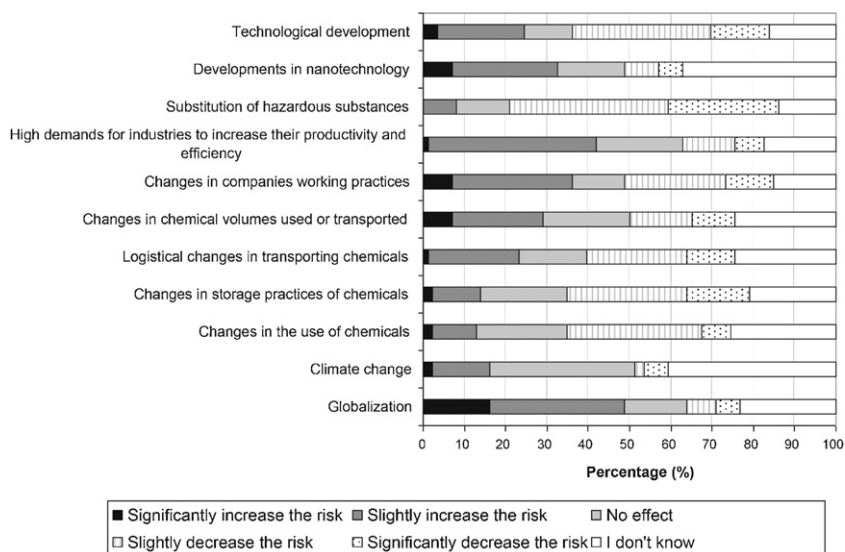


Fig. 2. Perceived influence of selected factors on the risk of acute health hazards caused by chemicals in the next 5–10 years ($n = 86$).

or a slight increase in the risk (Fig. 2). Globalisation, demands to increase industry productivity and efficiency, as well as changes in companies' working practices were also considered by many of respondents as potential negative impact factors on acute health hazards (Fig. 2). Factors such as technological development, substitution of hazardous chemicals, changes in use, storage and transport of chemicals were perceived mostly to decrease the risk whereas climate change was not expected to have any impact.

The respondents evaluated the influence of new regulations on the risk assessment and management in chemical emergencies. Improvements due to REACH were foreseen by 58% (43 out of 74) of respondents and the international harmonisation of the Regulation on Classification, Labelling and Packing of substances and mixtures (CLP) was judged to have a positive impact by 50% (36 out of 72) of the respondents. This was explained by increasing the amount of available data on chemicals and by improving harmonisation. About 30% (22–23 out of 72–74 respondents) felt that assessment and management will not improve by these new regulations (data not shown).

Table 1

Work categories of respondent organisations in the field of chemical emergencies (number of respondents, $n = 86$).

| Work category | Frequency (n) ^a | Percentage |
|---|--------------------------------|------------|
| Toxicological risk assessment | 37 | 43 |
| Legislation | 23 | 27 |
| Rescue services | 21 | 24 |
| Air dispersion modelling | 19 | 22 |
| Environmental health professional | 18 | 21 |
| Industry | 18 | 21 |
| Fire services | 17 | 20 |
| Poison centre | 14 | 16 |
| Toxicological laboratory | 14 | 16 |
| Medical professional (other than poison centre) | 12 | 14 |
| Police | 3 | 3 |
| Military | 2 | 2 |
| Other | 14 | 16 |

^a It was possible to select more than one category.

3.3. Risk assessment practises and tools

AERVs are clearly considered important risk assessment tools in acute chemical incidents; 94% (68 out of 72) of respondents thought they are very or somewhat important. Only two respondents thought that AERVs are not important. In general, AERVs are predominantly used for emergency planning and consequence analysis and to a lesser extent for land-use and medical planning (Table 2).

Most frequently used AERVs are ERPGs, AEGLs and IDLHs (Table 2). TEELs and AETLs are applied by one third of the respondents. Other values applied included for example national acute exposure values and occupational exposure values (STELs, short term occupational exposure limit values for 15 min). Most common uses of AERVs among the respondents were emergency planning and consequence analysis (Table 2).

