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How are asthmatics included in the derivation of guideline values for emergency planning and response?

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ABSTRACT

Guideline values for emergency planning and response are aimed to protect the general public, including asthmatics and other susceptible groups, during sudden airborne releases of chemicals. A precondition of asthma may increase the individual susceptibility to acute exposures. This paper studies to what extent experimental data on asthmatics are included in the rationale and derivation of guideline values. An analysis of the Technical Support Documents (TSDs) of the Acute Exposure Guideline Levels (AEGLs) shows that only 23 of the 176 TSDs include references to experimental studies on asthmatics, 30 include a statement on asthmatics but no reference to experimental data, and 123 lack any explicit statement on asthmatics. The TSDs were further compared with the support documents of nine other programs for acute or occupational short-term values. All programs were incomplete with respect to experimental data on asthmatics. Omission of asthmatics may interfere with trustful and efficient health protective actions. We suggest that the availability of data on asthmatics should be carefully examined in the development of guideline values, and that the lack of such data should be explicitly noted. In the latter case, available data for other irritants may be used to justify an appropriate assessment factor.

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1. Introduction

Health-based guideline values for short-term exposure are used in planning, preparedness and as decision support during emergency response. There are several programs available, all with the purpose of protecting humans against adverse effects from acute exposure to airborne hazardous chemicals. Examples are given in Table 1. Deviations among emergency short-term values have been shown previously (Öberg et al., 2010). Discrepancies between the available programs for emergency short-term values may hamper an effective risk management and communication during a sudden unintentional or intentional release of chemicals. It is therefore a need for international harmonization. Key factors for broad international acceptance of harmonized values include, e.g. transparency of the decision process and clear definitions on target population. It is therefore important to clarify if and to what extent data on susceptible subpopulations are included in the derivation process.

In general, emergency preparedness related to chemicals aims to protect the entire population, including relatively large but potentially susceptible subpopulations such as children, elderly and asthmatics. However, small groups of hypersensitive individuals, such as severely ill patients, are generally not included. To protect labor from acute effects related to occupational exposure, work environment authorities define occupational exposure limits for short-term exposure. These values differ from most short-term values for the general population in the definition of target population, i.e. they do not aim to protect sensitive populations that are not likely to be a part of the labor. To study the importance of the definition of target groups, it might therefore be informative to examine how data on asthmatics are included in the support documents for short-term values related to occupational settings as compared to values for the general population.

Among the support documents for the short-term values, the Standing Operating Procedures (SOPs) for the Acute Exposure Guideline Levels (AEGLs) program clearly includes asthmatics in their definition of susceptible groups: "*Although the AEGL values represent threshold levels for the general public, including susceptible subpopulations, such as infants, children, the elderly, persons with asthma, and those with other illnesses, it is recognized that individuals, subject to unique or idiosyncratic responses, could experience the effects described at concentrations below the corresponding AEGL*" (NRC, 2001a, p. 3).

Asthmatics constitute a relatively large proportion of the population at all age groups. The World Health Organization (WHO) reports that about 235 million people worldwide suffer from asthma and it is currently one of the most common chronic diseases (WHO, 2011). The prevalence ranges from 1% to 18% in different countries and has increased both among children and adults over the past decades (GINA, 2011; Masoli et al., 2004). Although other preexist-

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Table 1
Standard setting programs that include short-term values.

Program	Organization
Short-term values for the general population	
Acute Exposure Guideline Levels (AEGL)	US National Research Council and Environmental Protection Agency (NRC/EPA)
Emergency Response Planning Guidelines (ERPG)	American Industrial Hygiene Association (AIHA)
Minimal Risk Levels (MRL)	US Agency for Toxic Substances and Disease Registry (ATSDR)
Reference Exposure Levels (REL)	California Office of Environmental Health Hazard Assessment (OEHHA)
French Acute Toxicity Threshold Values (VSTAF)	French National Institute for Industrial Environment and Risks (INERIS)
Short-Term Exposure Limits (STEL) and similar occupational short-term values	
Limits recommended by the Dutch Expert Committee on Occupational Standards (DECOS)	Health Council of the Netherlands
Maximum Concentration at the Workplace (MAK)	German Research Foundation (DFG)
Limits recommended by the Scientific Committee on Occupational Exposure Limits (SCOEL)	European Commission
Swedish Occupational Exposure Limits (SE-OEL)	Swedish Work Environment Authority (SWEA)
Threshold Limit Values (TLV)	American Conference of Governmental Industrial Hygienists (ACGIH)

ing diseases (e.g. fatty liver disease) might also be widespread and affected subpopulations regarded as susceptible, there are several reasons to concentrate on asthmatics, as done in the current study. Many airborne hazardous chemicals are clearly irritants to the airways and the acute effects are possible to study in experimental settings using the target population, i.e. persons with mild asthma. In addition, one of the strongest risk factors for developing asthma is inhaled substances and particles that may provoke allergic reactions or irritate the airways (WHO, 2011). A precondition of asthma may therefore increase the individual susceptibility to acute exposure of airborne chemicals, especially chemicals with irritant properties (i.e. the first signs of discomfort due to irritation occur at lower concentrations).

