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Discrepancy among acute guideline levels for emergency response

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ABSTRACT

Acute guidance values are tools for public health risk assessment and management during planning, preparedness and response related to sudden airborne release of hazardous chemicals. The two most frequently used values, i.e. Acute Exposure Guidance Levels (AEGL) and Emergency Response Planning Guideline (ERPG), were compared in qualitative and quantitative terms. There was no significant difference between the general level of AEGL and ERPG values, suggesting the two systems are equally precautious. However, the guidance values diverged by a factor of 3 or more for almost 40% of the substances, including many of high production volume. These deviations could be explained by differences in selection of critical effect or critical study and in a few cases differences in interpretation of the same critical study. Diverging guidance values may hamper proper risk communication and risk management. Key factors for broad international acceptance of harmonized values include transparency of the decision process, agreement on definition of toxicological tiers, and a target population including sensitive groups of the general population. In addition, development of purely health based values is encouraged. Risk management issues, such as land use and emergency response planning should be treated separately, as these rely on national legislation and considerations.

1. Introduction

The need for control of major chemical releases has burgeoned in recent years related to globalization of the chemical market and stricter safety regulations, increased fear for terrorist acts and increased international collaboration during civil and military missions. Chemical release may be a consequence of fires, industrial and transportation accidents, natural accidents such as tornadoes, earthquakes and flooding, chemical spills, terrorism and chemical warfare. Depending on the nature of such releases, individuals or large groups may be acutely exposed to hazardous substances at levels ranging from lethal or life threatening to harmless.

During emergencies there is an urgent need for society to quickly decide which actions to take. In such situations, acute guidance values are very helpful. Acute guidance values are developed for once-in-a-lifetime, short term exposure to airborne substances. Being based on thorough toxicological health risk assessments, the guidance values give a rapid indication of potential health consequences of specific chemical exposures in the population. The acute guidance values are intended to give decision support during planning, preparedness and response on potential human health consequences of chemical releases [1–6]. Among those who use acute guidance values are: Community emergency planners, Emergency responders, Air dispersion modelers, Industrial process safety engineers, Local Emergency Planning Coordinators, State Emergency Response Commission, Industrial hygienists and toxicologists, Transportation safety engineers, Fire protection specialists, Civil and military government agencies, Risk assessors and risk managers, Resource Conservation and Recovery managers.

At present, several sets of acute guidance values are available in the global arena. However, there are no internationally accepted set of values and comparative analyses of the alternatives are absent. Furthermore, it has been argued that individual efforts by different countries may not be adequate to fill the gaps for several reasons: extensive resource requirement of having separate approaches, communication problems and practical difficulties associated with having numerous different ways of evaluating exposures to acutely toxic chemicals [4,7]. The lack of national and international harmonization thus hampers risk management and communication between stakeholders e.g. during national cooperation during large chemical accidents or during international collaboration in case of cross-national releases or at international civil or military missions. Seveso II is a European Council directive (96/82/EC) concerning the control of major-accident hazards involving dangerous substances. The lack of harmonization was illustrated in a survey of Seveso II competent authorities in 15 European countries [8]. The survey revealed that a variety of different types of acute exposure values are used for Seveso II applications and highlight an opportunity

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for greater collaboration on scientific inputs to application of the Directive in Europe.

The two internationally most frequently used guidance values are the Acute Exposure Guideline Levels (AEGL), developed by the U.S. National Advisory Committee for the Development of Acute Exposure Guideline Levels for Hazardous Substances (AEGL Committee) and the Emergency Response Planning Guidelines (ERPG) developed by the Emergency Response Planning Committee of the American Industrial Hygiene Association (AIHA) [1,2,9–11]. The AEGL and the ERPG systems are similar in that they have three comparable threshold levels (Tiers). Thus, inhalable exposure above the Tier 1 level causes slight, reversible effects such as discomfort and/or irritation. Notably, ERPG but not AEGL includes odor as a Tier 1 effect. When the exposure exceeds Tier 2 the health effects are disabling. The effects may be non-reversible and/or impair the ability to escape but they are still non-fatal. Exposure above Tier 3 is deemed to be life threatening or fatal.

The aim of the present study was to compare, in qualitative and quantitative terms, the AEGL and ERPG values. The analysis of the magnitude of divergence between the two sets of values and the evaluation of the underlying rationales for the divergence, was performed in order to elucidate the need for international harmonization.

2. Methods

2.1. The database

The following data were compiled in a database: Chemical name in English as named by AEGL and ERPG, Chemical Abstracts Service (CAS) number, AEGL guidance values for all three Tiers and for all exposure durations, ERPG guidance values for all three Tiers, point of departures (POD), critical studies, interspecies and intraspecies uncertainty factors (UF) and their rationales, modifying and adjustment factors and their rationales. In addition, risk phrases regarding acute inhalatory exposure and corrosion to the eyes were taken from the European Commission Directive 67/548/EEC. All information published until January 2009 was entered.