Evacuation distance estimation is an important application of AERV's. Again, ERPGs, AEGLs and IDLHs are the most commonly used values, in addition to national acute exposure levels (Fig. 3). ERPGs and IDLHs are set only for one exposure period (60 or 30 min, respectively), whereas AEGLs have been set for five different exposure periods and for three different severity levels (AEGL-1 AEGL-2 and AEGL-3) [7,9]. The use of different AEGLs for evacuation distance calculations was divided rather evenly among all respondents, so that only few respondents used a particular AEGL level (Table 3).

AERVs were, however, considered relatively easy to use by half of the respondents (37 out of 72). However, 25 out of 72 respondents thought that they are somewhat difficult or even very difficult to use. According to some comments received, the fact that ERPG and IDLH values are set only for 30 or 60 min exposure durations complicates their use. Related to the number of different AERVs, one respondent proposed to set up a coordinated database of all the different AERVs available for substances.

Respondents generally identified 10 min, 15 min, 30 min and 1 h as the most relevant exposure durations for AERVs (Table 4). When asking the question for which severity of the health effects AERVs should be derived, the answers did not uniformly identify a severity level as being the most important (Table 4). However, it seems so that less severe effects (*No significant health risks, not likely to*

Table 2
Use of different types of AERVs for different purposes (number of respondents indicating specific use).

| Use pattern ^a | AEGL (n = 65) ^b | ERPG (n = 66) | TEEL (n = 56) | IDLH (n = 66) | AETL (n = 59) | Other (n = 51) |
|----------------------------------|----------------------------|---------------|---------------|---------------|---------------|----------------|
| Land-use planning | 11 | 15 | 4 | 10 | 7 | 7 |
| Emergency planning | 27 | 32 | 6 | 22 | 7 | 19 |
| Planning medical | 7 | 7 | 3 | 8 | 3 | 3 |
| Consequence analysis | 23 | 19 | 14 | 23 | 11 | 19 |
| Other purpose | 4 | 5 | 3 | 6 | 3 | 7 |
| Total use for different purposes | 97 | 100 | 66 | 92 | 70 | 71 |
| Not used by organisation | 25 | 22 | 36 | 23 | 39 | 16 |

^a It was possible to select more than one use pattern.

^b Indicates the total number of respondents answering to this question.

