May 24, 2012

Exposure Assessment Module Outline:

Purpose: The exposure assessment module is expected to be used after the hazard assessment module in order to optimize risk reduction. By applying hazard screening first, one can narrow down the options to those that are more likely to be acceptable.

Exposure assessment can support selection of alternatives when the inherent hazards are equivalent or when the functional use of one alternative would result in an increased exposure profile, (The exposure profile encompasses risk due to the quality and quantity of the resulting exposure). ~~(exposure profile)~~. It is assumed that not all alternatives will result in the same exposure scenarios. Both near field (direct consumer) and far field (environmental) exposures are considered. This~~e~~ exposure assessment module may also be used independently of the other modules and applied to all options.

Comment [MG1]: As worded, could imply that the definition of " exposure profile"includes increased risk,

Background:

According to Centers for Disease Control and Prevention[1], a hierarchy of exposure controls has been used to protect workers. The same approach identified to protect workers applies to protecting consumers and the environment from exposure to hazardous chemicals. The concepts behind the hierarchy of exposure controls are integrated into the Alternatives Assessment guidance and can be summarized as follows:

1. Elimination
2. Substitution
3. Engineering Controls
4. Administrative Controls
5. Personal Protective Equipment

Comment [MG2]: What about process changes??? Just throwing that out

The control methods at the top of the list are considered more effective and protective than those at the bottom. Elimination and substitution are most effective at reducing hazards and risk. They can best be applied when the product or process is still open to design and/or development and may be the most inexpensive and simple to implement from the exposure perspective. Engineering controls can reduce risk by putting a barrier between the user and the hazard. While engineering controls may be effective, engineering controls can fail, upon which time, the risk will increase.

Administrative controls and personal protective equipment are frequently used in the work environment. They may be inexpensive in the short term but tend to be costly over time. Administrative controls and PPE are not feasible for reducing exposures to consumers and to the environment because manufacturers cannot fully control how chemicals and products are used.

With respect to consumers and consumer products, a similar control hierarchy can be defined. Elimination represents the removal of toxic chemicals from products; substitution represents the use of alternative and presumably inherently safer chemicals to make consumer products Engineering controls

[1] http://www.cdc.gov/niosh/topics/engcontrols/

refer to design such as packaging that is intended to prevent exposure during product use; examples of administrative controls on a consumer product could include careful directions and/or warnings for proper use such as use with ventilation; and personal protective equipment (PPE) may be recommended for use with certain products. As with the occupational hierarchy, the most effective mechanisms for consumer exposure to toxic chemicals in consumer products are the elimination of hazardous chemicals and/or the substitution with safer alternatives. It is beyond the control of manufacturers to prevent consumers from tampering with engineering controls or ensuring that they follow directions and use recommended PPE.

Need intro /transition here – something about "there are six levels, progressively more comprehensive. Users can work level 1 for an initial prelim/high level assessment (?) all the way to level 6 with very detailed and comprehensive assessment.

Question needs to be answered: If I want to conduct a level 4, do I go through level 1 to 3 first, or do I just skip straight to level 4?

Comment [MG3]: Also – seems like a few of these could be combined. Level 4, 5, 6 seem to have lots of redundancies… why would I pick a level 4, vs. 5, vs. 6?

Level 1

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The objective of this level is to determine if the exposure pathways and potentials are similar enough between the chemical of concern and potential alternatives that no further exposure evaluation is necessary.

Record the findings and answers to these questions for the final conclusion for level 1

Comment [M4]: Going thru these questions, the reader doesn't quite know the "end result" /outcome – answers to these questions will be used for. Are they supposed to answer all the questions in some sort of fashion/record it, etc. so they can follow the instructions on the "based on the …." Paragraph at end of level 1.

