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Interstate Chemicals Clearinghouse
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Re: Comments on the draft Guidance for Alternatives Assessment and Risk Reduction

Dear Sir:

On behalf of the Alliance of Automobile Manufacturers (Alliance), I am pleased to submit the following comments in response to the request for comments on the draft *Guidance for Alternatives Assessment and Risk Reduction* (Document).

The Alliance is a trade association of 12 car and light truck manufacturers, consisting of BMW Group, Chrysler Group LLC, Ford Motor Company, General Motors Company, Jaguar Land Rover, Mazda North America, Mercedes-Benz USA, Mitsubishi Motors, Porsche Cars North America, Toyota Motor North America, Inc., Volkswagen Group of America, and Volvo Cars of North America.

The Alliance appreciates the complexity of the task at hand, and the effort put forth in preparation of the Document. The Alliance has long been committed to safer chemistries, and embraces the goals and vision embodied by Green Chemistry principles. For example, automobiles are among the world's most-recycled consumer product; 95% of retired automobiles are processed for recycling every year. From floor mats and fluids to aluminum and steel, approximately 86% of a car's material content is recycled, reused, or used for energy recovery. Automobiles are a primary example of a product that's end-of-life recycling infrastructure is already thoroughly developed.

Nevertheless, the Alliance is concerned that the proposed Document, in its current form, could easily become unworkable for complex durable goods such as automobiles. We offer our willingness to work with the Technical Alternative Assessment Guidance (TAAG) Team, and share our experience with specific efforts to identify preferred chemistries in substitution for those that had been deemed undesirable. We suggest that it may be a valuable exercise for the TAAG Team and the Alliance to work together through the proposed process using a case study as a brainstorming effort to refine the guidance as it relates to complex, durable goods.

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EXECUTIVE SUMMARY

The Alliance has seven major concerns with the Document:

Final Product is a Complex Assembly that Relies on a Global Supply Chain

The text of the Document is relevant only to the direct manufacturers of a product. There is no differentiation made between the manufacture of generic products with potentially multiple applications and those products with dedicated purpose, such as a component which may be subject to multiple design restrictions as a part of a larger assembly. The Document does not address where the burden of an alternatives analysis and risk reduction (AA) responsibility falls, nor does it reflect an understanding of these complex and sophisticated global supply chains.

Due to the end-user position of automakers in the supply chain as assemblers of pre-manufactured and pre-formulated products, automakers have limited control over compliance with AA obligations. Automakers specify product performance and function, but do not design components or specify chemical composition, except to contractually stipulate chemical prohibitions. Consequently, the suppliers determine how to meet the requirements of both assemblers and regulators, and use their position in the supply chain (i.e., product design expertise, access to their own confidential business information, and knowledge of their own suppliers) to achieve these goals.

The Alliance members' position in the supply chain is not consistent with the ability to direct the AA efforts. While Alliance members are not the point of control for an AA, we exert influence regarding unwanted chemistries in the supply chain. Most notably, a global team representing automotive parts suppliers (tier suppliers) and chemical/plastics industries has organized the Global Automotive Stakeholders Group (GASG). The GASG's purpose is to facilitate communication and exchange of information regarding the use of certain substances in automotive products throughout the supply chain. The resulting Global Automotive Declarable Substance List (GADSL) is a single, globally harmonized list of declarable and banned substances.

Finally, the AA approach must respect and protect confidential business information and trade secret at all stages of the assessment. Information considered confidential may include the specific chemical identity and concentrations used, as well as manufacturing processes and equipment. Performance of an AA is expected to require an understanding these factors; companies at all stages in the supply chain require a workable plan in place that will protect this valuable information.

AA Approach Must be Integrated with Federal and Industry Safety Standards and Other Regulations.

The Document indicates that the decision framework selection will likely consider internal and external drivers. These may include, among others, company values, regulatory standards and brand identification as it relates to performance. Consideration is not given to whether a Chemical of Concern (COC) may have been intentionally added to fulfill a specific regulatory requirement. In the Cost and Availability Module and subsequent modules there is no identified path to terminate an AA due to regulatory, safety, or industry standards. Furthermore, there appears to be an inconsistency in the approach to termination points between modules (e.g., "deal-breakers" for the elimination of alternatives based on the Life-Cycle Thinking (LCT) Module).