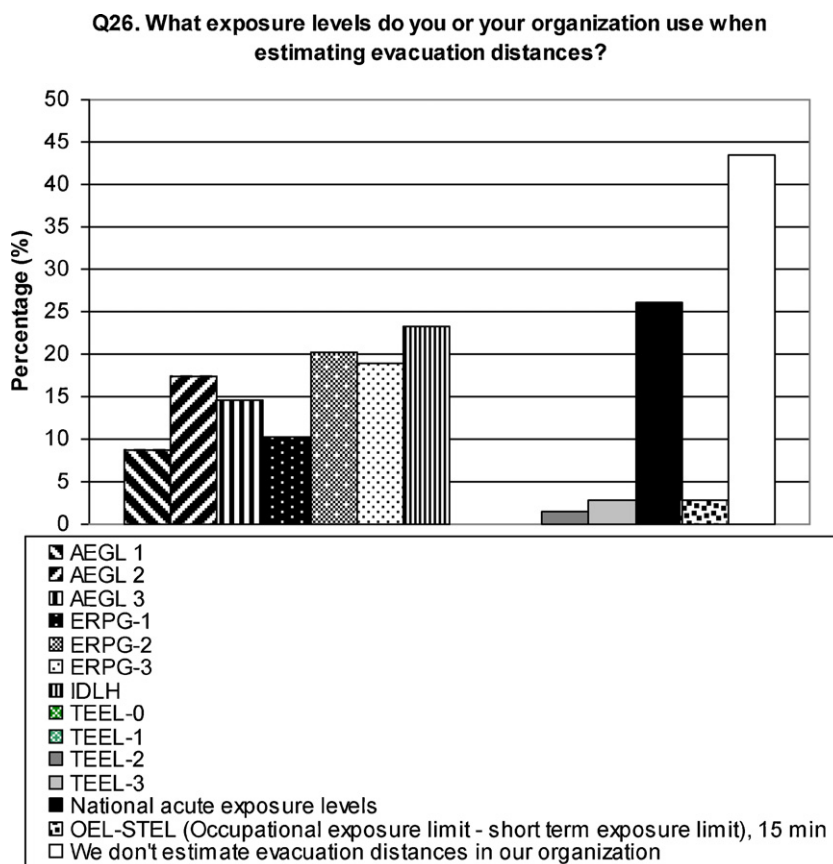


Fig. 3. AERVs used when estimating evacuation distances (n = 69).

cause discomfort and Objectionable odour) were considered the least relevant. Over 70% of those respondents expressing their opinion considered *Impairment of person's ability to take protective action or escape; Serious injury requiring prolonged treatment; Immediate or delayed permanent adverse health effects, irreversible health effects; Life-threatening effects; and Likely to cause death, lethal effects* to be relevant (Table 4).

Besides the obvious acute health effects, long term endpoints may also be of importance for the setting of AERV's. A majority of the respondents (41–50 out of 67–69 respondents) thought that it would be important to take into account respiratory sensitisation,

reproductive toxicity, long term neurotoxic effects, carcinogenic or mutagenic effects. No obvious differences between different target groups were noted in their responses (data not shown).

When asked whether susceptible subpopulations (such as asthmatics) should be considered when setting AERVs, 68% of the respondents (47 out of 69) felt that this would be appropriate.

3.4. Needs in the health risk assessment of chemical emergencies

Certain types of health effects following single exposures are considered more complex to assess than others. The health effects

Table 3
The use of different time frames of AEGLs for the estimation of evacuation distances.

| Severity level | AEGL 1 | | | | | AEGL 2 | | | | | AEGL 3 | | | | |
|--|--------|--------|-----|-----|-----|--------|--------|-----|-----|-----|--------|--------|-----|-----|-----|
| | 10 min | 30 min | 1 h | 4 h | 8 h | 10 min | 30 min | 1 h | 4 h | 8 h | 10 min | 30 min | 1 h | 4 h | 8 h |
| Number of respondents using the specific level | 3 | 2 | 4 | 1 | 1 | 6 | 7 | 9 | 5 | 5 | 5 | 5 | 8 | 5 | 5 |

Table 4
Relevancy of different time frames and severity grade for acute exposure reference values.

| Time frame | Relevant (n) | Not relevant (n) | I don't know or no answer (n) |
|------------|--------------|------------------|-------------------------------|
| 1 min | 19 | 22 | 45 |
| 10 min | 35 | 10 | 41 |
| 15 min | 27 | 12 | 47 |
| 20 min | 16 | 18 | 51 |
| 30 min | 35 | 8 | 43 |
| 1 h | 40 | 6 | 40 |
| 2 h | 12 | 19 | 55 |
| 4 h | 15 | 19 | 52 |
| 8 h | 16 | 24 | 46 |

| Severity grade | Relevant (n) | Not Relevant (n) | I don't know or no answer (n) |
|--|--------------|------------------|-------------------------------|
| No significant health risk, not likely to cause discomfort | 20 | 35 | 31 |
| Objectionable odour | 18 | 36 | 32 |
| Mild effects, discomfort, mild irritation | 37 | 20 | 29 |
| Likely to suffer clear but not life-threatening health effects, medical attention required | 39 | 11 | 36 |
| Impairment of person's ability to take protective action or to escape | 48 | 8 | 30 |
| Serious health effects, serious injury requiring prolonged treatment | 42 | 10 | 34 |
| Immediate or delayed permanent adverse health effects, irreversible health effects | 48 | 5 | 33 |
| Life threatening effects | 48 | 7 | 31 |
| Likely to cause death, lethal effects | 41 | 9 | 36 |

for which more guidance was requested by the respondents include carcinogenic, reproductive, mutagenic and neurotoxic effects, and sensitisation (Fig. 4). Based on respondents' open remarks, the current tools, guidance and information to assess delayed effects from short-term exposures were considered to fall short. One explanation given by the respondents is that these types of effects cause a lot of concern to the public, even if risks caused by acute exposure may be very low.

