Sustainable Chemicals & Materials Roundtable

An Information Exchange: Moving From High Risk to Low Risk Chemicals

December 6, 2013

Offices of The Horinko Group
2300 N St, NW
Washington, DC 20037

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EXECUTIVE SUMMARY

Our society is fundamentally moving towards the use of more sustainable materials and chemicals. However, there is no orderly process for that transition. Instead, there is a panoply of efforts, both public and private, driven by both regulatory and market forces. As a result, current manufactures and developers of new products cannot easily predict what chemicals and materials will be available for use in the future.

The Sustainable Chemicals & Materials Roundtable convened a group of public and private stakeholders to debate the current state of laws, policies, and procedures to integrate sustainable chemicals and materials into systems and products. The discussions focused on how risk assessment is used, how organizations target chemicals for attention, and how alternatives are selected.

Risk Assessment. Risk assessment is generally the precursor for regulations and sometimes for market decisions to create safer alternatives. The participants discussed the suite of risk assessment tools used by EPA, from the comprehensive, most readily observed IRIS process (focused on a small selection of existing chemicals) to the screening risk assessments used by TSCA's New Chemicals Program. There is a spectrum of risk assessment methods available, and the degree depends upon the chemical's importance in commerce and level of toxicity and exposure. While there are not sufficient resources available to conduct extensive risk assessments for every chemical in commerce, enough is known about different categories or families of chemicals to make some informed decisions as to priority.

> **Key Takeaway – The nature of a risk assessment should be tailored to the chemical's importance and impact. Stakeholders need to provide input early in the process, especially information about relevant studies. There exists a need for a more clearly defined process for targeting and reviewing existing chemicals coupled with more effective coordination, outreach, and communication.**

Targeting Chemicals for Action. A number of agencies and organizations have begun to develop lists of prohibited or restricted chemicals or substances of concern. Some of these lists are developed without any coordination across government or private sector networks. The lists can sometimes be used as either market pressure points or in litigation to force chemicals out of commerce. The group debated mechanisms for better collaboration to help ensure that scientific principals and good public communications inform the creation and use of these lists. Creation of functional categories is another potential solution, as chemicals have different exposure profiles depending upon their intended use. Combining a chemical's risk profile with its functional use may also help to preserve critical uses.

- **Key Takeaway – The process for identifying priority chemicals (or categories) should involve the stakeholder community and consider the hazardous nature and functional use of the chemical.**

Safer Substitutes. Developing, testing, and integrating safer chemicals present a host of challenges. Supply chain transparency, data gathering, and communications require extensive effort, and most companies/agencies do not have sufficient resources. In some cases, industry groups with similar product lines have developed joint efforts to track chemicals in their supply chains and assess alternatives. Performance specifications could be tested across functional uses. The systems have to accommodate trade secrets as well as data collection and access to both the public and private sector.

- **Key Takeaway – Chemical substitutions require sufficient lead-time for performance testing. Safer substitutes should be identified early and tested throughout the supply chain, in a manner that ensures market stability for the replacement. There also needs to be regulatory flexibility for specialized applications (e.g., defense, transportation) requiring high performance and where exposure potential is low.**

Ideas for Action. Going forward, the group agreed that shared information about risk profiles linked to a chemical's (or its analog's) functional uses, supply chain transparency, and safety/efficacy of alternative substitutes would be helpful. The ability to build organizations and networks for sharing this information is highly dependent upon the collaborative resources that can be brought to the table, either by a group of single large entities (EPA, states, large private companies) or groups of smaller organizations. Small business in particular will need special assistance. Joint testing protocols for substitutes would be one step in the right direction. Assembling a public-private partnership to accomplish this collaboration will require changes in organizational culture, mutual understanding, and working across sectors to achieve a common goal. Continuing the exchange of ideas combined with powerful pilot projects would be useful next steps.

- **Key Takeaway – Public-private collaboration in a shared-solutions, cross-networked manner is needed to accelerate progress and prevent market crises.**

INTRODUCTION

The Sustainable Chemicals & Materials Roundtable comprised a group of stakeholders from government, private industry, academia, non-governmental organizations, and other interested parties debating the current state of laws, policies, and procedures to integrate sustainable chemicals and materials into systems and products. Sustainable chemicals and materials (including products and processes) are those that:

1) Have less impacts on human health and the environment;
2) Have an adequate supply into the future;
3) Often can be recovered and re-used; and,
4) Meet performance requirements and are cost-effective.

The roundtable included discussions on processes for developing, testing, and implementing sustainable alternatives and provided a unique opportunity for mutual learning, information gathering, and sharing of views among affected stakeholders.

Refer to Appendices I, II, III regarding Participant List, Agenda, and Issue Overview Paper.

OPENING REMARKS

Marianne Horinko, President of The Horinko Group and former U.S. EPA Acting Administrator, commenced the roundtable with introductory remarks.

KEYNOTE REMARKS

Maria Doa, Director, Chemical Control Division, Office of Pollution Prevention and Toxics, U.S. EPA, introduced the Agency's efforts for improving the safety of chemicals and highlighted two focal areas: 1) TSCA reform; and, 2) enhancing EPA's Existing Chemicals Program under TSCA.

