Draft Scope for Alternative Assessment Guidance:

Objectives in creating a guidance document:

- Assist in the removal of toxic chemicals of concern from products. The objective is to provide a process that will facilitate replacement of toxic chemicals of concern currently in use with safer alternatives.

- Provide a venue for interested states and Federal Agencies to participate in formulating the guidance through the Interstate Chemicals Clearinghouse (IC2). The IC2 has endorsed this effort and interested states will participate in an Alternative Assessment Team (AAT) formed to create the guidance. Technical advice will be solicited from recognized experts in the field of alternative assessments and EPA’s Design for the Environment program has agreed to act as a technical advisor.

- Provide opportunities for stakeholder involvement and input. Businesses, environmental groups, academia, the public and other interest parties will be asked to participate through the stakeholder process. This effort will include opportunity for broad stakeholder input before the guidance development begins, midpoint and before the guidance is finalized.

- Begin with hazard assessment. Risk assessment tools typically used to evaluate the safety of chemicals often begin by looking for methods to assess exposure. Alternatives assessment begins with chemical hazard assessment and includes exposure assessment as a more secondary tool to be used to reduce risk in those instances when hazards cannot be reduced, when it is difficult to select between safer alternatives, etc. This process allows both components of the risk equation to be used to identify safer alternatives that have the lowest impact upon human health and the environment and prioritize the elimination of toxic chemicals of concern from the manufacturing process.

- Develop a continuum of requirements. The document will start with a basic level of chemical hazard alternative assessment and continue in step form with each step adding more detail and requirements. The intent is to produce a flexible guidance document useful to a wide range of users. For example, the needs of small and medium sized businesses with limited resources and expertise are quite different from international firms with the capacity to consider processes such as life cycle assessment. The continuum we envision will be designed for both ends of the spectrum. For example, simpler hazard assessment tools such as QCAT and GreenScreen™ may be sufficient for one end of the continuum while the other end might include more elaborate tools such as life cycle assessment.

- Provide guidance on the application of the continuum. The guidance was conceived as a tool to serve a variety of purposes and will remain flexible and allow different users, states, and other regulatory bodies to select a step that best fits specific needs. Part of the challenge is to also develop guidance that helps users decide what step on the continuum is appropriate to their particular situation.

- Ecology is considering including some of the following components at different steps and different levels of complexity within the guidance continuum:
  - Commercial availability of alternatives to the toxic chemical.
  - Cost effectiveness.
  - Performance including process-engineering considerations.
  - Opportunities for product reformulation, chemical substitution, chemical elimination, product redesign, and manufacturing process redesign.
  - Whether the alternative is commercially available.
  - Hazard data including information on the toxicity, persistence, and potential for bioaccumulation.
  - Environmental impact data of any alternatives including acute and aquatic toxicity and any other pertinent impacts on the specific species.
- Physical and chemical characteristics such as flammability, explosivity, etc. Will coordinate with requirements identified from other regulatory bodies such as REACH, GHS, etc.
- Disposal and end-of-life considerations.
- Likelihood of effecting lasting change.
- Social and environmental justice and other related concerns.
- Exposure concerns including but not limited to a full risk assessment.
- Life cycle concerns.
- Implementation of Green Chemistry criteria.
- Supporting pollution preventing planning requirements.

Stakeholder Scoping Questions:

1. What are your three main observations with the continuum process proposed by Ecology?

2. Has Ecology omitted any technical concerns as important components of the guidance continuum?

3. What are some of the positives this process might bring?

4. Do you have any other concerns with the proposed process?

5. Do you agree that the continuum approach is the best way to approach the various needs of an alternative assessment?

6. Given the aggressive timeline, which of the components listed above are most important to be tackled first?

7. The stakeholder group will have the opportunity to provide additional input once the draft guidance framework has been formed, midpoint and before the guidance is finalized. Do you have any additional input to provide before the states begin discussing the guidance document?