The data on toxic effects following single exposure are limited for many substances. In such cases, data from related substances (read-across/QSAR) may provide an alternative to help the risk assessment. When asked whether the respondents have expertise in this kind of evaluation, 26 out of 66 did not reply to the question or replied that they did not need that kind of expertise in their work. Of the rest, 25 considered the expertise to be at least somewhat adequate, whereas 15 thought

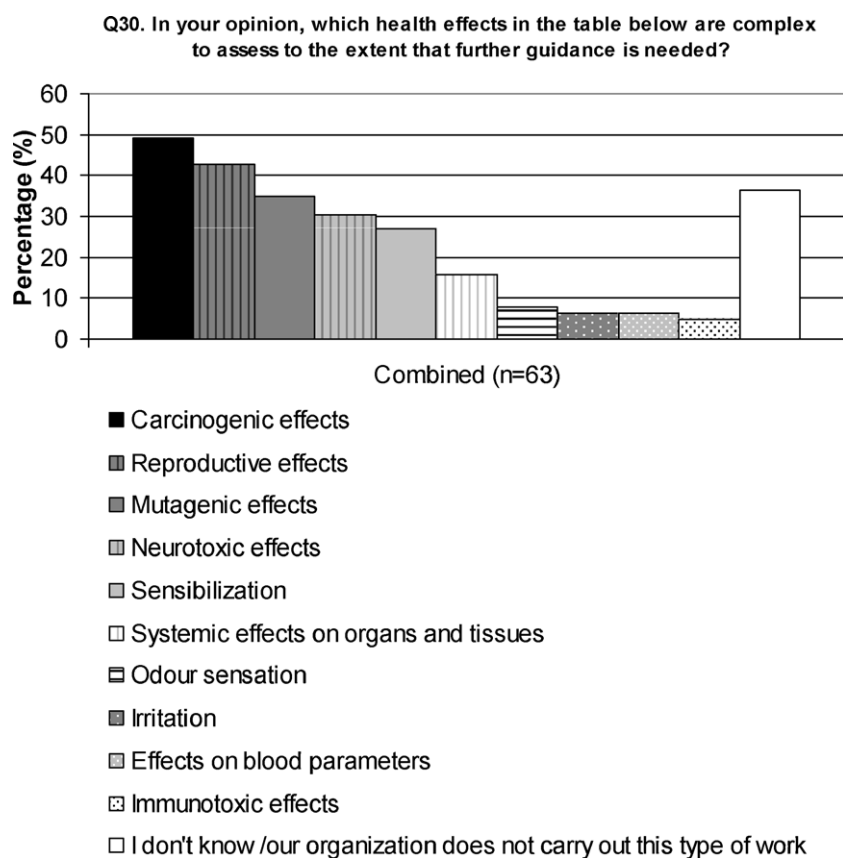
**Fig. 4.** Health effects for which more guidance is needed in order to make reliable risk assessment ($n = 63$).

Table 5
Sufficiency of guidelines, regulations and tools for the assessment and management of human health risks from chemical exposures in emergency response situations ($n = 74$).

| | <i>n</i> (%) |
|---|---------------------|
| Yes, guidelines, regulations and tools are sufficient | 37 (≈ 50) |
| No, new guidelines needed | 27 (≈ 36) |
| No, new regulations needed | 13 (≈ 18) |
| No, new tools needed | 25 (≈ 34) |
| I don't know | 5 (≈ 7) |

that it is somewhat inadequate or not at all adequate (data not shown).