Ms. Doa noted that TSCA was enacted in 1976; however, it is the only major environmental statute that has not been re-authorized. TSCA set a national program to: 1) gather information on new and existing chemical substances and mixtures; 2) require testing of chemicals and mixtures; 3) screen and control unreasonable risks of new and existing chemicals and mixtures; and, 4) coordinate with other federal agencies. Many claim the authority is more effective for managing new chemicals verses existing chemicals. Since there is no mandatory program to determine the safety of existing chemicals, significant legal and procedural hurdles have proven difficult to limit or ban existing chemicals. EPA has an ability to gather additional health and environmental information on chemicals; however, Confidential Business Information (CBI) claims continue to limit access of information by the public and other governments. The goals set out under the Administration's *Essential Principles for Reform of Chemicals Management Legislation* released in the Fall of 2009 are intended to help inform the discussion on TSCA reform.[1]

Ms. Doa explained the Agency's initiative of a multi-pronged approach for an Existing Chemicals Program strategy, which includes improvements in three areas: 1) risk assessment and management; 2) increased access to chemical data; and, 3) promotion for the design and use of safer chemicals.

She described an inclusive stakeholder process for selecting criteria to help identify and prioritize chemicals for risk assessment. The criteria included the following factors: 1) potential concern to children's health; 2) neurotoxic effects; 3) persistent, bioaccumulative, and toxic; 4) probable or known carcinogens; 5) used in products to which children may be exposed; and, 6) detected in biomonitoring.

In March 2012, EPA identified a Work Plan of 83 chemicals for review and risk assessment, resulting in an initial set of seven chemicals for risk assessment in 2012, followed by an additional set of 18 chemicals for risk assessment in 2013 and 2014. EPA intends to annually identify a new set of chemicals for risk assessment, and she clarified for the group that the risk assessments will take place within the Office of Pollution Prevention and Toxics. Furthermore, if an assessment indicates potential concerns, EPA will evaluate and pursue appropriate risk management efforts including voluntary and regulatory tools. Conversely, if risks are negligible, EPA will conclude its work on the chemical. Risk assessments will continue on the remaining Work Plan chemicals, and additional chemicals may be added to the Work Plan if warranted.

Since 2009, EPA has taken a range of significant steps to improve the accessibility and usability of chemical data, such as reducing unchallenged CBI claims (e.g. approximately 900 cases involving health and safety studies in which the chemical identity in the study has been declassified). Ms. Doa highlighted the development of a new tool, ChemView, which was released in September 2013 and provides enhanced access and use of EPA's chemical

[1] Essential Principles for Reform of Chemicals Management Legislation – http://www.epa.gov/opptintr/existingchemicals/pubs/principles.html

information.[2] She further explained that EPA's Office of Research & Development is currently developing a "dashboard" that will provide computational capabilities to assist users in researching and evaluating various TSCA chemicals. ChemView consolidates available TSCA information and provides more streamlined access to EPA assessments, hazard characterizations, and information on safer chemical ingredients, in addition to identifying particular end-points. EPA has incorporated stakeholder input into the design and welcomes feedback on the current version of the site.

Lastly, Ms. Doa called attention to the Agency's efforts with promoting the design and use of safer chemicals through a number of key programs and activities. EPA's Design for the Environment (DfE) works in partnership with industry, environmental groups, and academia to reduce risk to people and the environment by finding ways to prevent pollution. DfE encompasses an Alternative Assessment Program to identify and evaluate functional chemical alternatives through an inclusive stakeholder process, in addition to a Safer Product Labeling Program to promote the design of safer consumer, industrial, and institutional chemical-based products. Over 2,500 products maintain the DfE-label and in September 2012 EPA released a Safer Chemical Ingredients List for use in DfE-labeled products. She also highlighted EPA initiatives to promote Pollution Prevention (P2) through a variety of partnership programs, grants, frameworks, and challenge programs, such as: 1) Green Chemistry Annual Award Program; 2) E3: Economy, Energy, and Environment; 3) Green Suppliers Network; 4) Federal Electronics Challenge; and, 5) P2 State and Tribal Grants.

John Conger, Acting Deputy Under Secretary of Defense (Installations & Environment), explained his office's dual role regarding chemicals and materials that includes: 1) ensuring DoD's ability to obtain and use the chemicals and materials needed to accomplish its mission; but also, 2) promoting the integration of safer, more sustainable chemicals and materials into DoD.

He called attention to DoD's Emerging Contaminants Program, which was established nearly 6 years ago and encompasses a process known as "scan-watch-action" that: 1) monitors for evolving chemical science and regulations; 2) assesses risk to human health and DoD's mission; and, 3) implements proactive risk management actions. The program's forward-looking and preemptive approach has resulted in significant resource efficiencies, in addition to advanced lead-time for decision-making.

Lastly, Mr. Conger explained that the roundtable discussion concept evolved from DoD's interest in both preserving access to chemicals and materials needed to conduct its mission, and the desire to integrate safer products where they can meet performance requirements. However, there are many challenges when doing so. A particular challenge is the time and resources needed to fully research, develop, test, and evaluate the performance of these new chemicals. The chemicals used by DoD must ensure performance and that performance protects people and assets. It is also critical to ensure a full understanding of the environmental and human health effects of substitute chemicals prior to implementing such chemical phase-outs, whether by regulation or by market pressure.