Both Federal Motor Vehicle Safety Standards (FMVSS) and auto industry safety standards (e.g., Society of Automotive Engineers (SAE)) have a direct impact on this industry. Compliance with these requirements will supersede the AA when there is a conflict; chemicals required due to mandated

performance standards cannot be replaced without substantial testing and validation. The role of the standards in selection of component chemicals of products cannot be ignored in an AA method.

The automotive industry must meet other regulatory requirements in addition to auto industry-specific safety standards, and any AA needs to consider these requirements as well. For example, suppliers must ensure the chemicals they use are on the TSCA inventory, and that chemical applications remain within OSHA exposure limits (e.g., PELs). State-level regulations must also be met, and further, assemblers selling their products globally also need to meet intergovernmental (e.g., Montreal Protocol), regional (e.g., EU REACH) and country specific (e.g., China REACH) requirements.

Automobiles are composed of approximately 30,000 parts and assemblies that need to be evaluated separately. Per California's Zero Emission Vehicle (ZEV) regulation and industry practice, certain replacement parts must be available for 15 years beyond the closure of a specific model to facilitate repairs and/or recalls. These parts were developed under previous requirements and changes to the initial design are cost prohibitive, impractical, and infeasible. These components are made by numerous parts suppliers that are not under automaker direct control. Changes to future parts and assemblies can require 5-8 years of lead time due to testing required to meet safety and other regulatory requirements. Changes identified via AA need to be integrated into the "new model" process, which takes time.

Variability in Assessment Approaches Provides Inconsistent Results

The three decision frameworks (Sequential, Parallel, and Hybrid) give guidance that the four "core" modules (Performance, Hazard, Cost and Availability, Exposure) are preferred or specified for AAs. Conflicting statements indicate that the selection of the level of implementation employed is left to the assessor, though it is also stated that an outside party, such as a governmental agency, could constrain the AA approach by selecting modules and levels to be used. Conflicting information is also provided in the Document (Sequential Decision Framework flowchart) indicating that all modules are required.

As is stated in the Document, differing approaches to AA will yield differing results for product modification. Uncertain outcomes are unworkable in an industry that spans multiple states and countries. The ability of different jurisdictions to select different levels of implementation and to optionally select, non-core modules will lead to irreconcilable stakeholder disagreement over the criteria for decision making and AA outcomes. Notably, subjective criteria related to societal concerns will be difficult to resolve, as compared to more objective criteria, such as the cost of substitution and performance parameters.

While we appreciate the sentiment behind the stated intention to make the AA process flexible and approachable by a wide array of assessors, it must be considered that this Document may be used as a compliance tool by government agencies. Accordingly, the Document must impose a uniform approach and predictable decision criteria to achieving consistently reproducible results.

Insurmountable difficulties may be predicted in the absence of a consistent AA approach. If this Document were adopted in its current state to provide guidance regarding AA for government regulators, and if reciprocity were not established between regulating authorities, it could result in conflict and barriers to trade. Government agencies could set conflicting product design requirements for the industry based on agency specific preferences for specific modules or criteria that arrive at divergent AA results. Agency-specific AA approaches would also result in waste associated with duplicated compliance effort. Additionally, in the case of proposed regulations where public comment must be taken and considered, it potentially leaves the regulated parties subject to dramatic changes in AA approaches based on the public comments received. We suggest that the responsible entity should therefore have input with the state

regulatory agency or responsible assessor concerning which modules are relevant and appropriate prior to the initiation of the AA.

Established Approaches to Product Safety are Disregarded: Exposure Controls and De Minimis Concentration Thresholds for COCs

The Document does not recognize well-established international approaches to product safety that center on exposure concerns. For example, exposure control is not considered as a component of the Initial Evaluation Module; it is considered in the Exposure Assessment Module solely as an aid in the selection between alternatives. This is seemingly in conflict with the standard definition of risk as reported in the Document, where it is defined as a function of hazard and exposure. Similarly, there is a contradiction in the Document between the well-established definition of "exposure pathway" and the argument that exposure assessment cannot be used to justify the continued use of a COC, such as in the case of an encapsulated chemical which restricts the potential for exposure. Sophisticated manufacture and recycling practices play a critical role in whether there is a potential for exposure (i.e., the chemical is actually available for exposure) and an exposure control mechanism. This should definitely be taken into consideration earlier and throughout the assessment.