The identification of susceptible populations in AEGL as well as other short-term values is performed on a chemical-by-chemical basis with the aim to use all available data on the chemical in question. If relevant data are missing, an assessment factor (also called uncertainty factor, UF) of 10 is by default used to account for intraspecies (interindividual) differences in susceptibility to respiratory irritants (NRC, 2001a). If experimental data from susceptible groups are available there is in most cases no need for this intraspecies assessment factors. Experimental data for a large number of chemicals with similar mode of action might also be used as a base for development of chemical specific assessment factors. From a set of 11 studies (6 different chemicals) it has been suggested that the variation between asthmatics and healthy individuals are within a factor of 1–5 (Young et al., 2009). A similar conclusion for chemical irritants was also drafted in 2001 by the National Advisory Committee for the development of AEGL values (NAC/AEGL Committee) as basis for a recommended intraspecies uncertainty factor of 3 (NRC, 2001b).

This paper aims for a systematic overview regarding if and how asthmatics are included in the derivation of short-term values and to what extent experimental data on asthmatics are available and utilized in the derivation of short-term values. Data gaps and inadequacies are also meant to be identified and a database of experimental studies on asthmatics is aimed to be presented as a key to support the selection of interindividual assessment factors for chemicals with irritant properties. This information will be important in the process of harmonizing the procedures for short-term values and to ensure the protection of asthmatics at chemical accidents and other sudden releases of hazardous airborne chemicals.

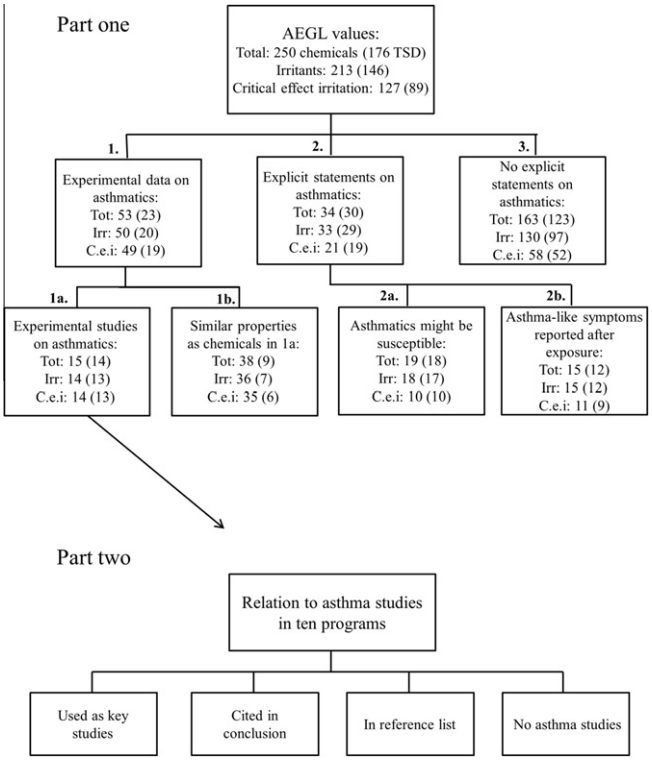

Fig. 1. Chemicals and support documents from 10 programs categorized based on information on asthmatic individuals. Part one of the study was performed on interim and final documents available in the AEGL program. The total number of chemicals in each category is presented. In addition, both the proportion of chemicals with irritating properties and the proportion of chemicals with irritation stated as critical effect at AEGL-1 are presented. Chemicals with other critical effect than irritation (28) or without AEGL-1 value (95) are not presented in the figure. Chemicals without AEGL-1 (whereof 81 in Category 3) did not include statements on critical effect. Four TSDs in Category 2a did not include explicit statements on asthmatics. However, individuals with compromised lung function or pulmonary conditions were stated as a possible susceptible population. In Part two, the consideration of asthmatics was studied in all 10 programs by comparing the 15 AEGL chemicals with data from experimental studies, Category 1a.

2. Methods

The principal study design is illustrated in Fig. 1. In the first part of the study, technical support documents (TSDs) from Acute Exposure Guideline Levels (AEGL) are categorized based on information about asthmatic individuals to obtain an overview on the consideration of this subpopulation. The reasoning for choosing AEGL as the prime source relates to the fact that the AEGL documents as well as the process for their derivation are well defined and transparent. In addition, all documents have open access and have undergone both peer and public review. The AEGL values are also widely used in an international context.

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