All available AEGL and ERPG guidance values were incorporated in the database. In some cases the committees did not recommend a value (a) because of insufficient data to derive a value or (b) because the derived AEGL or ERPG value was higher than the concentration derived for the next Tier. In some cases, as described below, the different sources for AEGL values and documents were unavailable or incongruous. The AEGL values for dimethylformamide and toluene were published on the internet, but the corresponding Technical Support Documents (TSD) were not available. AEGL values derived for the nitrogen mustards were contradictory in that three different sets of values were published (a) on the internet, (b) in the paragraph in the TSD were the AEGL values are derived and (c) in the summary of the TSD [1]. In addition, no specific interspecies or intraspecies UF were given to n-hexane (AEGL-2), 1,3-butadiene (AEGL-3) and butane (AEGL-2 and -3). The AEGL-1 values of monomethylamine and ethylamine and the AEGL-2 value of 1,4-dioxane were based on two different key studies and therefore added as two separate sets of data in the database.

2.2. Statistical analysis

The AEGL and ERPG values were compared at all three Tiers for all substances that appeared in both lists. Only the 1-h values were considered since this is the only exposure duration for which ERPG values are given. To facilitate comparisons, AEGL/ERPG quotients were calculated for each substance at each Tier. Normality was tested by Kolmogorov-Smirnov test and found to be non-significant. The overall comparison of guidance value quotients was performed using a Wilcoxon Signed Rank Test comparing medians with a hypothetical value of 1.0.

Table 1
Number of chemicals with available guidance values in January 2009.

Tier	AEGL	ERPG	AEGL or ERPG	AEGL and ERPG
1	142	105	187	60
2	224	138	274	88
3	218	137	268	87
Any Tier	226	138	279	88
All three Tiers	136	105	173	59

2.3. Qualitative comparisons

The major sources of information for qualitative comparisons are the standing operating procedures for AEGL and the Handbook for ERPG, respectively [2,11]. These documents were primarily used to analyze the transparency of the process, definition of Tiers and specification of target groups. The risk assessment documents of 34 compounds with AEGL/ERPG quotients above 3.0 or below 0.33 were studied in more detail in order to identify the reasons for divergence and to compare the completeness and transparency of the rationales for setting guidance values. The main reasons were classified in four categories; (1) Selection of critical effect or definition of Tiers, (2) Selection of critical studies, (3) Interpretation of data, and (4) Missing data.

3. Results

3.1. Quantitative comparisons

In January 2009, there were 226 compounds with final or interim AEGL values in at least one Tier (Table 1). The corresponding number of ERPG values was 138. The database contained 274 substances that either had an AEGL or an ERPG value in any Tier. However, only about 30% of the substances were assigned both an AEGL and an ERPG value.

The concordance between the AEGL and ERPG values is shown in Fig. 1. For majority of the chemicals the difference between the two systems was small, with AEGL/ERPG quotients falling within 0.33 and 3.0. Both the median (tested by Wilcoxon signed rank test) and the geometric means were close to unity. The latter were 1.26 (95% confidence interval 0.82–1.96) for tier 1, 1.03 (0.86–1.24) for tier 2, and 0.96 (0.81–1.15) for tier 3. This suggests that the two

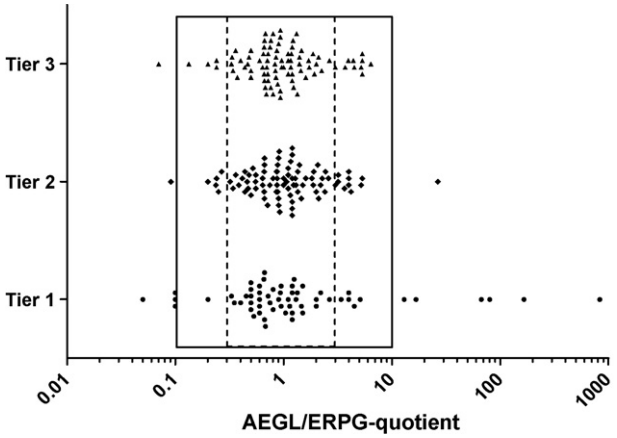

Fig. 1. AEGL/ERPG quotient for Tier 1 (●, notable discomfort), Tier 2 (⧫, severe effects and/or impaired ability to escape) and Tier 3 (▲, life threatening). The boxes mark quotients at the ranges 0.3–3 (dashed) and 1–10 (full), respectively.