The Document also fails to consider the concept of *de minimis* concentration of a COC in a product as a factor in the selection of products for AA. In contrast, international chemical authoritative or regulatory programs use *de minimis* thresholds to control risk. We currently employ the International Material Data System (IMDS) and GADSL: globally recognized standards for reporting material content in the automotive industry that aid in product stewardship. These systems rely on a 0.1% (percent by weight) concentration threshold. For reasons that include regulatory compliance, some chemicals are subject to further clarification concerning acceptable thresholds. Nevertheless, this 0.1% *de minimis* threshold is consistent with REACH, as well as other significant national and international regulation concerning public health and product safety. Without identification of acceptable threshold concentrations, it is impossible to prioritize and manage AA measures. Additional challenges may be identified for some COCs. Substances present in a product that are incidental to manufacture are addressed in the Document, but similar consideration should be provided for those substances commonly referred to as UVCBs (Unknown or Variable compositions, Complex reaction products and Biological materials). Unlike simple chemicals, UVCBs cannot be represented by unique structures and molecular formulas because they are composed of a complex combination of different molecules. For example, a number of chemicals, such as lead, are naturally-occurring in metals used to make steel, which will be present throughout life cycle of the product. To be a workable system, it is essential that a thoughtful approach to these types of substances is developed.

Degree of Guidance is Markedly Inconsistent Between Modules: Quantifiable vs. Less-Definable Concerns

Some modules, notably the non-core modules as well as portions of the Cost and Availability Module, provide much less detail concerning the assessment approach, while simultaneously requiring sophisticated cost-benefit analyses. At its higher levels, the Cost and Availability Module requires a cost-benefit analysis that describes the complete cost, which includes externalized costs not included in typical cost evaluations. The Document states that concerns related to human health and environmental costs include information on potential costs of externalities associated with emissions from raw material extraction or processing, from the transport, storage, use and disposal of chemical or materials. The Document further directs the assessor that it is important to assess how many people are exposed or if some groups of people are exposed more than others, or if certain environmental sectors are impacted more than others. Economic considerations include macro-economic implications such as economic growth, inflation, and taxes which are caused by the distribution of the economic impacts and how the

relevant markets function. The production of alternatives is likely to induce business opportunities, which also need to be included in the analysis of wider economic impacts. Examples of social costs provided in the Document include employment, working conditions, job satisfaction, education of workers and social security.

Similarly, the Social Impact Module requires evaluation of global societal impact of an alternative upon the workers, communities and societies involved in its manufacture, transport, use, and disposal. Examples of concerns that require evaluation include: quality of life including historical, cultural or religious priorities, quality of life including recreational activities, and empowerment of communities to take action to improve their health and environment.

Ultimately, many of these endpoints are beyond the scope of an AA. Endpoints for consideration are often qualitative and non-specific; only assessment endpoints that can be quantified and supported should be used in an AA effort. If these endpoints are to be given the same weight as other modules in the assessment framework, similar quality of effort should be expended to characterize the assessment approach as was spent on others, most notably, the Hazard Module. It is not sufficient to provide general statements to guide assessment of, for example, public health, macroeconomic, and societal impact. Further consideration should be given to identify those endpoints for which it is possible for industry to provide a quantitative assessment; in some cases, further guidance would not be sufficient, because the scope of the assessment is not within the reach of industry to quantify. For example, determination of the health and environmental impact would require a tremendously large and sophisticated epidemiological study or series of studies in order to arrive at a reliable answer; this is well outside the scope of any industrial entity. Similarly, prediction of how the selection of a specific alternative may affect macro-economic issues such as economic growth, inflation, and taxes is outside the scope of the details that any industrial entity has the ability to identify.

Recycling is Part of a Larger Market-Driven Infrastructure

The AA should not discourage beneficial recycling efforts. The Materials Management Module requires product stewardship of recycled materials. In the United States, recycling is a free enterprise effort with a well-established infrastructure that addresses the needs of diverse industries. In addition to the value found in the recycling industry itself, recycling is respected by industry both as a source of starting materials, as well as a responsible and economically advantageous way of "disposing" of what otherwise would be valueless waste.

This module needs to be considered carefully. The Document states that "…use of recycled materials also requires stewardship and monitoring to ensure that the recycling occurs in a safe manner and that the resulting materials do not contain toxins from contaminated input". As mentioned earlier, some UVCB substances may contain naturally occurring minor constituents that spur additional enquiry. For example, steel is known to be comprised of a number of metals which may include lead, which would be present throughout life cycle of the product. As described earlier, automobiles are among the world's most-recycled consumer product: fully 95% of retired automobiles are processed for recycling every year, and approximately 86% of a car's material content is recycled, reused, or used for energy recovery.