- Have you compared the exposure pathways between the chemical of concern and the potential alternative? Are they similar?
    - Are the chemical properties of the two chemicals similar for the following characteristics? Only evaluate those criteria pertinent to the chemicals being evaluated.
        - Volatility/vapor pressure
        - Molecular weight
        - Molecular size
        - Solubility
            - Log K_{ow}
        - Boiling point
        - Melting point
        - Density/specific gravity
        - pH
        - Corrosivity
        - Dissociation constant
        - Use characteristics (binding properties) or synergistic effects
        - Any others?
    - Are the manufacturing uses ~~criteria~~ similar?

- Do they perform the same function in the product?
- Are they used in the same relative amounts?
- Are they used in the same manner? For example, are they both blended into the product matrix as opposed to being chemically attached to the product matrix?

(Reference Performance Module for more information on manufacturing criteria)

- Are the fate, transport and partitioning in environmental media similar? Are releases for the two chemicals likely to be similar for the following pathways?
  - Air
  - Water
  - Sediment/soil

  (For example, you are replacing one plasticizer with another, safer alternative. The new plasticizer is from the same chemical family, uses the same amounts and is used in the product in the same manner. Are there any reasons why the fate and transport would be different for the new plasticizer compared with the previous, such as higher volatility?)

- Are the release mechanisms during the product life cycle similar? Are releases for the two chemicals likely to be similar for the following pathways?
  - Product
  - Manufacturing
  - Transport
  - End-of-life

  (For example, you are replacing a halogenated flame retardant with another, safer alternative. The new flame retardant is used in the same amounts, in the same manner (additive) and the product is going to undergo the same lifecycle, i.e. manufacture, use, end-of-life, etc. Is there anything that would affect its release to the environment that warrants further review, such as higher leachability?)

- Based upon the above evaluation, are there any substantive differences between the use, chemical properties, and physical characteristics that could substantively affect exposure, like what??? More explosive, reactive, flammable, requires additional handling, ?
  - If no, no need to proceed with any further exposure assessment. Identify that the uses, fate and transport, and potential exposure pathways are similar between the two chemicals so that exposure concerns become irrelevant.
  - If yes, continue with the exposure assessment.

Level 2

The objective of this level is ….

- Have you assessed the chemical options for hazard?
  - If no, start with Level 2 (of the hazard assessment module or this module?)

Comment [M5]: This seems unrelated to overarching bullet above – asking about the exposure path. The other 2 bullets I can make some connection to how these could impact exposure levels, but not directly obvious.

Comment [MG6]: Need better example – this means nothing to a non-chemist and doesn't tell me if there might be higher risk of exposure – e.g., say the new alternatives offgasses or creates more dust in the blending process…. Something a bit more tangible.

Comment [MG7]: I don't know if ithis is a good thing to add, but your examples need a little more suggestive/spurring concept.

Also, this one is not indented as far as above paragraph.

Comment [MG8]: Again, need an example (or a few) of the characteristics you are thinking about.

Comment [MG9]: And, if you saying to start with level 2 of the exposure module, then the user could have skipped all of level 1 above, but doesn't know that… confused.

- If yes, has the chemical been fully assessed and been defined as inherently benign for all hazard criteria (i.e. GS Benchmark 4)?
    - If yes, a full exposure assessment is not necessary
        - Engineering controls and proper risk management should always be applied (water can kill you!)~~)~~.
    - If no, select the lowest hazard options first to apply to Level 2
- Are there circumstances under which the chemical may still pose a risk based on its physical and biological hazard characteristics?
    - Inhalation (dust, oxygen displacement)
    - Temperature
    - Electrocution
    - Mold
    - Entrapment
- To what extent is the product designed to avoid such risks?

In general, this section doesn't compare the new alternative to the existing alternative like level 1 does.,

Level 3:

The objective of this level is….