The majority of all respondents (58%, i.e. 39 out of 67) considered the present models to assess health risks of single exposures to multiple chemicals or chemical mixtures are inadequate. 46 out of 67 respondents would require AERVs at least for some common mixtures. Organic solvents and gasoline or other fuels were mentioned as examples. New tools and more guidance were required also for dose-response and time scaling modelling in the setting of AERV's (35 and 34 out of 61 responses, respectively) as well as exposure modelling (25 out of 61) (data not shown).

When asked about the relevancy and sufficiency of guidelines, regulations and tools for the assessment and management of human health risks from chemical exposures in emergency response situations, 32 out of 74 respondents (43%) considered the present situation insufficient. These respondents expressed a need for new guidelines and tools and, to a lesser extent, for new regulations (Table 5). In open remarks, international harmonisation of guidelines and tools was suggested, as well as co-operation among local and regional authorities. Respondents expressed a need for material, such as reports on chemicals, AERVs, and standard operation procedures, which is easily available and useful to enable a valid and rapid risk assessment. Also a request for more training/education was given.

4. Discussion

4.1. Methodological considerations

This project marks the first effort in Europe to review current European practice and perspectives on the current needs regarding the development and use of information on acute health risks of chemicals for use in risk management applications. The findings offer new information on the current methodologies and practices in the risk assessment of single chemical exposures as well as on the needs and concerns related to chemical incident preparedness in various European countries.

The validity of a survey is dependent on the response rate. In this survey the response rate of the questionnaire was 32% (excluding Germans, see Results), which is more or less an expected rate for this kind of questionnaire. Thus, the results can be considered as a valid representation [17]. The advantage of this study was that it involved experts from various fields of expertise (e.g. toxicological risk assessment, policy and rescue services) and from different levels (local, national, international). Also different parts of Europe (northern, eastern, western and southern Europe) were represented although there was variability in the number of responses from different countries, with Germany, the Netherlands and Finland being the best represented. Thus, the results may be biased towards a better representation of the situation in those three countries. A large number of responses were from highly industrialised countries with a significant number of Seveso sites.

As always in this kind of questionnaires, there is a need to discuss whether the right persons were addressed. However, the distribution channel was specifically made by experts knowing specifically

about the responsible organisation and the responsible persons in the respective country. Thus, we are of the opinion that the respondents represented the panel of institutions and/or experts in the 24 countries who are responsible for chemical incident preparedness.

4.2. Chemical incident scenarios

According to the results of this study, irritating and corrosive substances, acutely toxic substances, and combustion gases are perceived as the most serious risks due to incidental releases and will remain serious risks also in the future. Also in the case of deliberate releases, common industrial chemicals are considered to be a more probable threat than actual chemical weapons. Therefore, the identification of these chemicals for further risk assessment is essential also for the preparedness towards deliberate releases. Hauschild and Bratt [3] has recently described an approach to evaluate over 1700 industrial chemicals in order to rank them from global military perspective according to their ability to cause physical or toxicological threat either from intentional attack or from collateral damage.

In addition to industrial chemicals, pesticides were ranked high regarding deliberate releases. This is likely to reflect the history of incidents involving pesticides and the known high toxicity of some pesticides (organophosphates, carbamates, nicotine). However, according to this survey, pesticides were not considered to pose serious health risk due to accidental releases, which may reflect the recent developments in the substitution of the most hazardous pesticides in Europe.

Surprisingly, risk from carcinogenic chemicals or chemicals toxic for reproduction did not rank highly, which is interesting insofar as for chronic exposure these effects are seen as a major threat for human health in the community. In contrast, these effects were identified as endpoints to be included when deriving AERVs and as endpoints for which more guidance is needed (Fig. 4). It might be that the answer of the first question is expressing a personal view on risk, whereas the answers to further questions mirror the situation of incidences with chemicals being carcinogenic or reprotoxic. As the responsible persons have to provide a scientifically based risk communication, an assessment of the risk of these effects has to be also performed.

