Comments on House Energy and Commerce Discussion Draft to Amend the Toxic Substances Control Act (TSCA)

May 24, 2010

The consumer product industry represented by the Consumer Specialty Products Association (CSPA), Grocery Manufacturers Association (GMA) and the Soap and Detergent Association (SDA) have appreciated the opportunity to participate in the series of stakeholder discussion sessions with Committee staff on the Toxic Chemicals Safety Act Discussion Draft ("Discussion Draft"). CSPA, GMA and SDA, the downstream users of raw chemicals, are committed to manufacturing and marketing safe, innovative and sustainable products that provide essential benefits to consumers, many of which have important public health benefits, while protecting human health and the environment. Product safety is the foundation of consumer trust and the consumer product industry devotes substantial resources to achieving this goal.

We recognize the tremendous amount of work that went into the Discussion Draft. It is the first step toward the necessary modernization of our chemicals management law, the Toxic Substances Control Act (TSCA) of 1976. A modern TSCA should reflect the more than three decades of scientific and technological advancements since it was first enacted. And the goals of a modern law should be, foremost, to protect the health and safety of all consumers, workers and the environment, while promoting jobs and innovation. That law should also provide resources for the U.S. Environmental Protection Agency (EPA) to ensure that the law can be properly implemented to achieve those goals.

We support a federal policy that regulates chemicals in commerce rather than a patchwork quilt of state laws making it difficult to manufacture and bring products to the marketplace. We also support specific concepts in TSCA reform, including a risk-based approach to prioritizing and reviewing chemicals in commerce, establishing clear but achievable deadlines together with ensuring EPA has adequate resources to meet those deadlines, clarifying EPA authority to manage and mitigate the use of chemicals that present risk concerns, efforts to minimize animal testing, and practical approaches to data development and information sharing.

We do, however, have significant concerns with both the workability and direction of the Discussion Draft, which we have outlined in the following pages and would oppose this if introduced into legislation as currently drafted. Our comments highlight some of the consequences that will result if these issues are not addressed as you move forward to develop a modern U.S. chemical management scheme.

We have a unique opportunity to modernize the U.S. chemical management framework in a critically important way that protects the public and the environment while retaining U.S.

leadership in chemical innovation. CSPA, GMA and SDA appreciate the opportunity to submit these comments and look forward to working to address this very important regulatory challenge.

New Chemicals and New Uses

CSPA, GMA and SDA believe that a modernized TSCA should boost confidence in government chemical management and promote even greater innovation by chemical manufacturers and users. The regulatory system can support both innovation and chemical safety by allowing manufacturers and importers of new chemical substances to address the risks posed by exposures expected from a substance's intended uses, and submit to EPA the safety assessment and supporting information that demonstrate that such a chemical is safe for its intended uses. The information needs will vary from substance to substance with this approach, but importantly, new data generation will be specifically tailored to support the safety of the chemical substance to avoid wasteful and needless animal testing and data collection that results from a minimum data set, "one-size-fits-all" approach.

The requirement in the Discussion Draft that a minimum data set must be submitted for all new chemical substances and new uses of existing substances in commerce will unfortunately serve to penalize the introduction of new technology to the U.S. market. It will do so by imposing duplicative, costly tests, many of which are not needed to address the risks posed by exposures to the chemical substance from its intended uses. This sets an unreasonable barrier to market entry (especially for small businesses) that will slow the commercial availability of chemical substances needed by downstream users to formulate new, sustainable consumer products.

By greatly expanding the scope of TSCA to include new uses of all chemical substances, mixtures and articles, the Discussion Draft, as currently written, would mean that every single change to a mixture and article would constitute a "new use" and require notification and approval by EPA. Consumer product manufacturers, on a regular basis, substitute new ingredients, use alternate material suppliers, switch among color shades and scents, and tweak formulations to rebalance existing ingredients in different proportions. These innovations would come to a halt if each change required a "new use" notice and approval by EPA. Agency resources would quickly be diverted to handle the millions of new notices required under this provision.

We are also concerned about the lack of direction on inventory exemptions and exclusions currently recognized under TSCA. For example, the Discussion Draft does not address polymers, non-isolated intermediates and chemical substances manufactured solely for export. Removing these critically important exemptions and exclusions could further multiply the number of notifications to EPA. Generation of test data for low priority chemical substances, that present limited exposure to the general public, sensitive populations and the environment, should not use up limited EPA and industry resources.