- Has the chemical been found in bio- and environmental monitoring studies?[2]
    - If yes, classify it as a non-viable alternative unless a higher degree of evaluation is performed. One cannot assume that a chemical found in monitoring studies poses a risk without additional evaluation. This could include hazard or exposure assessments. However, for this simplified initial evaluation, we are assuming that presence in monitoring studies is a concern.
    - If no, have ~~s it been looked for in~~ bio- and environmental monitoring studies been scanned/researched and the chemical not found?
        - If yes, identify the chemical as a viable alternative and proceed with evaluation.
        - If no, identify exposure as a serious data gap that may affect the chemical's viability as a safer alternative.
- Consider the chemical presence in the product. **Qualitatively**, what are the pathways of exposure during:
    - Manufacturing of the chemical or the product?
    - Transportation and/or storage of the chemical or the product?
    - Use of the product?
    - End-of-life?
    - Do any of these pathways pose a substantial exposure pathway?
        - If no, identify the chemical as a potential viable alternative and proceed with evaluation.
        - If no, identify exposure as a serious data gap that may affect the chemical's viability as a safer alternative.

[2] See Exposure Module Resources?

Comment [M10]: Unsure what the 'lowest hazards' are?

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Comment [MG11]: What if it was found in trace amount? Insignificant amount based on the environment fate of the chemical? Don't you want a threshold of some sort? Or, how would you do that for all chemicals….

Also – not sure which bio/environment monitoring studies or how many you would want the user to review?

And footnote 2 – I don't recall seeing anything in hazard module about such studies.

Comment [M12]: Same as above – are you

Comment [MG13]: If they don't pose a pathway, that makes it a data gap??? That doesn't make sense. It's a lack of data (not exposure /response data that makes a data gap, correct??)

- Have you screened the chemical for persistence and bioaccumulative properties based on risk and hazard phrases (Level 1 of Hazard Module)?
  - If yes, highly persistent and/or highly bioaccumulative and/or toxic chemicals (vPvB, vPT, vBT, PBT) should be removed from consideration.
  - If no, conduct a screen of the chemicals using hazard lists and risk or hazard phrases as defined in Level 1 of the Hazard Module.
    - Highly persistent and/or highly bioaccumulative and/or toxic chemicals (vPvB, vPT, vBT, PBT) should be removed from consideration.
    - Others (not vPvB, vPT, vBT, PBT), may still be considered
- Does the chemical have other inherent properties that contribute to its likelihood to lead to exposure?
  - ~~-~~Is it very water soluble?
  - Does it volatilize readily into the air?
  - Is it in a size or form that makes it easy to inhale or ingest?
  - Is it likely to escape into the indoor or outdoor environment?
    - Refer to Appendix[3]:
    - If yes, then what???
- Have steps been taken during the design and manufacture of the chemical or product to:
  - Eliminate the need for the chemical?
  - Or to allow for the substitution of a less hazardous alternative?
  - Or to reduce the possibility of exposure? For example, can the chemical be bound in the product in such a way that prevents dissociation, leaching or volatilization?

Level 4: (any new info required?)

The objective of this level is …

- Has the chemical been found in bio- and environmental monitoring studies?
  - If yes,
    - What are the levels at which it is found?
    - How broadly is it found in humans or mammals?
    - How broadly is it found ~~and~~ in the environment (water, air, sediment)?
    - Has it been found in sensitive populations?
    - Are there known hazards associated with this chemical? (Refer to Hazard Module)?
      - Eliminate from consideration chemicals found in monitoring studies with known hazards relative to the target organism or sensitive populations.
  - If no, continue with analysis.

- Consider the chemical presence in the product. Have emissions, worker, user or environmental exposures to the chemical been reported or measured during:
  - Manufacturing of the chemical or product?
  - Transportation and/or storage of the chemical or product?
  - Use of the product?
  - End-of-life?

[3] See Appendix #?: Examples of Exposure Pathways and Chemical Properties that May Enhance Exposure

Comment [MG14]: The v = "very". So, what if they get a "high" on P or B, but not a "very high"?

Comment [MG15]: If all chemicals are removed from consideration due to this, then do they stop the assessment process?

Comment [MG16]: What do you do if they are not on high/verh high?0

Comment [MG17]: Too detailed to try and put a threshold on when it becomes a concern?

Comment [MG18]: For what? And what's in appendix 3 – are you talking about the hazmodule?

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Comment [MG19]: Again, still confused on whether you progress from level 1 on, or just start at whatever level you want to….