The point of performing an AA is to determine whether the COC in the product can be removed, reduced or replaced. This very practice is employed to reduce risk of exposure and harm throughout the product's lifecycle, including recycle. Selection criteria may also consider whether potential alternatives are preferred based on the efficiency of material recovery and reuse/recycling. Outside of this activity, product manufacturers do not have control over how free-enterprise recyclers operate and are not in a position to "police" them.

Limiting Alternatives Based on Known Attributes

The directive to identify the universe of potential alternatives, including emerging technologies and novel chemistries, is in conflict with the directives of several other modules, such as the Social Impact and Cost and Availability Modules. Identification of Alternatives Module requires identification of "the universe of potential alternatives"; this is expected to be completely inclusive (use of alternative materials including emerging technologies, novel chemistries, those currently in limited production, and product redesign to eliminate the need for a particular chemical, etc.). Some modules require a deep understanding of potential global impacts that include human and environmental health and economic considerations. It does not seem likely that the cost-benefit evaluation required by these modules, as described above, would be possible for chemistries that have not been previously used in large scale implementation.

Furthermore, identification of alternatives should be limited to those that have a reasonable probability of being successful. Efficient assessment is an important concern where goods require a substantial lead-time for product development. The time required for assessment and expense required for a successful AA and subsequent re-design in this industry is not compatible with the scope of identification of alternatives in this Document.

DOCUMENT DETAIL

The Document provides four scoping modules and seven assessment modules. Module-specific detail is provided below, and includes a brief description of the module's scope, comments provided by the Alliance, and relevant page numbers regarding the Alliance's comments.

SCOPING MODULES

5a: Initial Evaluation Module

Scope of Module

The module examines the need for an AA based on the COC product status. The initial step involves determining if the COC is intentionally or unintentionally added to the product. If intentionally added, and may simply be removed without adversely affecting the function of the product, this simplistic phase-out avoids the need for an AA. An AA may thus be avoided by elimination during the next innovation cycle. For those unintentionally added COCs, the approach is to identify an alternative source that eliminates the "contaminant."

Alliance Comments:

Consideration is not given to whether the COC may be intentionally added for specific regulatory purpose.

Consideration is not given to whether the COC presents no risk to human health or the environmental due to lack of bioavailability.

Consideration is not given to whether the COC is present in the product at levels that are below an established *de minimis* value, as acceptable under well-established national and international regulation and guidance concerning public health and product safety.

While elimination of the COC may take place during the next innovation cycle, the replacement timeline is unknown. This is an important concern for where goods require a substantial lead-time for product development.

The directive to identify the universe of potential alternatives, including emerging technologies and novel chemistries, appears to be in conflict with the goals of other modules requiring prediction and quantification of social, health, and economic impacts. It does not seem likely that the deeper understanding required for completion of the higher levels of those modules would be possible for chemistries that have not been used in large scale implementation, and for which less is known.

Key IC2 Document Statements: Pages 24, 32, 33, 35.

5b: Identification of Alternatives Module

Scope of Module:

This module provides guidance in identification of the "broadest list of potential alternatives universe of potential alternatives" to be considered in the course of the AA. Alternatives may include emerging technologies, product redesign to eliminate the COC, and chemical substitution. The two key considerations are the availability of functionally equivalent alternatives, and the availability of these alternatives in the marketplace.

Alliance Comments:

It must be determined who will carry the responsibility of identification of alternatives.

Alternatives must be feasible. It would streamline the process if those alternatives known to be unacceptable based on expert judgment could be excluded from consideration at this point in the AA. The group empowered with performing this expert judgment would need to be identified.

The Document does not consider the restraints on products with dedicated purpose, such as a component which may be subject to multiple design restrictions as a part of a larger assembly. Redesign to eliminate a COC may require redesign of other components of the assembly which may or may not be produced by the same manufacturer. This may require substantial lead-time to accomplish.

The time frame is not specified for those redesign efforts expected to be achieved in a "reasonable time." Due to the complexity of the assembled product, and the requirement to complete the final design of the assembled product far in advance of production, the lead-time may be considerable.