Additional clarification is needed on how this process would function for imported chemical substances, mixtures and articles. There are potential impacts of revising the way in which mixtures and articles are currently treated under TSCA that may not have been fully considered. For example, if a product is imported into the U.S. and was not previously included in a declaration to EPA, the import may constitute a new chemical substance/new use for which

notification to EPA will be required. Presumably such notification will require notification to EPA of the complete composition of the product, which may not be definitively known.

We interpret the Discussion Draft as a use registration system in the U.S. for new chemical substances and new uses of existing substances that will significantly impede time to market for new technologies and the establishment and growth of American small businesses. This impact on innovation should be weighed carefully when considering the future competitiveness of the U.S. economy in the global marketplace.

Minimum Data Set/Data Requirements

A key concern under §4 of the Discussion Draft is the provision for EPA to require industry to provide exposure and use information on both new and existing chemical substances and mixtures (impacting all physical items in the U.S. economy). This broad definitional change greatly expands the scope of the existing TSCA to include the thousands of unique chemical substances listed on the current TSCA Inventory and the millions of mixtures in manufacturing and processing systems and in end-product mixtures which these chemicals are formulated, including articles. It would mean that animal testing would be required on all products in the American economy. The change would mean that, in the safety determination process, EPA would need to collect, evaluate and regulate aggregate and cumulative exposure from every chemical and mixture use and exposure. EPA already has authority for mixtures in current law, and it is not clear why additional provisions are necessary. We do not believe this expanded scope is workable under TSCA, and, in effect, would serve to undermine existing statutory and regulatory authority(s) and expertise of the U.S. Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA).

CSPA, GMA and SDA believe that manufacturers and processors should have the responsibility for providing sufficient information for the EPA to make prioritization decisions on the chemical substance and also for providing the information needed to make timely determinations on priority chemicals in the chemical safety assessment process. Subjecting every chemical to a minimum data set within five years will unfortunately result in the generation, collection and review of animal-intensive data and will needlessly stretch the limited resources of both government and industry. An additional concern is that a fixed set of data requirements could miss key information needs of chemicals or drive the generation data that is irrelevant for a safety assessment.

EPA's prioritization should be based on existing information available to the Agency through resources such as the Inventory Update Rule (IUR), the European Regulation on Registration, Evaluation and Authorization and Restriction of Chemical Substances (REACH), Canada's Chemical Management Plan, the EPA's High Production Volume (HPV) program, the Organization for Economic Cooperation and Economic Development (OECD) eChemPortal and biomonitoring reports published by the Centers for Disease Control and Prevention (CDC). We understand that there will be instances where additional information is needed for EPA to make prioritization decisions. In these instances, it is appropriate for EPA to have the regulatory tools to allow for the timely gathering of the necessary information. Additionally, once a chemical substance is categorized as a high priority, EPA can then more fully evaluate the data needed for

a robust safety assessment and use improved §4 authority to require the development of new test data needed to assess the risk posed by exposure to the chemical substance from its intended uses.

As the Discussion Draft outlines, a tiered approach should be applied to safety testing requirements. EPA should structure these requirements based on the expected risk of the chemical substance, including the volume and exposure of the chemical substance, and accounting for the known safety profile of the category of chemical substance. Data for structural analogues should be acceptable (subject to EPA agreement) in order to address all applicable toxicological endpoints per chemical substance, rather than require generation of new safety study data.

We appreciate that an understanding of the use of chemicals in downstream products is necessary for EPA to conduct sound scientific risk assessments. While it is recognized that this will pose an additional burden on our industry, consumer and commercial product companies are in a unique position to provide the use and exposure information needed by EPA to administer and enforce a risk-based chemicals management system. Use information is critical to establishing priorities for assessment. Exposure information is critical for making determinations about the safety of a particular chemical use.

The most recent data obtained from the 2006 IUR reports show that the information provided by the IUR data on downstream uses of chemicals is limited and would benefit from additional use data provided by consumer and commercial product companies. Currently, individual chemical manufacturers are responsible for reporting under the IUR and may not always have complete disclosure on how the chemicals they manufacture are used by their customers, the downstream formulators. In some instances, incomplete use information makes it difficult for EPA to properly identify priorities for further assessment. In conducting risk assessments, detailed knowledge about product formulations, product use habits and practices, and other exposure information is necessary.