Mr. Conger's closed his remarks with recognizing the importance of convening federal and state agencies, industry, and non-governmental organizations in an effort to exchange information and perspectives and seek mutual understanding of the challenges in front of us.

[2] ChemView – http://www.epa.gov/oppt/existingchemicals/pubs/chemview.html

DISCUSSION OVERVIEW

Drew Rak, Senior Principal Scientist, Noblis Inc., described the framework of the discussion, which would be broken into four parts and roughly mirror the risk assessment/risk analysis framework.

MODERATED DISCUSSION

PART 1 – The risk assessment process; general overview and participant observations: *How does a chemical become a concern?*

Discussion & Analysis:

Participants discussed the spectrum of risk assessment processes, tools, and applications, including the most readily observed EPA's Integrated Risk Information System (IRIS) toxicity assessments for a select group of chemicals to new chemical reviews, in which EPA's New Chemical Program assesses over 1,000 new chemicals per year each within a 90-day timeframe. Among the varying types of risk assessment exists an effort to create a more transparent and predictable process for assessing not only new chemicals but also the existing TSCA chemical inventory. However, participants described the critical need for a more clearly defined process for targeting and reviewing existing chemicals coupled with more effective coordination, outreach, and communication. New and improved tools from EPA's Office of Research and Development are helping shape this process in an effort to effectively gather, store, and disseminate wide volumes of chemical data in a manner more meaningful for stakeholders.

Participants described the significant influence of EPA's IRIS process. Stakeholders rely on IRIS toxicity assessments to make decisions, and the results can have material economic and procedural implications. There are also multiple types of risk assessments that do not use data from IRIS, and some of those assessments are much less intensive than the IRIS assessment; however, stakeholders remain concerned with the thoroughness of any risk assessment because of potential implications.

Participants also acknowledged a much-heightened awareness of chemical risk among the general public. There exists an increased concern for exposures and desire to make sound choices. It was stressed that improved communications around risk assessments will be critical. Risk communications can be misleading, and further education through accurate communication remains necessary, as consumer reaction is a real market driver.

Perspectives Shared:

- *Power of risk assessments* – IRIS develops toxicity values, and those values drive regulatory action. Even when risk assessments are in draft form, state organizations will rely on these values to shape decisions. The use of draft risk values is controversial and has resulted in many disputes over the science.

- *Application example* – IRIS assessments are vitally important to DoD's "scan-watch-action" process. Anticipated IRIS assessments help determine which chemicals should receive a Phase I Impact Assessment. Toxicity level changes have implications (financially and in defense missions) across different functional areas that can result in changes to engineering controls, protective equipment, and cleanup levels.

- *Clarifying risk assessment from risk management* – IRIS is a hazard, or toxicity, assessment. Toxicity is assessed and then applied to exposure information, technology, and economic considerations, in order to characterize that risk and result in a risk management decision. Historically, risk assessment findings have been controversial

and drive a lot of decision-making. IRIS numbers are weighed heavily because they are often the only benchmarks available. A challenge will always exist with taking scientific information and translating it into a policy decision.

- *Sensitivity of toxicity parameter* – The toxicity (or hazard) can dictate the outcome of any risk assessment. This is especially challenging with new chemicals. How do we assess and make a decision before a chemical is fixed into our product line and drives the economics around that product?

- *New chemical review* – EPA's New Chemical Program has proven its ability to review chemicals in a relatively short period of time. New chemicals move to market typically within 90 days, and EPA reviews in excess of 1,000 new chemicals a year, assessing hazardous characteristics and reviewing chemical categories. Generally, for 80% of new chemicals, there are no concerns, and experience has shown that new chemicals do tend to be "greener." However, chemicals with concern may result in a consent order defining manufacturing specifications or specific use-based restrictions. For new chemicals, a complete IRIS assessment is not performed; however, there is a hazard evaluation process. Subsequently, a summary relevant to the chemical's hazards and further testing requirements is produced. The chemical manufacturer then provides information to EPA as to how the chemical will be made and how they intend to market it for use. EPA takes this information into account and applies models to estimate potential exposure. The result informs the EPA's risk management decision. At times, this decision results in a Consent Order including a Significant New Use Rule.

- *Existing chemical review* – There is a challenge with how to handle existing chemicals and chemicals that were grandfathered into the TSCA inventory. Many involved in the TSCA reform debate would support some sort of mandate with deadlines for EPA to review existing chemicals. Predictability and communication are vital to this effort. There remains a critical need for an open, clear, and consistent process for reviewing existing chemicals within the TSCA authorities to minimize disruption and controversies.

- *Two Risk Estimates* – One participant suggested that it may be useful to develop two risk estimates for each chemical/pathway: one would be the protective level upon which standards are based; and, the other, average level, would be predictive. Other participants believe that two risk estimates would be confusing from a risk communication perspective and that the lower estimate would, as a practical matter, be used for risk management actions.

- *Personal Risk Management* – Risk assessments are not only important to risk managers, but also to receptors (the public), so people can make personal risk management decisions to limit their exposures. For example, women of childbearing age may decide to work from home when TCE is discovered in the indoor air in their workplace and mitigation has not yet been implemented.