Key IC2 Document Statements: Page 39.

5c: Decision Module

Scope of Module:

This module provides three frameworks from which to choose for implementing the modules of the Document. The frameworks guide the user through the process of evaluating large amounts of often conflicting data to select preferred alternatives.

Alliance Comments:

The frameworks provided do not result in a robust assessment: different alternatives are expected to be identified by different assessors due to the ability for assessors to select differing modules and levels of implementation. AA efforts require a uniform approach for consistent and predictable decision criteria.

Guidance concerning which modules are preferred is conflicting; it is indicated that only portions of the AA need to be used at any time and that selection of modules is the preference of the assessor. Nevertheless, the three decision frameworks give guidance that the four "core" modules (Performance, Hazard, Cost and Availability, Exposure) are preferred or specified for AAs. Conflicting information is also provided in the Document (Sequential Decision Framework flowchart) indicating that all modules are required. As stated before, this AA Document is likely to be used to meet regulatory obligations; therefore, it is imperative that the guidance provide enough specificity to allow a regulated entity to know what must be done in order to comply.

Key IC2 Document Statements: Pages 18, 24, 82, 85, 89, 90.

5d: Stakeholder Involvement Module

Scope of Module:

This module is intended to provide information so that concerned parties are able to understand what decisions are being made, the rationale for the decisions, and provide an opportunity to have input into the process. The module provides three levels that limit or expand the role of stakeholders in the decision making process.

Alliance Comments:

Stakeholder groups should be identified by the Assessor.

Potential stakeholders may include diverse groups such as company representatives, the supply chain, customers, NGO's, local community and governmental representatives. In dealing with complex engineered products, not all stakeholders will be able to provide meaningful technical input. Stakeholder conflict due to opposing positions may make it challenging to identify a result that meets the needs of all. It may also add unwarranted cost, complication and time, should revision and reassessment be required by consideration of modules and alternatives originally ruled out. Resolution of conflict may be challenging even when stakeholder groups share a desired outcome.

Key IC2 Document Statements: Pages 43, 45.

ASSESSMENT MODULES

6a: Performance Evaluation Module

Scope of Module:

The objective of this module is to ensure that alternatives are appropriate for the potential application, and will enable the products to meet performance requirements. Three levels of evaluation assess the alternatives based on qualitative to quantitative information.

Alliance Comments:

It is essential that performance be considered a critical part of the AA. Performance standards are dictated not only by authoritative, regulatory, and industry bodies, but also by the consumers, who serve as essential stakeholders in the ultimate product design.

The module is accessible, and leverages publicly available information at the lowest level of assessment, and technical expertise and quantitative testing at the highest level of assessment.

Evaluation is terminated for those alternatives that are not viable based on lack of appropriate performance.

Key IC2 Document Statements: Pages 45, 119.

6b: Hazard Module

Scope of Module:

The objective of this module is to determine what hazards are posed by the target chemical and potential alternatives. This approach is based on Clean Production Action's GreenScreen, a hazard assessment process that builds upon the work of the EPA's Design for the Environment (DfE) approach by using the DfE criteria with a transparent scoring system. The module provides two levels of hazard assessment, and three potential screening levels.

In a Level 1 assessment, three screening methods identify chemicals that have been identified by regulatory or authoritative agencies as posing a known or suspected hazard. This assessment guidance is available free of charge for AA purposes. Because only a small subset of the chemicals in commerce have been assessed by these agencies, where information is not identified by the screens 1-3, additional information must be sought from other publicly available sources to fully characterize the chemical. Briefly, the absence of an authoritative or regulatory statement regarding a chemical does not indicate an absence of hazard. In these cases, a Level 2 assessment is performed; Level 2 requires greater expertise and evaluates data for a greater number of hazard traits and from a greater number of data sources, ultimately providing more complete information. Level 2 assessment includes additional hazard traits as identified by the state of California. Upon completion, it is subjected to peer review and validation: it is not stated, as it is for Level 1 Assessments, that the process is free of charge.

Alliance Comments:

- The Hazard Module and supporting documents provide abundant guidance, spanning 72 pages of text, and approaching 30% of the full 250 page draft Document, which is not consistent with the level of guidance provided for the other modules.

- We object to the promotion of a single, non-profit company, Clean Production Action (CPA), as a means of hazard assessment. No provision is described for use of a competing hazard assessment approach, or development of a scientific, robust, and reliable hazard assessment approach based on, and consistent with, authoritative guidelines or regulation.

