

IC2 AA Guide

Minimum Recommended Modules



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Minimum Recommended Modules

- Hazard Evaluation
 - Hazards are associated with alternatives?
- Performance Module
 - Do alternatives function?
- Cost & Availability
 - Are alternatives sufficiently available at a reasonable cost?
- Exposure
 - What exposure potential is associated with alternatives?



Hazard Module

Alex Stone
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Hazard Module

- Hazard: Set of inherent properties of a substance, mixtures or processes that, under production, usage, or disposal, makes it capable of causing adverse effects to humans, animals, & the environment.
- Basis of an AA:
 - Increasing consumer concerns about toxic chemicals in products & impact upon human health & environment.
 - Documented cases of regrettable substitution.



Hazard Module (cont)

Regrettable substitution:

- Replace toxic chemical with one of equal, or even higher, toxicity.
- Swap devil you know for devil you don't!



Hazard Module (cont)

- Asks what hazards are associated with COC & alternatives?
- Initial screen & three levels of evaluation.
- Greater expertise needed as levels increase.



Hazard Module (cont)

Initial Screen	<i>Initial Screen:</i> Uses several readily available sources to evaluate whether a chemical, product or process appears on authoritative lists of hazard criteria.
Level 1	<i>Basic Evaluation:</i> Utilizes the Quick Chemical Assessment Tool (QCAT) to determine if hazards exist for specific hazard criteria using well-defined, readily available data sources.
Level 2	<i>GreenScreen[®] Evaluation:</i> Uses the GreenScreen for Hazard Assessment tool (GreenScreen [®]) to conduct a thorough hazard evaluation. The GreenScreen [®] is a free, publicly available hazard assessment tool.
Level 3	<i>Expanded GreenScreen[®] Evaluation:</i> Expands upon Level 2 by eliminating data gaps & requiring an independent, third party verification.

Hazard Module (cont)

Initial Screen-List Translator:

- Compares alternatives against authoritative lists.
- If alternative found on list, identified as less favorable alternative.
- Removed from consideration as alternative.
- Little expertise needed.
- Inexpensive sources available.



Hazard Module (cont)

Level 1-Quick Chemical Assessment Tool:

- Developed by Ecology primarily for small & medium businesses.
- Reviews 9 hazard endpoints: PBTs, CMRs, Worker Health & Safety & Aquatic toxicity.
- Two step process:
 - Step 1: List Translator, same as Initial Screen.
 - Step 2: Specific, accessible authoritative sources.
- If no data available, alternative identified as less favorable & removed from consideration.
- Little knowledge or expertise needed to implement.



Hazard Module (cont)

Level 2-GreenScreen[®] for Safer Chemicals:

- Collects data on 18 hazard endpoints.
- Bins alternatives into four ‘benchmarks’ from BM 1 (avoid) to BM 4 (Preferred)
- Higher benchmark alternatives identified as favorable & continue in assessment process.
- If no data available, alternative identified as less favorable & removed from consideration.
- Requires knowledge or expertise to implement.

Hazard Module (cont)

Level 3-Advanced GreenScreen[®]:

- Builds upon analysis in Level 2.
- Data gaps not allowed.
- Uses modeling, professional judgment, etc. to fill in data gaps.
- Requires considerable knowledge or expertise to implement.
- Most complete analysis.



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Performance Module

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State of Massachusetts**



Helpful Sources Used

Massachusetts Toxics
Use Reduction
Institute (TURI)
methodology

http://www.turi.org/Our_Work/Research/Alternatives_Assessment/TURI_Alternatives_Assessment_Method_-_5_Chemicals_Study

European Chemicals
Agency (ECHA)
guidance

http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf

US EPA Design for
Environment (DfE)
Program

Cleaner Technology
Substitutes
Assessments

Guide Provides Levels of Detail

Table 8: Performance Levels

Level 1	<i>Basic Performance Evaluation:</i> Identifies a few, very basic questions about whether the alternative performs the required function in the product. This level uses qualitative information readily available from manufacturers and other sources to evaluate alternatives.
Level 2	<i>Extended Performance Evaluation:</i> Builds upon the information obtained in Level 1 to determine whether the alternative performs the required function in the product. It uses quantitative information of existing data reviewed by technical experts in the field to evaluate alternatives.
Level 3	<i>Detailed Performance Evaluation:</i> Expands upon the previous levels. It uses quantitative information to evaluate alternatives based upon results of specified tests reviewed and validated by technical experts.

