Alternatives Assessment Discussion Webinar:

Alternatives assessment in exposure-based safety standards: Are they mutually exclusive?

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Goals



- Continuing education and dialog
- To advance the practice of alternatives assessment for informed substitution across federal, state, and local agencies through networking, sharing of experiences, development of common approaches, tools, datasets and frameworks, and creation of a community of practice.

Background

- Alternatives assessment is focused on evaluating safer alternatives for a particular functional use and application of a chemical.
- Most alternatives assessment focus primarily intrinsic hazard and exposure properties.
- Focus is on "safer" options safest option may still be toxic for a particular function.
- Alternatives assessment is used most often in discretionary programs
- Many agencies implement policies that are primarily focused on establishment of "acceptable" or threshold emissions or exposures or risk-based safety standards that tend to have a more

Example – OSH Act

- The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.
- OSH Act Section 6 (b) (5)

Food Quality Protection Act

- Section 408 b(2) Authority to issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food
- The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.
- "(ii) DETERMINATION OF SAFETY.—As used in this section, the term 'safe', with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

Other Exposure-Based Safety Standard Policies

- FFDCA Food additives (ADI) and cosmetics
- CPSC/CPSIA/FHSA Consumer goods/toys
- EPA Clean Air Act
- Significant risk/acceptable risk, safe definitions not well defined in many laws and differ by law

Challenges

- Black and white approach where a chemical either meets the standard or doesn't. How do you have safer if already considered "safe"?
- Even with "safer chemical ingredients" there may still be residual risks for which exposure controls are needed.
- What is safe in one medium may not be safe in another.
- Exposure based safety standards may lead to a focus on meeting the standard by controlling exposure rather than by reducing hazard through informed substitution.

 The purpose of this discussion webinar is to discuss the role of alternatives assessment in standardsbased agencies and programs, including how alternatives assessment can help enhance the ability of an agency to support companies in complying with a standard as well as how alternatives assessments can help avoid unintended consequences that might result from complying with a standard affecting one media or population.

Questions for discussion

- What is the role of alternatives assessment in regulatory agencies whose mandate is to ensure safety or avoid unacceptable risks?
- How can alternatives assessment support evaluation and adoption of informed substitutes while meeting safety standards (given a different focus on hazard reduction versus exposure-basis)? Or is there a need for a different type of safety standard, i.e. criteria for a particular function/process, that would allow the use of alternatives meeting those criteria?
- Where does exposure assessment fit in in such efforts?
- Can we avoid time consuming and resource intensive debates over acceptable levels of exposure if we focus on alternatives assessment?

Agencies Represented

- OSHA
- CPSC
- NIOSH
- EPA
- Environment Canada
- DoD
- States: NJ, MA, NY, WA, CA, MI, NE
- Others: SF, PPRC