PART 2 – Regulatory and market mechanisms that control, restrict, or remove a chemical from commerce: *What are the pros/cons of restricted chemical lists?*

Discussion & Analysis:

A number of agencies and organizations are developing and maintaining lists of prohibited or restricted chemicals. Participants shared views about the pros and cons of such lists. Lists can provide clarity and transparency and function as an easily understood tool for communicating broadly. However, listing severely stigmatizes a chemical, and in turn may affect the creditability of its application where exposures are otherwise acceptable. This also presents the issue of integrating newly released information for a listed chemical that has otherwise become "static" – integrating new versus static information is an overarching issue facing all actions to address chemical risk management. Participants further explained how some of these lists are developed without any coordination across government or private sector networks, resulting in varying conclusions and market uncertainty, and then may be used as either market pressure points or in litigation to force chemicals out of commerce.

The group debated mechanisms for better collaboration to help ensure that scientific principals and good public communications inform the creation and use of lists. Creation of functional categories is another potential solution, as chemicals have different exposure profiles depending upon their intended use. Combining a chemical's risk profile with its functional use may also help to preserve critical uses. It may be practical to have a list that distinguishes critical uses that are appropriate based on minimal exposure or where a lack of safer, functional alternatives exists. Listing chemicals along with critical uses can and should drive R&D. Sufficient lead-time is essential for planning substitutions around critical uses and construction of highly durable goods.

Perspectives Shared:

- *Categories* – Categories and analogues reveal similarities, and when looked at in terms of chemical groups, there is an opportunity for more recognizable chemical substitution.

- *Development of lists* – There are many rational processes for listing chemicals. EPA has undertaken several chemical prioritization processes over the last 30 years. In the 1990's, EPA funded an effort out of University of Tennessee to look at chemical ranking, scoring, and prioritization systems, and it developed its own internal system. Internationally, the chemical secretariat in Sweden collaborated with an NGO on a list called the SIN (Substitute it Now) list completed by a group of toxicologists. Sectors are beginning to develop lists as well. For example, footwear and apparel companies created a list primarily based on regulatory restrictions, and they have begun coordinating with their manufacturers.

- *Pros and cons with lists* – A challenge persists with educating small businesses and the public on chemical regulations that will impact them. Lists are an easy and necessary way to get information out and a first step of what to potentially avoid for companies without significant resources. However, multiple uncoordinated lists that characterize chemicals differently do create confusion among consumers. Further, listing severely stigmatizes a chemical. This stigma, with potentially negative consequences, can carry over even when a chemical was listed for a particular use, but in other uses the exposures are acceptable. After a chemical is listed, it is important to consider how to integrate new released information for a chemical that has otherwise become "static."

- *Functional categorization* – There are differing rationales for how chemicals are placed on lists. One interesting approach considers both structural and functional categorization. Chemicals are designed for a particular function. The level of granularity for that function could be examined. For instance, if the functional use is for space exploration, the performance needs are very different. A comparison can be made within that functional category for options that meet that particular functional use, followed by prioritization based on structure. There is work required to determine how this process can be applied to more effectively navigate the chemical universe and identify chemicals of lower or higher concern. EPA developed a computer-based risk-screening system known as *Use Cluster Scoring System*, which takes a chemical's functional use and then applies a risk ranking to inform choices.[3]

- *Lead-time* – Sufficient time is critical for incorporating changes into the process for constructing durable goods. There is a desire to better understand future anticipated actions by EPA and other regulatory authorities (e.g. similar to TSCA chemical-specific work plans), and there exists a need for clearer, consistent EPA processes for identifying emerging issues or actions that in turn provide sufficient lead-time for outreach, communication, and reasonable action by the regulated community. To the extent that lists and categories can help the regulated community better understand where things are headed, this can be a good thing.

- *Proposition 65, California litigations, and removal of chemicals* – Major concern exist about chemicals being removed from commerce or being placed on a list for the wrong reasons. One example of this is related to Proposition 65 in California. There are now a number of litigations and private settlements being proposed in California. Roundtable participants had differing opinions on the effects of the private settlements nationwide. It was explained that as a result of the private settlements with chemical companies, whole classes of chemicals are being proposed for removal from commerce (at least in California), including whole classes of potentially safer flame retardants that have yet to be developed. Where a chemical company may be trying to develop safer substitutes, their options are taken away. A number of different institutions, including the American Chemistry Council, are currently reviewing these cases. It is important to note that Prop 65 is a labeling law. It does not ban chemicals in commerce; it is meant for disclosure. Stakeholders are under the impression that Prop 65 is being used improperly in these private settlements.[4]

- *Critical uses and lists* – It may be useful to have a list that distinguishes critical uses that are appropriate based on minimal exposure versus a list that is tailored to broad consumer uses. A specific set of applications should be delineated. Listing chemicals that distinguish critical uses can and should drive R&D. This is a market issue as well. If there is a highly critical but finite use of something (e.g. rocket launchers), the market supply can vanish before there is available time to find effective substitutions.

- *Rethinking substitution policy* – There is currently an ongoing debate in the defense industry about whether we should have a list and what should be on it or not. DoD issued a strict policy for hexavalent chromium. Previously, the policy was aimed at promoting pollution prevention: "We would like you to use substitutes." The new policy turned this on its head: "You will not use hexavalent chromium unless a senior executive certifies that there are no alternatives that can meet performance requirements."