Comment [MG20]: What does one do with this information then?

Comment [MG21]: Above, you said, if no data on bio/environmental studies, that it was a data gap ???

Comment [MG22]: Reported to who? By who? Where would one find reported exposures? OSHA?

- What is the quantity of the chemical(s):
  - Used during manufacture of the product?
  - In the product as it is used?
  - Released after use or at end-of-life?
  - Do changes in quantity affect the exposure at any of those stages?
- How could the product be redesigned to reduce exposure during manufacture, transportation and/or storage, use and end-of-life?
  - Does redesign affect the type or extent of exposure?
  - Does redesign affect the quantity of the chemical used?
    - If yes:
      - Does it allow for elimination, substitution or reduction in use of the chemical?
      - Do changes in quantity affect the exposure?
- Have you evaluated the chemical for persistence and bioaccumulative properties based on estimated or measured properties (Hazard Module Level 3)?
  - If yes, highly persistent and/or PBT chemicals should be removed from consideration based on estimated or measured properties
  - If no, estimate values for P and B using computer models such as the EPA PBT profiler (Hazard Module Level 3)
    - Highly persistent and/or PBT chemicals should be removed from consideration based on estimated or measured properties.
- Does the chemical have other inherent properties that contribute to its likelihood to lead to exposure? (See Appendix for examples of pathways of exposure to consider.)
  - Is the chemical more likely to volatilize or leach from a product or from the manufacturing process
    - Is it more volatile or soluble?
    - Are particle sizes and/or shapes, etc. a factor?
    - Inhalation potential?
    - Consider physical properties relevant to exposure
  - Eliminate chemicals that have a higher likelihood of completing a human or environmental ~~n~~ exposure pathway.

Level 5

The objective of this level is …

- Has the chemical been found in bio- and environmental monitoring studies?
  - How do those levels compare to toxicity thresholds for the spectrum of hazard endpoints in a chemical hazard assessment?
  - How does it compare to ambient levels?
  - How do these levels compare to levels associated with adverse effects, particularly for sensitive populations?
    - Eliminate from consideration those chemicals with a higher likelihood for exposure via relevant pathways and known physical properties relative to their toxicity, particularly to sensitive populations
- Have you evaluated the chemical for persistence and bioaccumulative properties based on reviews of scientific literature, test data, and public data repositories (Hazard Module Level 4~~2~~)?

Comment [MG23]: The existing, and the new? Do you want to compare - otherwise you don't really have anything to base a decision on.

Comment [MG24]: Above, you had 'very high', not just the "H" rank.

Comment [MG25]: Possibly you should discuss the pathways briefly, at beginning of document?

- If yes:
  - Highly persistent and/or PBT chemicals should be removed from consideration based on estimated or measured properties.
  - Chemicals with low persistence and bioaccumulation potential ~~should be~~are preferred.
- If no:
  - Evaluate persistence and bioaccumulation based on reviews of scientific literature, test data, and public data repositories including octanol-water (K_{ow}) and organic carbon coefficients (Koc) and models such as EPISUITE. (Hazard Module Level 4).
    - Highly persistent and/or PBT chemicals should be removed from consideration based on estimated or measured properties.
    - Chemicals with low persistence and bioaccumulation potential should be preferred.
  - Measure how the product redesign leads to reduced exposure during manufacture, transportation and/or storage, use and end-of-life for the chemical or product.

Level 6

The objective of this level is …

- Consider all possible pathways of exposure for the chemical in scenarios related to manufacture, transportation and/or storage, use and end-of-life for the chemical and product:
  - Have you estimated exposure from each scenario?
    - If not:
      - Justify estimates or conduct testing and measurement of levels of exposure of the chemical during manufacture, transportation and/or storage consumer use, and end-of-life**.**
- Do you have good data for the chemical for persistence and bioaccumulative properties based on reviews of scientific literature, test data, and public data repositories?
  - If yes:
    - Ensure quality and accuracy of results by engaging expert assessment and/or peer review.
  - If no:
    - Supplement data gaps with test data.
  - Chemicals with low persistence and bioaccumulation potential are ~~should be~~ preferred
- Consider likelihood of exposure to populations that may have greater sensitivity (developing fetus, young children, those with specific conditions).
  - Eliminate chemicals that have a higher likelihood resulting in exposure to humans, accumulating in the environment or in humans, especially sensitive populations.
- Consider likelihood of exposure to organisms in the environment that are important for healthy ecosystems (aquatic and terrestrial).
  - Eliminate from consideration those chemicals with a higher ecotoxicity and likelihood for exposure via relevant pathways and known physical properties.