The majority of respondents did not perceive nanoparticles and nanomaterials as a significant concern in the future. However, it was noted that many of the respondents did not answer this question and we interpret this finding as an indication of lack in knowledge. Currently, the knowledge of the health effects of nanomaterials is limited and until now, there are no cases of acute accidents in which nanoparticles or nanomaterials have been specifically identified as the major hazard, aside from nanoparticles generated naturally, for example, from fires or volcanic eruptions. Although nanoparticles were not perceived as a serious health risk at the moment, nanotechnology was considered by most respondents as a potential risk driver in the future. This may reflect the expected increase in the importance/volumes of nanotechnology in future. Other potential risk drivers cited by a number of respondents included globalisation, productivity demands in companies and changes of company working practices which we interpret as an expression of increased time pressure with a potential loss of diligence and an increased risk of non-conformity with safety rules.

The survey also indicated that respondents generally considered REACH and CLP regulations as positively influencing risk assessment and management of acute chemical incidents in Europe. REACH is expected to provide more information on the hazardous properties of the chemicals, which is likely to contribute to better management of chemical incidents, although, it should be noted here that REACH concerns only the normal expected handling and

use of chemicals, excluding abnormal/accidental operations and deliberately inappropriate uses [1].

4.3. Risk assessment tools and practises in Europe

One of the main results of the study was the obvious variability in the risk assessment practices. This same variability has been noted also in the use of acute exposure levels in Seveso II applications [6]. Multiplicity of AERVs appears to cause confusion and result in variable practices.

It has been shown by Öberg et al. [18] that there is a significant discrepancy among AERVs for single chemicals. According to Öberg et al. [18], AEGL and ERPG values diverge by a factor of three or more for almost 40% of the substances. When different values are used by different countries/bodies, it may cause problems especially in transboundary incidents, when different risk assessment practises might confuse the public and complicate risk communication. Thus, there is a clear need for harmonized AERVs and clear guidance and/or training to use an appropriate value for particular purposes.

The observation that AEGL and ERPG values are the most frequently used is consistent with the recommendation of the US Subcommittee on Consequence Assessment and Protective Actions (SCAPA) on the use of different AERVs. According to SCAPA recommendations, primarily AEGLs should be used and if AEGLs are not available ERPGs would be the second choice [12]. TEEL values, derived by SCAPA, are recommended in absence of AEGLs or ERPGs.

IDLH values were also quite frequently used among respondents. The reason for this might be that they have a long history, are widely known, and are available for many chemicals. They are not, however, intended or appropriate for use in situations such as emergency response and land-use planning. IDLH values have been established to determine a concentration from which a worker could escape without injury or without irreversible health effects in the event of respiratory protection equipment failure and a concentration above which only “highly reliable” respirators would be required [14].

Short term occupational exposure limit values (15 min STEL values) were also used by some of the respondents which is contradictory to their aim. STEL values are aimed at preventing adverse health effects due to peak exposures that will not be controlled by the application of an 8 h time-weighted average (TWA) limit at workplaces [19]. They are intended for use in normal work situations and must not be used as a basis for determining measures to protect against emergency situations [19].

The limited use of AETLs is explained by the fact that these values were derived as case studies for only 22 chemicals within the ACUTEX project, which was aimed at developing a methodology for developing AERVs. These existing AETLs do not have an official status and were never published.

A large group of potential AERV users seem to have problems with the application of the currently available values. This was seen also in the wide variability of the use of values set for different severity grades of health outcome or for different time-frames. There are currently no recommendations available in Europe on the use of specific time frames or severity of health effects for specific risk assessment purposes. These findings show that the derivation of AERVs alone is no guarantee for their successful application, and that guidance on possible application areas and on how to apply them should be an integral part of an AERV development programme.

4.4. Identification of present needs

Based on the results of the study, there is a clear need for guidance on the use of AERV's in Europe. This guidance should involve

clear recommendations on the use of an appropriate value for particular purposes with the aim to harmonize risk assessment and management practices. At a national level, for example France has developed a guidance to help national stakeholders in choosing different AERVs for mainly land-use planning purposes [20].