[3] Use Cluster Scoring System – http://www.epa.gov/oppt/exposure/pubs/ucss.htm

[4] Refer to Appendix IV stakeholder letter sent to California Attorney General regarding the Proposition 65 settlements

Stakeholders wonder if this will be done for every category, along the same lines as a list. This is a risk-based approach. There are efforts underway to go back upstream early in the acquisition process to the design phases and encourage suppliers to look at all the alternatives, to consider future regulations, and to incorporate the best chemicals. Suppliers are being asked to take a conscious look at regulatory regimes. A form of life cycle assessment is being used to help make the most sustainable choices in chemicals and materials in defense systems. The idea is to embed this approach formally into the acquisition process.

PART 3 – Transitioning to substitutes: *What are the challenges and resource/testing requirements?*

Discussion & Analysis:

Developing, testing, and integrating safer chemicals present a host of challenges. Supply chain transparency, data gathering, and communications require extensive effort, and most companies/agencies do not have sufficient resources. Participants debated the practicality of collecting chemical data from downstream purchasers at the base of the supply chain. Nevertheless, the intrinsic value of such data cannot be dismissed.

In some cases, industry groups with similar product lines (e.g. automotive sector, aerospace sector) have developed joint efforts to track chemicals in their supply chains and assess alternatives. In addition, performance specifications could be tested across functional uses. The systems have to accommodate trade secrets as well as data collection and access to both the public and private sector. With substitutions, participants stressed the concept of stability in the marketplace and the required due diligence for prevention of regrettable substitutes.

Perspectives Shared:

- *Supply chain transparency, data gathering, and communication* – When a chemical comes under regulatory or public pressure to remove or restrict it, the first questions asked are: do we use it and where in the supply chain? It is very difficult and time consuming to go back into the supply chain and identify where chemicals exist. One proposed action to fix this is for downstream purchasers to collect data on the chemical and material content of all components coming from the supply chain. Not knowing this information can lead to various problems, including failure to recover strategic materials and liability issues, among others. A new proposed policy being discussed at DoD would collect key information on chemical content of material acquired. The implementation cost to commercial suppliers should be manageable because it will trickle down through the supply chain. At the base of the supply chain, someone must know the content, and that information can then be passed up the supply chain.

- *Value of supply chain transparency* – Regulatory processes like REACH started 15 years ago and registration of the first chemical may be in 7-10 years. Any regulation on international chemicals management takes at least five years. Five years is a reasonable timeframe to start the process of going through supply chains to identify chemicals that may be on a regulatory list. Without the proper request from a regulatory agency, however, many companies would not have the authority to do this. The supply chain database initially will be very complicated, and there are costs to set up this type of system. However, it is likely cheaper to maintain a system than to repeatedly return to the supply chain. More so, the clarity of the supply chain to consumers and society is an added value. For instance, if retailers decide to eliminate a certain chemical, their actions are viewed as protecting the public, and this adds value.

Costs and data gathering challenges – It cannot be expected that end-use manufacturers know exactly what is in their original product. Factories use chemical mixtures and may not know the specific chemical contents; a chemical used in a reaction along the way may not be present at the end. There were differing opinions on the resources required to report the chemical/material content of products and articles up the supply chain. Some participants believe that collecting such information would inflict significant resource costs and other burdens. If data reporting is not currently happening today, then it will result in an added cost. Other participants believe that a company at the bottom of the supply chain that manufacturers an article knows the chemical/material content and simply has to list it on purchase documents.

- *Confidential Business Information* – As the transition to safer chemicals occurs, there is likelihood that new innovative chemicals will be a trade secret. Generic names and categories in contracts may be one way to address this, sourcing a third-party to collect and make the information generic. However, if companies are required to disclose this sort of information, they may forego that market, possibly leading to more offshoring of manufacturing. Not adequately protecting CBI may also have the unintended consequence of decreased investment and innovation in green chemicals; if companies cannot protect their investment from competitors, they may forgo the investment.

- *Substitutions and stability* – With substitutions, sufficient lead-time to make changes is crucial. Development, testing, and validation may complicate the selection of substitutes and require additional time. Without adequate time, regrettable substitutes may be selected. Furthermore, a critical concept is stability in the marketplace. For example, the U.S. Navy spent hundreds of millions of dollars phasing-out ozone-depleting Chlorofluorocarbons (CFCs) used in refrigeration equipment aboard ships. Hydrofluorocarbon (HFCs) were the logical replacement. Now the science has turned from concerns about ozone depletion to global warming, and HFCs are under regulatory pressure. The Navy could face additional costs to develop substitutes or new cooling technologies to replace HFCs. A life cycle assessment may have prevented this by identifying the issues early on. With the current state of information and knowledge, it is very important to complete due diligence on the substitution end and ensure the substitutes have stability in the marketplace.

- *Guidance on substitutions* – Several frameworks to help with transitioning chemicals are being developed.[5] EPA has also funded an NAS study on design and evaluation of safer chemical substitutes.[6] The goal is to establish a framework that would outline a minimally acceptable evaluation of alternatives that could be implemented for different types of uses—regulatory or supply chain—to help inform a suitable alternatives assessment. However, there are value judgments that are going to differ if it is a consumer product company versus a company putting in an airplane engine.