To positively expand upon this effort, CSPA, GMA, SDA and their member companies have collaborated on how best to provide this information to a knowledge-driven chemicals management system in the U.S. This can be accomplished by straightforward extensions of the current IUR system. These new burdens are intended to help provide necessary and relevant use and exposure information for the priority setting to better inform risk-based decision-making. Consumer and commercial product companies should assume a role in reporting use information for TSCA-regulated chemicals and their uses by reporting end-use IUR category information. This would include an indication of use in products intended for children and information about the concentration of the ingredient in the product.

For existing chemicals that EPA identifies as high priority, consumer and commercial product companies could provide use and exposure information to support an assessment that shows with reasonable certainty whether a chemical is safe for its intended use. This may involve supply chain collaboration or individual company responsibility for safety assessment. Case by case determination as to who conducts the assessment for each use of the priority chemicals could be made (e.g., the chemical manufacturer, downstream users, trade associations, consortia). A recommendation could then be provided to EPA on a chemical's safety based on the safety

assessment conducted by the chemical producers and/or users. Finally, EPA would make the final determination of safety for the ingredient.

Priority Setting

CSPA, GMA and SDA testified before the House Energy and Commerce Committee in November 2009 that we should adopt an approach under TSCA where EPA would identify and address priority chemicals based on consideration of a chemical's hazard *and* exposure as indicators for the chemical's risks. This is a crucial element in TSCA modernization and especially important in building confidence in the U.S. chemical management system. While the Discussion Draft recognizes the need for risk-based priority setting, it does not clarify that both hazard and exposure information should drive the identification of priorities. Also, it is unnecessary for every chemical to fall under a priority chemical process and/or require a safety determination. There are thousands of benign, low risk chemicals that should not require a safety determination. We would urge the adoption of a priority setting process where, besides identifying high priority chemicals, EPA could identify those chemicals where more work is not necessary and that would allow a chemical to be identified as low concern until more information becomes available changing the priority level of a chemical.

With no comprehensive priority setting mechanism in TSCA for more than thirty years, there is an understandably high interest in identifying those chemicals of highest concern and beginning their assessments on an expedited basis. Beyond supporting overall priority setting, CSPA, GMA and SDA encourage the adoption of a mechanism that would enable EPA to quickly identify the chemicals of highest priority for immediate assessment. We recommended a process that would require EPA to screen the data from the most recent IUR submissions to identify chemicals that have the highest hazards (i.e., carcinogen, reproductive or developmental toxin or PBTs) **and** highest potential exposures (i.e., chemicals that have been measured in the CDC's biomonitoring program or chemicals in products intended for children). Our analysis indicates that such a process could be quickly completed and would identify approximately 50 to 100 chemicals that could rapidly move into EPA's deadline-driven safety assessment process while the Agency works on prioritizing the remaining chemicals in commerce. This process, constructed properly, could be done to avoid any unnecessary delays.

EPA should work with chemical manufacturers and users to ensure that EPA has timely and adequate information of chemical hazards, exposures and uses, including uses in children's products. While the legislation should identify risk-based criteria for priority setting—including expedited action—the selection of chemicals should be left to scientists at EPA. We believe that opportunity should be provided to allow information on safety for intended use to be submitted to EPA, and that EPA should be given sufficient time to complete safety assessments and to decide on and work with manufacturers and processors on appropriate risk management action.

Safety Standard

The Discussion Draft introduces a new safety standard for TSCA that "takes into account aggregate and cumulative exposure to chemical substances or mixtures," provides "reasonable certainty of no harm" to the public, including vulnerable populations, and protects the public welfare and environment from "adverse effects." The definition of adverse effect is broadened

from irreversible changes to any biochemical change. With such major changes, it is difficult to know what this proposal really means or what impact it will have. At a minimum, the adoption of the reasonable certainty of no harm standard for TSCA presents several workability challenges that must be considered.

First, because the proposed standard is taken from the Food Quality Protection Act (FQPA), where it is applied to issues of food safety, applying this standard to the vast number of chemicals that are not intended for food use is not necessary or appropriate. The cumulative assessment required in FQPA has EPA simply to look at one set of applications (pesticide residues on food crops) and one exposure pathway (ingestion of the food crops). FQPA does not require EPA to look at multiple exposures to workers, neighbors, and environmental risk; nor does FQPA require EPA to evaluate exposure during manufacture and disposal. This level of exposure assessment exceeds EPA's current capacity and has no existing precedent to commercial chemicals with widespread applications.