Performance, Level 1: Basic Evaluation

Assess if an alternative is favorable based on current knowledge of:

- Existing use
- Marketing information
- Publicly available reports

Focus is on qualitative information

Asks series of questions

Questions Explored

- What are the performance needs & function?
 - on chemical, material, product & process levels
- Are alternatives already being used?
 - Similar application/function
 - Being marketed
- If an alternative is currently being used successfully & is applicable to company's needs
 - **DONE**



Continued Questioning

- Do authoritative studies suggest adequate function for similar application?
 - If yes, consider this viable
- Are there other indications that it might NOT function adequately?
 - Is the difference related to a critical performance criterion?
 - If yes, **STOP**
- Do expert sources consider alternative to NOT be viable?
 - If identical application, **STOP**
 - If information related to a different application, can modifications be applied? If no, **STOP**



Performance, Level 2: Extended Evaluation

Assess if an alternative is favorable based on guidance from technical experts

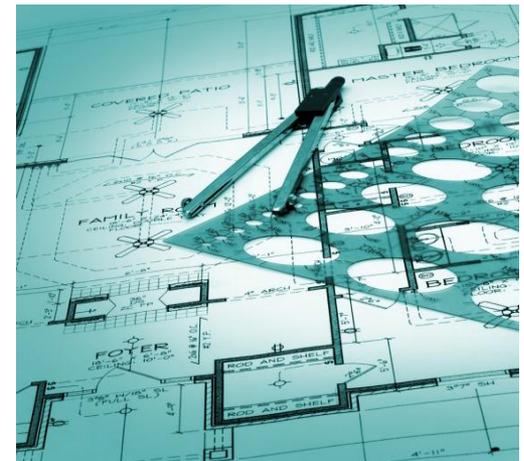
- Process engineers or scientists
- Academic researchers
- End users
- Marketing or sales staff
- Consultants

Uses both quantitative & qualitative information

Asks series of questions

First Screen for Technical Expert Independence or Bias

- Are experts part of management structure?
- Are experts influenced by external factors that could bias results?
 - If yes, obtain additional experts or document information used to reach conclusions
- Has the information been corroborated by ≥ 2 independent experts
 - If yes, proceed



Test Data on Performance of Alternatives

- Consider:
 - Regulated performance
 - Customer acceptance
- Sufficient to assess technical feasibility?
- Other means available to determine technical feasibility?
 - ECHA guidance suggests use of performance scale for each critical performance measure
 - Consider only **objective** (e.g., determined according to industry standards) characteristics
 - Document results



Possibility of Adverse Impacts

Consider:

- Reliability
- Quality & Useful Life
- Customer Acceptance
- Efficiency
- Downstream Process Performance
- Maintenance Requirements

If yes,

- Are modifications to mitigate the impact possible?
- Test & document results

If no,

- **DONE**

Performance, Level 3: Comprehensive Evaluation

Rely on quantitative results from additional experiments or tests

Consult with technical experts

Asks series of questions

Testing, using industry standards & tolerances

- Already conducted? If not, perform appropriate testing.
 - If alternative passes, proceed to product design/development
 - If not, can modifications be made to accommodate alternative?
- Do results support assessment of technical experts
 - Process modifications possible?
 - Is discrepancy sufficient to disqualify alternative?



Lead



Perchloroethylene



FIVE CHEMICALS

ALTERNATIVES

ASSESSMENT STUDY

Executive Summary

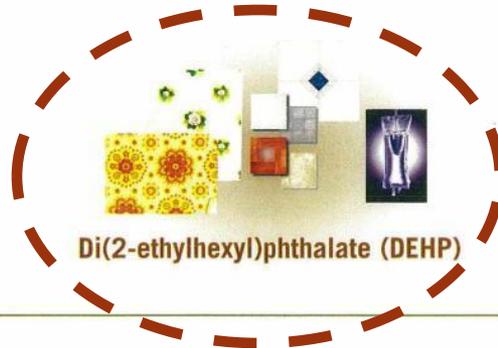
June 2006



Hexavalent chromium



Formaldehyde



Di(2-ethylhexyl)phthalate (DEHP)

Example of Level 2
Performance
Evaluation:
TURI's 5 Chemicals
Alternatives
Assessment Study



Prepared by the Toxics Use Reduction Institute at the
University of Massachusetts Lowell



