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Commentary

Acute Exposure Guideline Level (AEGL) Development for Emergency Planning: the Ammonia Example

By Robert A. Michaels

In 1984 methyl isocyanate was released from a chemical plant in Bhopal, India; killing approximately 2,000 local residents; and irreversibly injuring the eyes and lungs of 20,000. Governments recognized the need to identify extremely hazardous substances (EHSs) and assist communities to prepare for chemical emergencies (1). The U.S Environmental Protection Agency (EPA) identified 366 EHSs, as required by the Community Right-To-Know Act. Community emergency planning requirements followed under the Risk Management Program (RMP), in Section 112(r) of the 1990 Clean Air Act Amendments.

Industrial facilities exceeding threshold quantities of EHSs on site are subject to the RMP. The RMP defines Emergency Planning Zones around facilities, and requires facilities to submit to the EPA a Risk Management Plan aimed at preventing catastrophic chemical releases, and averting Bhopal-type consequences of releases. The cost of community emergency planning for a facility is likely to roughly depend upon the area of its Emergency Planning Zone, which in turn depends upon the square of the radius around the facility deemed necessary to attenuate a worst-case chemical release to specified airborne concentrations, termed Acute Exposure Guideline Levels (AEGLs).

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AEGLs for each EHS have nothing to do with routinely acceptable exposures. Acceptable community and occupational levels are set by a host of other, more conservative parameters. Rather, AEGLs must be set in the context of "exposure at high levels but of short duration, usually less than one hour, and only once in a lifetime" (1).

AEGLs are under development by the National Advisory Committee on AEGLs (NAC AEGL). NAC AEGL's composition is legislatively defined to assure balance, although some NAC AEGL actions on ammonia were taken (and reported in the media) before the Committee reached a full complement. RMP success depends upon the performance of NAC AEGL in setting AEGL values realistically reflecting the risks and magnitudes of industrial accidents. This Commentary evaluates the early performances of NAC AEGL, as exemplified by its year-long deliberations about ammonia, a chemical of great concern to companies and communities.

NAC AEGL's selection and treatment of bioassay data was affected by its unwillingness to abandon belief in highly conservative, though questionable, human lethality data.

"During the 20th century, humanity has almost quadrupled its numbers. Although many factors have fostered this unprecedented expansion, its continuation during the past generation would not have been at all possible without a widespread — yet generally unappreciated — activity: the synthesis of ammonia:"
Vaclav Smil
Scientific American, July 1997

AEGL-3 Definitions and the Ammonia Review.

Three types of AEGLs are defined (1): AEGL-1, to protect against nuisance exposure; AEGL-2, against irreversible injury or disability; and AEGL-3, against lethality. Each type of AEGL is quantified via multiple combinations of airborne concentration and exposure duration to protect against health effects of concern in exposures lasting from minutes to hours.

Ammonia was among the first EHSs considered when NAC AEGL began meeting in June 1996. Ammonia remained on NAC AEGL's Agenda even at its fifth (quarterly) meeting, on June 9-11 1997. NAC AEGL decided in June to formally propose very low AEGL concentrations for ammonia corresponding to exposure durations of five minutes, 30 minutes, one hour, four hours, and eight hours. The proposed AEGL values are too low by a factor of approximately 4.5, producing Emergency Planning Zone areas and planning costs generally 20 times greater than necessary. The proposed values will be published in the *Federal Register*, and NAC AEGL will then receive and respond to comments. Further review will be undertaken by an independent entity, namely, the Committee on Toxicology of the National Research Council (NRC).

Lethality Data Selection and Rejection

To derive AEGL-3 values (for example; 3,800 ppm at five minutes; vs. 16,869 ppm which I recommended), NAC AEGL used human data for range-finding, and bioassay data to flesh out the dose-response curve over the eight-hour range of exposure durations of concern (1). However, NAC AEGL applied this proper approach in an improper manner. For range-finding, NAC AEGL gave undue credence to human lethality data (5,000 to 10,000 ppm for 5-10 minutes) pre-dating World War 1, when ammonia was marketed as a war gas to military buyers interested in its high toxic potency against enemy soldiers engaged in trench warfare. Whereas such 'data' should have been accorded a low threshold for refutation, NAC AEGL instead rejected reconstructions of several relatively recent industrial accidents involving ammonia release, each conflicting with the pre-World-War-1 'data'. For example, in 1973 a tank failure in Potchefstroom, South Africa released 36 metric tons of anhydrous ammonia, killing 12 employees and six others, but demonstrating survival of 97 percent of 350 employees (most outdoors), and of 100 percent of those outdoors who were exposed to ammonia at ≤33,737 ppm-v for five minutes. NAC AEGL's rejection of accident reconstructions was based upon findings of an air modeling consultant explicating uncertainties intrinsic to air modeling. Yet, air modeling is intrinsic to the RMP.