We also believe that TSCA modernization should embrace a safety standard determination process that focuses on those use categories which EPA identifies as presenting significant exposure and risk issues. Care also needs to be taken to ensure that a safety determination is based on intended uses of the chemical substance. The concept of "known or anticipated uses" would include accidental releases or misuse, which imposes a standard that cannot successfully be applied.

Finally, whether a chemical meets the applicable safety standards should be based on use categories, not for specific uses, mixtures, or products. More appropriately, a chemical assessment should demonstrate that the chemical can reasonably be expected to be safe for its intended uses based on hazard and exposure risk assessment methodology, using recognized and validated scientific methods – including methods used by EPA for the assessment of chemicals. EPA should be required to establish guidelines for assessment that consider the above factors, and others, setting forth its process to determine whether a chemical is safe for its intended uses. In assessing the safety of each chemical, EPA should consider factors including:

- The effect of exposure of humans, including children and other sensitive subpopulations, to the chemical;
- The reasonable and foreseeable uses, including associated existing risk mitigation measures;
- The probable human exposure to the chemical because of those uses;
- The probable environmental releases of the chemical because of manufacturing, distribution, storage, use, and disposal;
- The effect of those environmental releases on humans or the environment; and
- Appropriate, generally recognized safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of the use of a particular chemical, are based on scientific evidence.

Risk Management

EPA should have clearer risk-based authorities to specify risk management measures that will ensure that chemicals of concern are reasonably expected to be safe for their intended uses.

Risk management is the process of selecting and implementing actions on an assessed chemical that has been determined in the safety standard assessment to pose an unacceptable risk. Risk management measures should be considered as part of, and integrated with, the safety standard determination process, and EPA should be provided the authority to impose a broad range of controls to ensure that chemicals are safe for their intended use. Where it is determined that risk management tools are required, they may be developed for use to control any appropriate aspect of the substance's life cycle – from the design and development stage to its manufacture, use, storage, transport and ultimate disposal – to meet the safety standard.

As drafted, the legislation would require EPA, on one hand, to impose conditions on not only a specific use or use category, but also to require EPA to establish **and enforce** conditions for warning and use labels, as well as the method or manner a manufacturer or processor may use to manage risk and meet the safety standard. While EPA has the authority to determine safety of a chemical substance, it is unclear how these determinations will be coordinated and enforced when they cross jurisdictional lines of other federal or state regulatory agencies. We encourage a system where EPA continues to work on safety assessments, in coordination with other agencies that have the specialized regulatory responsibility with regard to chemical use or process restrictions. However the main regulatory responsibility for risk management should stay with currently established federal agencies.

EPA should develop appropriate risk management measures for application to categories of use of the chemical, not for each individual mixture or product. The process should also allow industry to develop alternative risk management measures, but such alternatives would be subject to EPA approval. Limits or prohibitions on categories of use should not be imposed at the time of a safety determination, but only if control measures cannot bring the use within the standard. Additional test data may reduce the uncertainty associated with a risk or exposure assessment and reduce or eliminate the need for use of a risk management measure.

Declarations, Reporting & Retention of Information

We have serious concerns with the approach laid out in the Discussion Draft that would require the collection of an expansive amount of information, most of which has previously not been sought by EPA. The new requirements would also accelerate periodic information collection from five years to every three years, and apply to mixtures as well as chemicals. This information would be made publicly available on the Internet. We have significant concerns with these provisions and their impact on innovation and competitiveness of US industry.

In discussions with Congressional leaders and stakeholders, CSPA, GMA and SDA have acknowledged that EPA needs better use and exposure information to be able to complete risk-based prioritization of chemicals for assessment. As described earlier, this can be accomplished by straightforward extensions of the current IUR system – to collect use and exposure information from chemical users rather than from manufacturers. Of course, much more detailed use and exposure information is needed for priority chemical safety assessments and chemical

users/processors should be involved, but these requirements should focus on priority chemicals and not try to track every physical item in commerce.

We have also stated that existing information should be the basis for EPA prioritization, especially for toxicity information. EPA already has significant toxicity information on chemicals from industry submissions through the years and from the tens of thousands of studies submitted on 1,800 chemicals in the U.S. and OECD HPV programs. Additionally, in 2010, data will be submitted and made publicly available on more than 4,400 high production volume and high hazard chemicals under REACH. As described in our November 17, 2009 testimony, EPA could do initial priority setting using a combination of improved IUR use and exposure information and the greatly expanded hazard information that is or soon will be available.