Comment [MG26]: Above, "very"

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Comment [MG27]: How do we know which of these organisms are "important for healthy ecosystems"?

Comment [MG28]: This almost sounds like a command relevant to a hazard assessment, not an exposure assessment, but maybe I'm ignorant.
And, what constitutes "higher" ecotoxicity – refer back to hazard assess criteria?

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Appendix
Examples of Exposure Pathways and Chemical Properties that May Enhance Exposure

For each level in this module, some examples of pathways of exposure to consider:

- Inhalation
  - Outdoor~~s~~
    - Emissions to air during manufacture (volatile and particulate)
  - Indoor~~s~~
    - Volatilization
    - Particulates
- Ingestion
  - Discharge to water during manufacture
  - Leaching or disassociating or degradation from the product into:
    - Water (groundwater or surface water)
    - Food (including wildlife that could become a food source)
    - Mouth (e.g. food containers or children's toys)
    - Indoor dust
    - Soil
- Dermal
  - Products ~~intended for~~ used on skin
  - Products that have the potential to be in contact with skin
  - Leaching or disassociating from the product
    - Indoor dust
  - Water used for washing/cleaning
- Injection
  - Products for use in medical treatment
  - Products for cosmetic use (e.g., tattoos)
- Presence in the environment and in living organisms
  - Biomonitoring
  - Environmental monitoring
- Inherent properties of the chemical including:
  - Persistence
  - Bioaccumulation potential
  - Volatility
  - Particle size and shape
  - Bioavailable

Comment [MG29]: With kids, if emissions travel, end up in soil at residences? Maybe a stretch, but…. The lead people always talk about kids hand-to-mouth results in ingestion of soil

Comment [MG30]: This does not represent an exposure pathway example (as stated in intro to this section), this is a property thing only. It needs to be moved, or explained that these properties can affect exposure/dose response

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Terms for Glossary: (check to ensure that these are in the Master Glossary and provide definitions)

1. Risk assessment
2. Hazard assessment
3. Exposure assessment
4. Exposure profile
5. Functional use
6. Exposure scenarios or exposure profile
7. Exposure pathways – general definition in glossary; refer to appendix in Exp. Module for detail and clarification
8. Near field exposure
9. Far field exposure
10. Bio-monitoring
11. Environmental monitoring
12. Life cycle includes mention of life-cycle stages; what do we mean by "end of life"?)
13. vPvB, vPT, vBT, PBT

Resources (TBD)
(See EPA Workplan for Chemical Screening for Additional Monitoring Resources)

PBT lists
See hazard criteria for P and B (link to hazard module)
PBT Profiler
VOC lists
MSDSs
Chemical properties
Resources for bio and environmental monitoring studies? E.g. WA Children's Safe Products Act published the list of chemicals found in monitoring studies; other resources and websites; e.g. NHANES, Texas, WA State- how would we compile and maintain this? Is CA doing anything like this with their Green Chemistry legislation? Is it part of the Toxics Clearinghouse?