Bioassay Data Selection and Treatment

Animal bioassay data are appropriate for elucidating the shape of a dose-response curve, where human data are incomplete. Scaling bioassay exposure levels to Human Equivalent Concentrations (HECs) produces lethality values consistent with the industrial accident reconstructions rejected by NAC AEGL. However, NAC AEGL's selection and treatment of bioassay data was affected by its unwillingness to abandon belief in highly conservative, though questionable, human lethality data. Data on mice (3) were preferred, despite the author's caveat: *"experiments using mice do not provide an appropriate basis for predicting quantitatively the mortality response in humans."* If NAC AEGL's assumption were correct that human and mouse sensitivity to ammonia are equal, the death toll at Potchefstroom should have been at least an order of magnitude higher than that observed.

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Rat data are more relevant (1), and rats are three times more tolerant of ammonia than mice. Even using mice, however, NAC AEGL has difficulty deriving AEGL-3 values below those assumed lethal for humans. Consequently, NAC AEGL declined to upwardly scale exposures to HECs, though NRC and EPA guidelines require it. Resulting AEGL values were still so high that NAC AEGL deemed their further reduction by a factor of three necessary to protect 'sensitive subpopulations' not already protected by mouse LC0.1 (one-per-thousand lethality) values (already very protective). Finally, NAC AEGL claimed it could produce similar AEGL-3 values using rat data (2) but, in that case, required a further interspecies safety factor of three.

AEGL-3 Definition: Death Vs. Coughing

NAC AEGL deviated from AEGL definitions. AEGL-3 was not required to be based upon actual lethality, but conditions which could eventually become lethal if exposure persists and/or medical attention is denied:

"No verified lethal concentrations for ammonia were found ... coughing may indicate that the absorptive (scrubbing) capacity of the upper respiratory tract has been exceeded and that ammonia is penetrating to the lower respiratory passages ... [and] death in humans exposed to ammonia is associated with damage to the lower respiratory tract... that would be lethal without prompt medical attention. Therefore, concentrations of ammonia that ... cause coughing ... have lethal potential" (2).

AEGL-2 Definition: Impairment of the Ability To Escape, Vs. Lacrimation

Similarly, AEGL-2 need not be based upon irreversible injury or disability. NAC AEGL based the ammonia AEGL-2 upon "intolerable" lacrimation (eye tearing) and respiratory irritation at ammonia levels of 380 ppm for five minutes (vs. 1,704 ppm which I recommend), 160 ppm for 30 minutes (vs. 696 ppm), and 110 ppm for one hour or longer. However, the description of these exposure levels as "intolerable" was derived from volunteers, who tolerated them (for example: 140 ppm for two hours, 500 ppm for 30 minutes), without adverse effect. Further, household ammonia, which can be purchased in grocery stores and accidentally overturned in bathrooms, rapidly releases ammonia at 20,000 ppm. In an industrial accident in Florida in 1996, a front-end loader drove under an overhead tank containing tons of anhydrous ammonia, and punctured a downwardly protruding nipple, releasing a strong stream of liquid anhydrous ammonia (1,000,000 ppm) onto the driver. He was able to exit his vehicle, run to a telephone, and summon assistance. He was hospitalized for 17 days with lung and eye injuries. In Texas in 1973, an individual was pushed back 12-15 feet by pressurized anhydrous ammonia, but was able to run approximately 100 feet. He returned to work after being hospitalized for six months with eye and skin injuries. Thus, the meaning of "intolerable" exposure is context-specific.

Inconsistent NAC AEGL Adherence to NAC AEGL Policy

Levels deemed (correctly or incorrectly) to impair the ability to escape should not be reduced to accommodate longer exposures than 30 minutes. This policy was adopted by NAC AEGL in September 1996. Yet in June, NAC AEGL denied having adopted this policy, and set ammonia AEGL-2 values of 160 ppm for 30-minute exposures and 110 ppm for exposures longer than 30 minutes. Given the extreme volatility of ammonia, however, it can be expected to completely dissipate within 30 minutes following a release.

Self-Evaluation

A day after setting ammonia AEGL values, NAC AEGL evaluated itself. Members suggested producing a document setting forth standard operating procedures (SOPs). A member suggested that SOPs should be "artfully constructed to be defensible in court, and soon." Another indicated that NAC AEGL had not even "done lip service" to its SOPs or definitions, and that its future actions would have to be more defensible. One suggested that SOPs "should not specify AEGL derivation in a strict way" and, similarly, another suggested that SOPs be written in a sufficiently flexible manner so NAC AEGL would not have to adhere to them, "to permit consensus to evolve." These suggestions may be viewed optimistically as a form of recognition that NAC AEGL procedures must be refined and followed to assure success of the RMP. However, I believe that legislative control over the composition of NAC AEGL has proved inadequate, to assure balanced treatment of Extremely Hazardous Substances. Companies with interests in such chemicals must participate in the AEGL process to a greater degree than has been evident.

Literature Cited

1. *NRC Committee on Toxicology. Guidelines for Developing Community Emergency Exposure Levels for Hazardous Substances.* Washington, DC; National Research Council, National Academy Press, 109 pp. 1993;
2. ORNL. *DRAFT Acute Exposure Guideline Levels (AEGLs) for Ammonia.* Oak Ridge, Tennessee; Oak Ridge National Laboratory, 61 pp., 2 June 1997;
3. Ten Berge, W.F.; A. Zwart, and L.M. Appelman. *Concentration-time mortality response relationship of irritant and systemically acting vapors and gases.* Journal of Hazardous Materials, 13: 301-9, 1986.

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