- *Transitioning to safer substitutes* – With respect to transitioning, there seem to be two basic needs: 1) Better science to enable rapid evaluating of substances to understand potential tradeoffs and red flags (like those in the HFC case), and 2) greater investment in Test & Evaluation and basic R&D on greener chemicals. EPA's Green Chemistry Program is largely underfunded. A federal R&D bill for Green Chemistry has been on the table for the last 10 years, and it still has not made its way through Congress. More

[5] Interstate Chemicals Clearinghouse is releasing a reference guide on transitioning to safer alternatives; OSHA has a website on transitioning to safer alternatives; EPA has its DfE framework for comparative chemical hazard assessment or alternatives assessment; Massachusetts' toxics use reductions program has for years looked at the performance and the hazard side; California is expected to develop its own guidance.

[6] http://dels.nas.edu/Study-In-Progress/Design-Evaluation-Safer-Chemical/DELS-BCST-13-02

effective supply chain collaboration to evaluate alternatives, including shared-testing, is also an excellent example of shared-resource burden in a pre-competitive stage of substitution analysis.

PART 4 – Concluding Discussion: *What ideas are there for an improved process?*

Discussion & Analysis:

Going forward, the group agreed that shared information about risk profiles linked to a chemical's (or its analog's) functional uses, supply chain transparency, and safety/efficacy of alternative substitutes would be helpful. The ability to build organizations and networks for sharing this information is highly dependent upon the collaborative resources that can be brought to the table, either by a group of single large entities (EPA, states, large private companies) or groups of smaller organizations. Small business in particular will need special assistance. Joint testing protocols would be one step in the right direction.

Assembling a public-private partnership to accomplish this collaboration will require changes in organizational culture, mutual understanding, and working across sectors to achieve a common goal. Continuing the exchange of ideas combined with powerful pilot projects would be useful next steps.

Perspectives Shared:

- *Considerations for small business – S*mall business creates a great deal of competition and innovation, and without the proper protections, this could disappear. The resource requirements of testing often deter small businesses and decrease the diversity of players in this space. Record keeping costs and other activities associated with tracking chemicals in the supply chain are much more burdensome for small business. Having tools in place to support smaller business that could allow them to more rapidly screen chemicals and understand the contents, potential risk, and hazards could be helpful. Providing a forum for small business to understand EPA's process for screening chemicals would allow for more effective business planning. Additionally, there are consortiums where small and large companies pay a percentage proportional to the benefits they will receive from testing. A tool that would allow small businesses to pay proportionate to their size would be very useful.

- *Available modeling tools* – EPA modeling tools are all publicly available, although many require fairly advanced scientific understanding. A non-profit called Clean Production Action developed a tool known as GreenScreen. It is a hazard benchmarking approach that follows the Globally Harmonized System decision logic, and the DfE approach for benchmarking. A tool that flags hazards and identifies chemicals that businesses may need to be aware of (rudimentarily doing what a toxicologist does) could help inform decisions.

- *Federal outreach and assistance* – EPA staff within the Chemical Control Division work closely with chemical companies before there is a submission. The companies come in and talk about their process, and EPA advises them on what may raise a concern and what else should be considered. Engaging with EPA early on in the process has saved businesses time and resources. Nevertheless, there is a clear desire from both public and private stakeholders for EPA to further build-out its outreach efforts to include increased engagement with the entire federal family, who are also subject to its chemical risk management decisions. Separately, small businesses should consider the Department of Commerce's Manufacturing Extension Partnership Program, which provides assistance and resources to small and medium-size business in an effort to strengthen the country's manufacturing base.

- *Joint testing* – DoD would like to develop joint test protocols that would make testing for substitute chemicals more collaborative in a time of scarce resources. When a new chemical comes into the marketplace, collaboration on a joint test protocol and joint funding may be considered.

- *Mutual understanding* – Regulators and industry need to better understand each other. Companies need to look for more opportunities to engage not only with EPA but with European regulators as well to help improve their understanding of unique processes and characteristics. That way, when it comes time for regulators to exercise authority, they can do so in a thoughtful manner. Furthermore, the European counsel for REACH is based in Washington D.C. through the European Commission. They are very good about outreach and are willing to provide information and guidance.

- *Working across sectors* – Most industrial processes have more similarities than differences. More opportunities for working across sectors to share experiences are needed. Aggregating chemical lists, design practices, and testing and evaluation protocols could serve as a foundation for information sharing. More public-private collaboration to leverage know-how and resources should be explored. For instance, The Sustainable Chemicals and Materials for Defense Forum used a survey to identify the top 10 problem chemicals. This could be a good starting point for collaboration.

- *Pilot consideration* – DoD will consider a small pilot program, or survey, to engage small suppliers and ask whether it would be burdensome to report the chemical and material content. The purpose of the pilot would be to receive feedback on what may be viewed as problems, costs, barriers, etc.

CLOSING REMARKS

Marianne Horinko concluded the discussion by thanking all participants for their time and observations. She briefly summarized the day's discussion. Key takeaways included: the distinction between the IRIS process and new chemical management; the utility of identifying groups of chemicals based on structure and activity in certain applications; the positive and negative role that lists of chemicals can play to both inform and shape chemicals management; collaborative approaches for researching, testing, and evaluating alternatives; using functionalities for identifying alternatives and developing lists; the need to collect information to get ahead of the problems and opportunities for the future and the potential means to manage and use this data; managing this process of change collectively; and, the importance for all stakeholders to continue to collaborate on these issues going forward.