Contamination in wildlife: http://www.pwrc.usgs.gov/ceetv/ceetvform.cfm

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Notes (not part of module):
NR notes – Could use some references here to models or sources of literature to check for Levels 3 and 4, such as appear in Safer Product Alternatives Analysis: Methods, Models, And Tools Report to the Department of Toxic Substances Control by Brandon Kuczenski and Roland Geyer, January 2011. Section 4.21 Exposure Screening Methods
Notes from exposure research:[4]

1. **Capture near field and far field exposure over the life cycle**
2. compartments: air, water, soil, food
3. source to dose
4. frequency
5. persistence in the environment
6. persistence in the indoor environment
7. Use of exposure surrogates or sentinels
8. Product use scenarios
9. Use rates
10. Potential to get to groundwater
11. Potential for exposures to children
12. Quantity in commerce
13. Number of companies making or using it
14. Expert judgment based on use
15. Physical-chemical properties
16. Bioavailability
17. P
18. B
19. Bioaccumulation, bioconcentration, biomagnification
20. Direct consumer exposure relative to indirect environmental exposure
21. P and B do not reflect exposure due to consumer use
22. Reaction products, degradates and metabolites
23. Exposure scenarios (mfg, use, end-of-life)
24. Emissions over lifecycle
25. Fate and distribution (degradation, transformation, reaction processes)
26. Exposure estimates (workers, consumers, environment)
27. See figure 1 as an exposure overview model
28. Mass balance in food
29. Intake
30. See REACH guidance
31. Tiering, frequency, duration
32. See ECHA guidance(guidance.echa.europa.eu
33. EPA: production volume, chemical release, product formulation, use category, PChem properties; P and B; # producers; consumer use, mfg use
34. Env release, environmental fate
35. See risk based prioritization re exposures to children (Alex)

[4] Egeghy, P.P., et al., Exposure-based prioritization of chemicals for risk assessment. Environ. Sci. Policy (2011), doi:10.1016/j.envsci.2011.07.010

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From ECHA guidance
Exposure assessment aims to make a quantitative or qualitative estimate of the dose / concentration of the substance to which humans and the environment are or may be exposed. Exposure assessment under REACH consists of two steps: 1) Development of Exposure Scenarios and 2) Exposure Estimation, which have to be iterated until it can be concluded that the resulting exposure scenarios would ensure adequate control of risks upon implementation.

Exposure scenario
Set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control exposure of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

Run through module considering alternatives that are:
1. completely low hazard (eg BM4)
2. mixed hazard
3. high hazard
4. what has been done to address exposure
5. use scenarios and exposure estimates over the life cycle

NIOSH hierarchy
Here is a link to the hierarchy: http://www.cdc.gov/niosh/topics/engcontrols/

Hierarchy of Controls (download ref and page)

Controlling exposures to occupational hazards is the fundamental method of protecting workers. Traditionally, a hierarchy of controls has been used as a means of determining how to implement feasible and effective controls. One representation of this hierarchy can be summarized as follows:

1. Elimination
2. Substitution
3. Engineering controls
   - Modification
   - Containment
   - Ventilation
4. Administrative controls; *work practices*
5. Personal protective equipment

The idea behind this hierarchy is that the control methods at the top of the list are potentially more effective and protective than those at the bottom. Following the hierarchy normally leads to the implementation of inherently safer systems, ones where the risk of illness or injury has been substantially reduced.

Elimination and substitution, while most effective at reducing hazards, also tend to be the most difficult to implement in an existing process. If the process is still at the design or development stage, elimination and substitution of hazards may be inexpensive and simple to implement. For an existing process, major changes in equipment and procedures may be required to eliminate or substitute for a hazard.

Administrative controls and personal protective equipment are frequently used with existing processes where hazards are not particularly well controlled. Administrative controls and personal protective equipment programs may be relatively inexpensive to establish but, over the long term, can be very costly to sustain. These methods for protecting workers have also proven to be less effective than other measures, requiring significant effort by the affected workers.

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The initial cost of engineering controls can be higher than the cost of administrative controls or personal protective equipment, but over the longer term, operating costs are frequently lower, and in some instances, can provide a cost savings in other areas of the process.

Image but slightly different:

The National Institute for Occupational Safety and Health (NIOSH) has established a hierarchy of exposure control practices, as is shown in Figure below. Switching to inherently low hazard chemicals can benefit workers by decreasing workplace risks through elimination and substitution of hazardous chemicals.

Figure 1: NIOSH Traditional Hierarchy of Exposure Control Practices