We are uncertain of the purpose of the requirement for EPA to collect, within one year, an enormous amount of information on every chemical and mixture in the American economy. EPA would be required to collect information on chemicals and end-product mixtures, as well as every change within plant manufacturing and processing streams, every change in a blend or mixture or every modification in a product concentration. This requirement would undoubtedly create a bottleneck for review and in making safety determinations on every future change to each and every chemical and mixture in commerce.

Confidential Business Information (CBI)

CBI protections are essential to the innovation, including the development of more sustainable "greener" products and job creation of U.S. industry, and would hinder industry's ability to carry out the goals found in Section 36 of the Discussion Draft promoting green chemistry. Federal policy, as well as many decades of case law, recognize how the disclosure of trade secrets will harm business, inhibit American competitiveness in the global economy, and the protection of legitimate intellectual property interests.

Under the Discussion Draft provisions, in order to be eligible to secure CBI protection for information submitted to EPA, a submitter must fully justify the claim at the time of submission. CSPA, GMA and SDA embrace this up-front substantiation in light of well-established criteria. However, amendments to TSCA should not alter the current Freedom of Information Act (FOIA) protection of trade secrets, commercial information and financial information that is privileged and confidential under the current FOIA. We would note any requirement for companies to resubstantiate every historical claim would be overly burdensome and unnecessary. We would advise that provisions apply solely to future claims of CBI; however, a need to re-substantiate could be required when prompted by appropriate triggers.

The sharing of CBI with other government authorities, in particular foreign entities must ensure that appropriate safeguards are in place. This would include a bilateral agreement with EPA and such state and foreign government guaranteeing the same level of CBI protection to prevent unauthorized disclosures. Additionally, we have particular concerns about the capabilities of municipal governments to protect confidential information— and urge that any needs they have should be worked through their respective states – eliminating the need for EPA to share CBI with these local governments.

The Discussion Draft would prohibit CBI protection for chemical identity. In stakeholder meetings, CSPA, GMA, and SDA pointed out how disclosure of chemical identity could result in competitive harm. If chemical identity is not protected, competitors could begin to utilize the innovative technology without having to undertake the costly and time consuming research and development (R&D) efforts which the initial company had to do. In the alternative, generic chemical names can be used where chemical identity is claimed CBI, and would provide interested parties with all of the information they needed to assess and manage health and safety concerns. Companies have the incentive to undertake R&D efforts only if they have a reasonable probability of being able to recover their investment through marketing the products they create. Robust protection of CBI provides industry confidence that they will be able to reap the benefits from their expenditure of both the time and resources in R&D efforts to create new and better products thereby allowing continued innovation.

The Discussion Draft arbitrarily sets time limits that would protect CBI for no more than five years. The need to protect such information from disclosure to competitors is directly related to the commercial value companies derive from the investments they have made in developing their products: a five year time limitation bears no reasonable relationship to the time necessary for companies to realize a return on those investments. EPA should determine legitimate CBI claims based on initial substantiation requests, and require re-substantiation of CBI claims that would be prompted by appropriate triggers determined by EPA.

Under provisions for safety-standard information, EPA would be required to make public "any safety standard" that the Agency develops in the regulation of a particular chemical (or a category of chemicals), including any information developed by EPA in support of the standard. To develop and justify safety standards, EPA likely would obtain CBI from companies pertaining to their production, handling, use and disposition of the subject chemicals. This information should continue to have CBI protection. Moreover, EPA also would be required to make public "[a]ny information indicating the presence of a [chemical] in [an article] intended for use or reasonably expected to be used by children or to which children can otherwise be reasonably expected to be exposed". Such terms/phrases as "article", "children", "any information", "indicating the presence", and "an article . . . to which children can . . . be reasonably expected to be exposed" are subject to a wide degree of interpretations and appear to eliminate most CBI protections.

We understand the policy interest of a more active, systematic review of CBI claims by the Administrator. However, the Discussion Draft requires EPA to set CBI rules by order without a traditional notice and comment period. In the alternative, a notice and comment period to develop such rules would allow all interested stakeholders to provide valuable input in order to develop sound and transparent policies.

Conclusion

We appreciate the opportunity to provide these comments and to address the Discussion Draft and the effect the proposed amendment would have on all aspects of the innovative and world-class U.S. chemical management system. It is essential that any modernization of TSCA result in a successful program that is workable and allows for EPA to meet its regulatory obligations.

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