APPENDICES

- **APPENDIX I – PARTICIPANT LIST**
- **APPENDIX II – AGENDA**
- **APPENDIX III – ISSUE OVERVIEW PAPER**
- **APPENDIX IV – LETTER TO CALIFORNIA ATTORNEY GENERAL RE: PROPOSITION 65 SETTLEMENTS**

APPENDIX I – PARTICIPANT LIST

Marianne Horinko (Facilitator)
President
The Horinko Group

Andrew Rak (Moderator)
Sr. Principal Scientist
Noblis, Inc.

Steven Bennett
Director for Scientific Affairs
Consumer Specialty Products Association

Bob Boughton
Senior Hazardous Substance Engineer
Pollution Prevention & Green Technology Program
California Department of Toxic Substances

Sarah Bresolin
Assistant Chief Counsel, Environment
U.S. Small Business Administration, Office of Advocacy

John Conger
Acting Deputy Under Secretary of Defense (Installations & Environment)
U.S. Department of Defense

Maria Doa
Director, Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Charles Ingebretson
VP, Energy & Environmental Policy
The Boeing Company
Representing, Aerospace Industries Association

Samantha J. Jones, Ph.D
Associate Director for Science,
Integrated Risk Information System (IRIS) Division, Office of Research and Development,
U.S. Environmental Protection Agency

Dan Newton
Senior Manager, Chemical Risk Management Policy & Advocacy
Society of Chemical Manufacturers & Affiliates

Julia Rege
Senior Manager, Environment & Energy
Association of Global Automakers

Leslie Riegle
Director, Environmental Policy
Aerospace Industries Association

Lenny Siegel
Executive Director
Center for Public Environmental Oversight

Stacy Tatman
Environmental Affairs Manager
Alliance of Automobile Manufacturers

Joel Tickner
Associate Professor, Community Health & Sustainability
UMass Lowell University

Blandine Trouille
Analyst, International Trade Administration
U.S. Department of Commerce

Patricia Underwood
Deputy for Risk Assessment Office of the Deputy Under, Secretary of Defense (Installations & Environment) Science & Technology Directorate
U.S. Department of Defense

Linda Wennerberg
Environmental Management Division
NASA

Paul Yaroschak
Deputy for Chemical & Material Risk Management, Office of the Deputy Under Secretary of Defense (Installations & Environment)
U.S. Department of Defense

APPENDIX II – AGENDA

Sustainable Chemicals & Materials Roundtable
An Information Exchange:
Moving From High Risk to Low Risk Chemicals

Washington, D.C.

December 6, 2013

Registration **8:45 – 9:00am**

Welcome and Introductions **9:00 – 9:15am**

Marianne Horinko, President, The Horinko Group (Facilitator)

Keynote Speakers **9:15 – 9:45am**

Maria Doa, Director, Chemical Control Division, Office of Pollution Prevention and Toxics, U.S. EPA

John Conger, Acting Deputy Under Secretary of Defense (Installations & Environment)

Issue Introduction and Discussion Overview **9:45 – 10:00am**

Drew Rak, Senior Principal Scientist, Noblis Inc. (Moderator)

Moderated Discussion **10:00 – 11:30pm**

- Part 1 – The risk assessment process; a general overview and participant observations: *How does a chemical become a concern?* (45 minutes)

- Part 2 – Regulatory and market mechanisms that control, restrict, or remove a chemical from commerce: *What are the pros/cons of restricted chemical lists?* (45 minutes)

Networking Lunch **11:30 – 12:30pm**

Moderated Discussion **12:30 – 2:00pm**

- Part 3 – Transitioning to substitutes: *What are the challenges and resource/testing requirements?* (45 minutes)

- Part 4 – Concluding Discussion: *What ideas are there for an improved process?* (45 minutes)

Take-Aways, Next Steps & Wrap Up **2:00 – 2:15pm**

Marianne Horinko, President, The Horinko Group

APPENDIX III – ISSUE OVERVIEW PAPER

Sustainable Chemicals & Materials Roundtable
An Information Exchange:
Moving From High Risk to Low Risk Chemicals

Washington, D.C.

December 6, 2013

Roundtable Purpose

A roundtable workshop among public and private sector leaders in the chemical management arena will provide a forum for discussion on the laws, policies, and procedures for integrating sustainable chemicals and materials into systems and products. Sustainable chemicals and materials (including products and processes) are those that:

- Have less impacts on human health and the environment
- Have an adequate supply into the future
- Often can be recovered and re-used
- Meet performance requirements and are cost effective.

The roundtable will include discussions on processes for developing, testing, and implementing sustainable alternatives. The roundtable is a public-private dialogue that can provide a unique opportunity for mutual learning, information gathering, and sharing of views among affected stakeholders.

Issue Overview

There are a number of federal, state, and industry initiatives regarding green chemistry, safe consumer products, and chemical alternative assessments (See Attachment A). There are also a number of old and new statutory requirements and regulatory actions that affect the use of chemicals and the shift towards sustainable alternatives (See Attachments B and C). Global manufacturing, market trends, and consumer influences also play a large role. Federal agencies and industry generally support efforts to reduce the use of hazardous chemicals. There are significant programs, goals, and research (both public and private) dedicated to developing, testing, and applying sustainable chemical alternatives.