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Cost & Availability Module

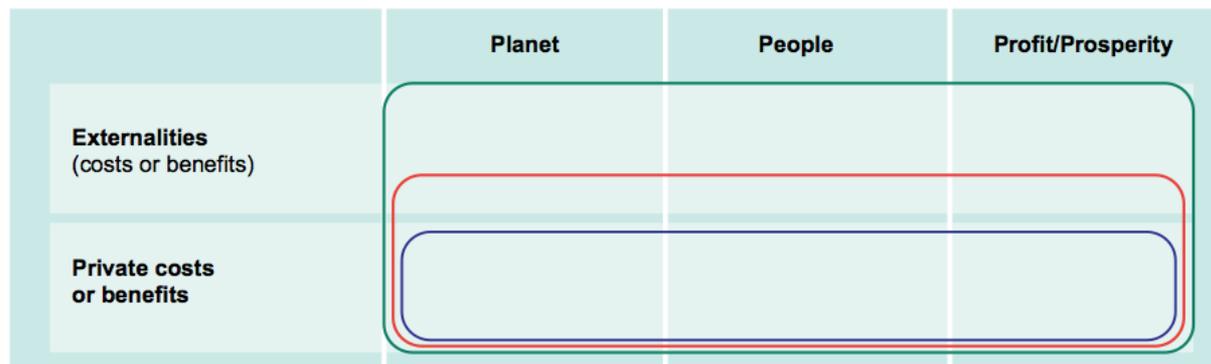
**Bob Boughton
State of California**



Cost & Availability Module

Cost & Availability Module:

- Determines if alternatives are cost effective & available in sufficient quantity.
- Important to consider whether market could respond to request.
 - If demand increases, can alternative be produced at



- Conventional LCC: assessment of private costs and benefits, internal to the organization
- LCC: additional assessment of external relevant costs and benefits anticipated to be privatized
- Societal LCC: additional assessment of further external costs

Cost & Availability Module (cont.)

Impacts Associated with Life Cycle Costing:

- Human health & Environment.
- Economic.
- Social.
- Consists of:
 - Four levels of increasing complexity & detail.
 - Advanced options including full Cost/Benefit evaluation.

Cost & Availability Module (cont.)

C & A Levels:

Level 1	<i>Basic Cost & Availability Evaluation:</i> Few, very basic questions about whether alternative is being used in cost competitive products. If yes, alternative is considered feasible.
Level 2	<i>Extended Basic Cost & Availability Evaluation:</i> Builds upon Level 1 to determine if the alternative is both available & cost effective. Goes beyond whether or not alternative is currently being used to determine if it could be available & cost effective if selected.
Level 3	<i>Chemical & Material Cost & Availability Evaluation:</i> Expands upon Level 7 to include cost & availability of the material in which it will be used. It also introduces LCC & requires an initial review of possible impacts due to LCC.
Level 4	<i>Chemical, Material & Re-designed Cost & Availability Evaluation:</i> This level adds requirements to assess costs & benefits associated with product redesign to accommodate use of the alternative. The focus is on private costs & benefits. It also includes a more detailed LCC evaluation.
Advanced (see LC Mod., Level 3)	<i>Full Cost/Benefit Analysis Evaluation:</i> Implements full cost/benefit analysis & a more detailed LCC evaluation including externalities as appropriate. It is the most complete & comprehensive evaluation of cost & available considerations.

Cost & Availability Module (cont.)

Level 1:

- Limited evaluation.
- Only limited knowledge & expertise required by assessor.
- Two simple questions:
 1. Currently used in similar applications?
 2. Alternative offered for sale for application of interest.
- Throw broad net to answer questions including suppliers, suppliers competitors, trade associations & other readily available information.

Case Example: *Deca-BDE in Televisions & Computers & Residential Upholstered Furniture, Washington Department of Ecology & Washington Department of Health*

In 2008, the Washington Departments of Ecology & Health conducted an [AA for Deca-BDE](#) in electronic housings & residential upholstered furniture. For both types of applications, the assessment found that alternatives to Deca-BDE were already widely used. The AA found that the alternatives must be cost-effective, or manufacturers would not voluntarily be using them.

Cost & Availability Module (cont.)

Level 2:

- Builds upon Level 1 evaluation.
- Requires additional information including detailed pricing & availability of alternatives.
- Determination includes assessment if alternative **COULD** be available & cost competitive if demand increases.

Case Example: *Five Chemicals Study AA Study, Toxics Use Reduction Institute*

In 2006, the Toxics Use Reduction Institute (TURI) at the University of Massachusetts-Lowell assessed alternatives for five chemicals: lead & lead compounds, formaldehyde, perchloroethylene, hexavalent chromium, & di(2-ethylhexyl)Phthalate (DEHP). The legislature directed TURI to assess potential effects on the employment level & the economic competitiveness of the Commonwealth associated with adopting alternative chemicals or technologies. An evaluation of cost & availability was an integral part of the assessment.

Cost & Availability Module (cont.)

Level 3:

- Builds upon Level 2 evaluation.
- Includes evaluation of material to determine if any changes could be made to the material(s) used to reduce cost & availability limitations for the alternatives.
 - For example, alternative may be unacceptable because of a need for an increased amount of chemical. Can the product formulation be changed to reduce the chemical need, thereby making the alternative more favorable?
- Requires broader perspective on how alternative could be used.
- Mitigation review added to determine if any other actions can eliminate potential limitations.

Cost & Availability Module (cont.)