- CPA has approved free use of the lower level screening tool (GreenScreen) for AA purposes, but where additional information is required by its system, the assessment must be reviewed and validated by a third party, which is not described as free of charge.

- No provision for protection of CBI or Trade Secrets is described where information is required to be validated by an outside party.

- Where a more extensive assessment is required by the GreenScreen tool, the approach used incorporates endpoints selected by the State of California. It is likely that other states may not be content to rely on this state-specific guidance, potentially resulting in a patchwork of AA approaches: the very situation this cooperative draft Document was intended to prevent.

- The hazard assessment is expected to be costly to implement based on the commitment of time and resources. Assessments rely on publicly available data, in combination with professional judgment by experts skilled in toxicology, chemistry, computer modeling and other scientific areas.

- Approaches to hazard assessment that have been well-defined by ECHA are not described as incorporated into the GreenScreen tool, such as preference for more reliable (Klimisch score) or authoritative data, or a Weight of Evidence approach to evaluate larger quantities of lower-quality data.

Key IC2 Document Statements: Page 48, 54, 57, 58, 127.

6c: Cost and Availability Module

Scope of Module:

The purpose of this module is to evaluate the cost and availability of potential alternatives for consideration in the AA process. Any alternative that can't be found in sufficient quantity should be identified and potentially eliminated from consideration. Both internalized as well as externalized costs are considered. Changes in cost based on increased demand are also considered. The module uses five levels of assessment ranging from a simple assessment of chemical cost and availability, to the combined chemical and material cost and availability, the overall cost of a redesigned product, and ending with full cost/benefit analysis. Human and environmental health costs, economic costs, and social costs are expected to be included at the higher levels.

Alliance Comments:

This module integrates Life Cycle Thinking and considers costs or benefits directly or indirectly created by a product, such as proper hazardous waste disposal and health costs.

It must be stressed that the environmental and human health costs, as well as social costs, require extensive effort and expertise to render them quantifiable. An expert in the area of environmental and health economics may be consulted.

Relatively sparse guidance was provided regarding the use of this approach in a quantifiable manner.

Additional guidance would not be sufficient to render some endpoints assessable by manufacturers. For example, determination of the health and environmental impact would require a large and sophisticated and epidemiological study or series of studies in order to arrive at a reliable assessment of impact. Similarly, prediction of how selection of a specific alternative may affect macro-economic issues such as economic growth, inflation, and taxes is outside the scope of the details that any industrial entity has the ability to identify.

At higher levels, the module requires a cost-benefit analysis that describes the complete cost, which includes externalized costs not included in typical cost evaluations.

The Document states that concerns related to human health and environmental costs include information on potential costs of externalities associated with emissions from raw material extraction or processing, from the transport, storage, use and disposal of chemical or materials. The Document further directs the assessor that it is important assess how many people are exposed or if some groups of people are exposed more than others, or if certain environmental sectors are impacted more than others.

Economic considerations include macro-economic implications such as economic growth, inflation, and taxes which are caused by the distribution of the economic impacts and how the relevant markets function. The production of alternatives is likely to induce business opportunities, which also need to be included in the analysis of wider economic impacts.

Examples of social costs provided in the Document include employment, working conditions, job satisfaction, education of workers and social security.

Key IC2 Document Statements Include: Pages 22, 61, 62.

6d: Exposure Assessment Module

Scope of Module:

This module is expected to be used after the Hazard Module in order to reduce risk. Five levels of assessment are provided, which range from a go/no-go for exposure assessment to five levels of exposure review that culminate in a complete and detailed exposure assessment as defined in the Risk assessment Process by the National Academy of Sciences.

Exposure assessment can support selection of alternatives when the inherent hazard are equivalent, or when the functional use of one alternative would result in increased risk due to the quality and quantity of the resulting exposure (exposure profile). This is intended to comply with the spirit of the CDC hierarchy of exposure controls used to protect workers, which relies on, in this order: elimination of adverse chemistries; substitution of adverse chemistries; engineering controls; administrative controls; and finally, personal protective equipment. The controls methods at the tip of the list are considered more effective and protective than those at the bottom of the list. Using this approach, a similar control hierarchy is defined with respect to consumers and consumer products.