Based on results of the questionnaire, the time frames of interest are especially 10 min up to 1 h, and the health effects of interest are those of a higher grade of severity including mild effects but excluding odour perception and no effect levels. However, some respondents were in favour of having AERVs also for shorter and longer time periods or for no-effect level or odour perception. This reflects the variable needs for AERVs, which also have previously been reported [6].

In addition, there was an evident need for more guidance and information to assess delayed effects (carcinogenicity, reproductive, mutagenic and neurotoxic effects, and sensitisation) from short-term exposures although these substances are not ranked as high risks in acute releases. The main challenge related to these compounds is a scientifically based risk communication [5]. In addition, in the development of risk assessment guidance and AERVs it should be addressed how the impact of exposure on susceptible subpopulations can be taken into consideration.

Models to assess health risks of single exposures to multiple chemicals or chemical mixtures were also requested, as well as guidance on how to assess their risks. In occupational health, for example, the question of multiple chemical exposures is commonly addressed by assuming that toxic effects of similarly acting chemicals are additive [21]. However, since, in these cases, the limit values are usually based on no observed adverse effect levels (NOAELs) and the use of safety factors to account for uncertainties, the effect of additivity can be assumed to be lower than in incidental releases of chemical mixtures because of the possible scenario of high exposure with clear adverse effects. For this risk assessment of acute incidental exposures, no guidance is currently available to address these issues.

A need for training/education was also expressed. Differences in educational background are evident from the survey, something which may hamper common hazard assessment, efficient communication and mutual understanding in management of cross-border chemical disaster incidents. This calls for an urgent need of training courses in real-time hazard identification and quantification, hazard management, individual monitoring of victims, medical handling and treatment.

Further improvements in the field of dose-response modelling and time-scaling in the setting of AERVs, as well as exposure modelling were requested by many of the respondents. Read-across and QSAR seem an important area for further work, given the future scenario with the political aim of avoiding animal testing. These methods are under active development for the purposes of other legislations like REACH in Europe [22]. However, their application for the assessment of health risks arising from acute exposures has yet not been considered.

5. Conclusions

This survey was the first of this kind on acute chemical health risks in Europe. Its results are of high interest for further developments and scientific and training investments in a field of high public interest, in particular when considering new and emerging risks. Based on the results it can be concluded that:

- European consensus on the process and methodology to derive and use AERVs should be developed. It should take into account also possible long term effects of short term exposures and susceptible subpopulations.

- There is a clear need for training materials and courses on acute health risk assessment, both at local, national and European level. Training is especially needed on the practical application of acute exposure reference values, and their role in the assessment and communication of health risk of acute chemical incidents.
- Although acutely toxic and irritating/corrosive substances will remain serious risks also in future, development of plausible scenarios for potentially emerging risks from chemical incidents is also needed. This includes potential exposure associated with new mixtures and substances including nanoparticles. Also better understanding of the potential influence of issues like globalisation, productivity demands and companies working practises on chemical incident preparedness is needed.
- Further scientific work related to the risk assessment of single exposures should be initiated in the field of dose-response modelling including time extrapolation and exposure modelling. Given the political pressure to avoid animal testing read-across and QSAR are scientific fields which need further development.

Conflict of interest

The authors declare no conflicts of interest.

Acknowledgements

The study was part of the EU FP7 project iNTeg-Risk (Early Recognition, Monitoring and Integrated Management of Emerging, New Technology related, Risks).