Level 4:

- Builds upon Level 3 evaluation.
- Includes evaluation of possible product re-design to determine if any changes could be made to reduce cost & availability limitations for the alternatives.
 - For example, alternative may be unacceptable because of a need for an increased amount of chemical. Can the product be redesigned to reduce the chemical need, thereby making the alternative more favorable?
- Requires broader perspective whole product perspective.
- Mitigation review added to determine if any other actions can eliminate potential limitations.

Cost & Availability Module (cont.)

Advanced Level:

- Most complete & detailed evaluation.
- Uses traditional cost benefit analyses (CBA) & LCC techniques.
- Deferred to Life Cycle Module as consideration of a more detailed analyses is most effective when adopting a full life cycle perspective.
- Indicative that other models & options that are more detailed & comprehensive may be used.

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Exposure Module

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Exposure Module

- Used after Hazard Assessment to reduce risk by optimizing both components of risk equation.
- Supports selection of alternatives when inherent hazards are equivalent.
- Not all alternatives will result in same exposure scenarios.
- Both near field (direct consumer) & far field (environmental exposures) are considered.

Exposure Module (cont.)

- Based upon Centers for Disease Control & Prevention hierarchy of exposure controls.

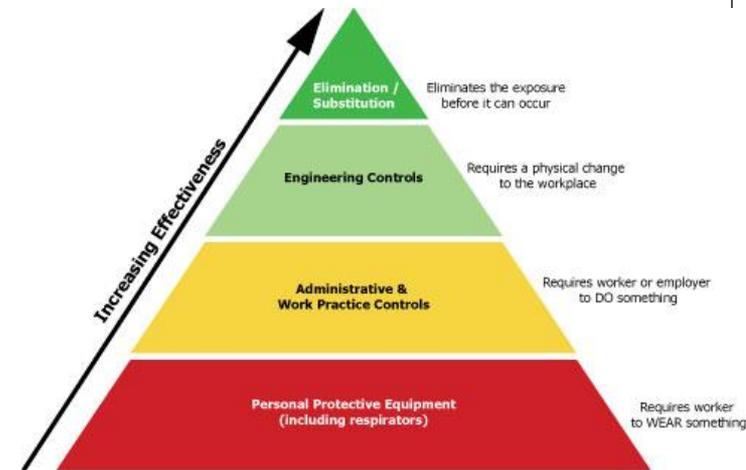
1. *Elimination.*

2. *Substitution.*

3. *Engineering Controls.*

4. *Administrative Controls.*

5. *Personal Protective Equipment.*



- Methods at top of list are considered more effective & protective.
- Contains initial screen, 3 Levels & advanced

Exposure Module (cont.)

Exposure Levels:

Initial Screen	<i>Initial Exposure Assessment Evaluation:</i> Asks if sufficient similarities exist between COC & potential alternative(s). If so, differences in exposure concerns between the COC & potential alternatives are inconsequential to the AA.
Level 1	<i>Basic Exposure Evaluation:</i> Identifies potential concerns & how concerns may be addressed. Qualitative assessment using readily available data.
Level 2	<i>Expanded Exposure Evaluation:</i> Increases quality & quantity of information. More detailed quantitative data is required to evaluate exposure in AA process.
Level 3	<i>Detailed Exposure Evaluation:</i> Requires detailed scientific studies as basis for decisions. If studies unavailable, conducted & data used to evaluate exposure.
Advanced	<i>Full Exposure Assessment:</i> Recommends detailed exposure assessment as defined in the Risk Assessment Process by the National Academy of Sciences.

Exposure Module (cont.)

Initial Screen:

- Asks question ‘Is an exposure assessment necessary?’
- If exposure pathways & potentials are similar between COC & alternatives, no exposure evaluation is necessary.
- Assessor should evaluate this decision throughout guarantee that no actions are taken which negatively impact this assumption.

Exposure Module (cont.)

Level 1: Basic Evaluation

- Uses readily available qualitative data.
- Alternatives labeled as unfavorable if:
 - Found in monitoring studies.
 - Persistent, bioaccumulative and/or toxic.
 - Pose a substantial exposure concern.
- Alternatives that can potentially be mitigated may still be considered.

Exposure Module (cont.)

Level 2: Expanded Evaluation

- Builds upon Level 1.
- Uses more detailed quantitative data.
- Considers the following:
 - Presence in biomonitoring studies.
 - Quantities involved.
 - PBT characteristics.
 - Inherent chemical properties.
 - Re-design & mitigation to resolve problems.

Exposure Module (cont.)

Level 3: Detailed Evaluation

- Builds upon Level 2.
- Uses higher quality data.
- Validated studies conducted to fill data gaps.

Advanced: Full Exposure Assessment

- Exposure assessment as defined by National Academy of Sciences.

Questions?

Comments?