Alliance Comments:

The Document does not recognize established principles of toxicology and public health when it fails to consider the concept of *de minimis* concentration of a COC in a product and whether this affects the need for an AA. A 0.1% *de minimis* threshold is consistent with REACH, as well as other significant national and international regulation concerning public health and product safety.

The Document does not recognize exposure control as a component of the Initial Evaluation Module and only considers it in the Exposure Assessment Module as an aid in the selection between alternatives. In summary, exposure considerations and bioavailability are specifically NOT permissible as a means of allowing continued use of a COC. Sophisticated manufacture and

recycling practices, for example, play a critical role in whether there is a potential for exposure (i.e., the chemical is actually available for exposure). This should definitely be taken into consideration earlier and throughout the assessment.

Key IC2 Document Statements: Pages 12, 14, 18, 65.

6e: Materials Management Module

Scope of Module:

The purpose of this module is to aid in consideration of how different choices can impact natural resources and generation of waste, both hazardous and non-hazardous. The module provides three levels that are all intended to be completed. These include: Inventory of raw materials used and waste generated; Assessment to quantify the raw materials used and wastes generated; Optimization to identify those alternatives that most further the materials management objectives; and evaluation using a material flow analysis. The primary goals include: using sustainable raw materials, which includes less resource-intensive materials, and incorporation of sustainably renewable or recycle materials; using fewer materials in products. The ultimate goal is to emphasize alternatives that can further the Cradle to Cradle design through materials management.

Alliance Comments:

The Document assumes that the manufacturer has complete control over the supply chain, but Assemblers are not in a position to "police" recyclers. If original equipment manufacturers have a process in place, the Alliance members cannot guarantee third-party compliance. The materials management module requires product stewardship of recycled materials. For example, recycling must be done in a "safe manner" and must ensure that the recycled product is "toxin-free".

Key IC2 Document Statements: Page 68.

6f: Social Impact Module

Scope of Module:

The purpose of this module is to ensure that the AA process does not result in unduly shifting a burden from one community of people to another. This requires the evaluation of the impacts of an alternative upon the workers, communities and societies involved across its full life cycle: manufacture, transport, use, and disposal. While elements of this module may already be addressed as important components in other modules, the intent is to draw attention to specific issues affecting worker health and safety, community and global societal issues, including environmental justice concerns. There are four levels of assessment that range in scope from local to global impact assessment.

Alliance Comments:

The module contains worker, community, and global societal considerations that include, for example: quality of life including historical, cultural or religious priorities; quality of life including recreational activities; and corruption. Only assessment endpoints that can be quantified and supported should be used in an AA effort.

The direct manufacturer of the product is the entity that would have access to information concerning worker- or community-level quality-of-life details.

Many of these concerns are outside the scope of research by product manufacturers (e.g., public health assessment). The assessment endpoints should be reasonable and within the ability of the manufacturer to evaluate.

Key IC2 Document Statements: Page 70.

6g: Lifecycle Thinking Module

Scope of Module:

This module supports AA by helping to inform decision makers about life cycle impact associated with the baseline product and the alternative(s) so that they may 1) further discriminate between safer alternatives by comparing them for life cycle tradeoffs, 2) identify opportunities to mitigate any undesirable impacts and 3) avoid moving to an alternative that has undesirable life cycle impacts that cannot be mitigated. While elements of this module may already be addressed as important components in other modules, the intent is to evaluate life cycle impacts from the product level rather from an individual chemical perspective. Although alternatives may involve replacing a chemical of concern with another chemical, evaluating the life cycle impacts from the full product perspective provides a more detailed and comprehensive evaluation of the impacts involved in the substitution. The module provides a preliminary go/no-go step to determine whether further analysis is required, as well as two levels of assessment.

Alliance Comments:

Substantial overlap with other modules exists (Cost and Availability, Social Impact or Materials Management Modules).

Detail concerning boundaries on the assessment approach is needed. Endpoints for consideration are often qualitative and non-specific; only assessment endpoints that can be quantified and supported should be used in an AA effort. If these endpoints are to be given the same weight as other modules in the assessment framework, similar quality of effort should be expended to characterize the assessment approach.

Key IC2 Document Statements: Pages 75, 76, 78, 79.

Thank you for your time and consideration of our comments. If you have any questions, please feel free to contact me at frio@autoalliance.org or (202) 326-5551.

Sincerely,

Filipa Rio

Filipa Rio
Director, Environmental Affairs