References

- [1] EC (Ed.), Regulation No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 2006.
- [2] Reassessing the Threat, Chemical Biological Warfare Review, 2006.
- [3] V.D. Hauschild, G.M. Bratt, Prioritizing industrial chemical hazards, *J. Toxicol. Environ. Health* 68 (2005) 857–876.
- [4] M. Christou, Carcinogens in the context of council directive 96/82/EC. Report by technical working group 8, Joint Research Centre, European Commission, 2000.
- [5] P.M. Bos, B.J. Baars, M.T. van Raaij, Risk assessment of peak exposure to genotoxic carcinogens: a pragmatic approach, *Toxicol. Lett.* 151 (2004) 43–50.
- [6] M. Wood, A. Pichard, U. Gundert-Remy, C. de Rooij, S.M. Tissot, The AETL methodology as a potential solution to current challenges associated with the development and use of acute exposure levels in Seveso II applications, *J. Hazard. Mater.* 133 (2006) 8–15.
- [7] Subcommittee on Acute Exposure Guideline Levels, Committee on Toxicology. Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, Standing Operating Procedures for Developing Acute Exposure Guideline Levels for Hazardous Chemicals, National Academy Press, Washington, DC, 2001.
- [8] J.V. Bruckner, D.A. Keys, J.W. Fisher, The acute exposure guideline level (AEG) program: applications of physiologically based pharmacokinetic modeling, *J. Toxicol. Environ. Health A: Curr. Issues* 67 (2004) 621–634.
- [9] D. Krewski, K. Bakshi, R. Garrett, E. Falke, G. Rusch, D. Gaylor, Development of acute exposure guideline levels for airborne exposures to hazardous substances, *Regul. Toxicol. Pharmacol.* 39 (2004) 184–201.
- [10] F. Cavender, S. Phillips, M. Holland, Development of emergency response planning guidelines (ERPgs), *J. Med. Toxicol.* 4 (2008) 127–131.
- [11] D.K. Craig, J.S. Davis, D.J. Hansen, A.J. Petrocchi, T.J. Powell, T.E. Tuccinardi Jr., Derivation of temporary emergency exposure limits (TEELs), *J. Appl. Toxicol.* 20 (2000) 11–20.
- [12] U.S. Department of Energy, DOE Handbook – Temporary Emergency Exposure Limits for Chemicals: Methods and Practice (DOE-HDBK-1046-2008), U.S. Department of Energy, Washington, DC, 2008, <http://orise.orau.gov/emi/scapa/files/doe-hdbk-1046-2008.ac.pdf>
- [13] D.K. Craig, C.R. Lux, Methodology for Deriving Temporary Emergency Exposure Limits (TEELs) (U), Westinghouse Savannah River Company, Project Engineering & Construction Division. Available from: http://orise.orau.gov/emi/scapa/files/Method_for_deriving_TEELs.pdf, Aiken, SC, 1998.
- [14] The National Institute for Occupational Safety and Health (NIOSH), Documentation for Immediately Dangerous to Life or Health Concentrations (IDLH), 1994, <http://www.cdc.gov/niosh/idlh/idlh-1.html>
- [15] Health Council of the Netherlands, Derivation and utility of intervention values for decisions involving disasters with hazardous substances, Health Council of the Netherlands. Publication No. 2007/16, The Hague, 2007.
- [16] A. Baulig, G. Vincent, S. Tissot, Methodology for determining French acute toxicity thresholds of lethal effects, irreversible effects and reversible effects, INERIS (2007).
- [17] R. Curtin, S. Presser, E. Singer, The effects of response rate changes on the index of consumer sentiment, *Public Opin. Quart.* 64 (2000) 413–428.
- [18] M. Oberg, N. Palmén, G. Johanson, Discrepancy among acute guideline levels for emergency response, *J. Hazard. Mater.* 184 (2010) 439–447.
- [19] SCOEL, Methodology for the Derivation of Occupational Exposure Limits. Key Documentation (version 6). European Commission., 2009.
- [20] S. Tissot, G. Vincent, Technical Guidance document for selecting acute toxicity threshold values in the absence of official French values, INERIS (2009).
- [21] A. Vyskocil, D. Drolet, C. Viau, J. Brodeur, R. Tardif, M. Gerin, M. Baril, G. Truchon, G. Lapointe, Database for the toxicological evaluation of mixtures in occupational atmospheres, *Environ. Toxicol. Pharmacol.* 18 (2004) 235–242.
- [22] A.P. Worth, C.J. Van Leeuwen, T. Hartung, The prospects for using (Q)SARs in a changing political environment—high expectations and a key role for the European Commission's joint research centre, *SAR QSAR Environ. Res.* 15 (2004) 331–343.