Federal agencies must be able to meet their mission requirements. Likewise, industry must provide products that meet specific performance standards. In the defense and aerospace industries in particular, performance specifications are exacting and demanding, requiring chemicals and materials that perform under extreme conditions. Premature phase-outs

(before substitutes are fully tested) of chemicals can result in the forced selection of alternatives with important data gaps in performance, toxicity and environmental fate/effects. This can lead to "substitution regret" whereby substitutes subsequently prove to be a high risk to human health and/or cause performance failures. Roundtable participants will discuss ways to meet the dual objectives of integrating sustainable chemicals and meeting demanding performance standards. In some cases, performance standards are out-dated or were written based on the performance of a specific chemical.

The following issues were identified for discussion and information sharing:

- What are the statutory and regulatory actions and market pressures that can lead to a chemical phase-out and removal from commerce?

    - U.S. EPA has several programs, initiatives, and tools that can influence or even initiate a chemical phase-out. These drivers represent a range of methods for managing and assessing risks and include approaches such as information gathering, analysis, and regulatory action. Other drivers include international or state-led regulatory actions, non-governmental organization initiatives, broad-based public scrutiny, or even voluntary sustainable procurement standards. Attachments A, B, and C provide a summary of these drivers.

- What are the statutory or regulatory criteria and/or market considerations for deciding that a chemical presents a high risk to human health and should be phased-out of production?

- Before a chemical is phased-out of production, what are (or should be) the criteria for ensuring that adequately performing and low risk alternatives exist? Should there be a relative risk analysis? (What is the risk of not using the chemical?)

- What are the challenges in developing, testing, and certifying new chemicals for a myriad of different applications? Should there be a national estimate developed, with input from stakeholders, regarding the time and cost for fully integrating alternative chemicals? Considering the resources required to adopt lower risk alternative chemicals, are there ways to create assurance in the marketplace that substitute chemicals will maintain a long-lived commercial application in an effort to prevent substitution regret?

- In what ways can public and private stakeholders work more collaboratively to identify chemicals of most concern and develop and test substitutes in order to create a more coordinated effort overall? Are there particular responsibilities for which stakeholders should plan? A supplier stopping production can be a surprise to users. What are the most effective ways that stakeholders can stay apprised of chemicals that have the potential to be phased-out?

- What are the opportunities and challenges associated with the management of available data, data-sharing, and disclosure of proprietary information in an era of constantly evolving science?

Desired Outcomes

Desired outcomes include:

- Transferring information and knowledge among stakeholders which manage or become affected by the process of phasing-out and substituting chemicals;

- Forging a clear dialogue with EPA about regulatory actions and initiatives that can result in chemical or material phase-outs;

- Helping create a better understanding of the process for researching, developing, testing, evaluating, and certifying substitute chemicals and materials in the aerospace and defense sectors.

- Exchanging ideas on how stakeholders can work more collaboratively to set priorities and ensure predictability and consistency throughout the process.

Attachment A

A Sample of Green Chemistry, Safe Consumer Products, and Chemical Alternative Initiatives

Federal

Environmental Protection Agency (EPA). The EPA has several initiatives regarding green chemistry and toxic chemicals not based on regulatory or enforcement requirements. These include:

- ***American Chemical Society (ACS) Green Chemistry Institute Partnership.*** EPA's Green Chemistry program partners with ACS to research and develop educational materials on green chemistry primarily targeted at undergraduate and graduate chemistry students. They distribute this material through conferences, workshops, and national meetings.
- ***Design for Environment (DfE) program.*** EPA partners with industry, environmental groups, and academia to evaluate traditional and alternatives chemicals and identify safer chemicals through alternatives assessment. To inform consumers, DfE allows safer and effective products to carry its label.
- ***New England Green Chemistry Challenge.*** Sponsored by EPA Region 1, the challenge seeks to "broaden the understanding and adoption of green chemistry practices and principles," including building understanding, supporting dialogue, and fostering relationships. The challenge consists of six sector based groups: (1) policy, (2) production and work, (3) investment and development, (4) education, (5) advocacy and demand, and (6) healthcare.
- ***Presidential Green Chemistry Challenge.*** An EPA award that seeks to support further green chemistry research by recognizing "outstanding" examples of chemical technologies which incorporate green chemistry. The selection criteria are "novelty, environmental and human health benefits, and impact or applicability in industry".

National Institute of Standards and Technology (NIST) Initiatives. NIST is a non-regulatory federal agency within the U.S. Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life***.***

- ***NIST Annual Federal Interagency Chemistry Representatives (FICR) Meeting.*** In 2013, the meeting will focus on green chemistry research and development activities within federal agencies. It aims to allow participants to gain an understanding of the scope of federal research efforts, share their insights, and build connections.

State

California. In 2008, led by the California Department of Toxic Substance Control (DTSC), the California Green Chemistry Initiative made six recommendations: expand pollution prevention, develop green chemistry education/training and R&D, establish an online product ingredient network, establish an online toxic clearinghouse, hasten the search for safer products, and move toward a "cradle to cradle" economy. California passed two parts: 1) AB 1879 requires the identification and prioritization of chemical of concern, evaluation of alternatives, and specification of regulatory responses and 2) SB 509 establishes an online toxic information clearinghouse. California partially implemented SB 509 in January 2012 under Title 22, which requires specification of hazardous traits (see Attachment B). The legislature is currently considering the California Safer Consumer Products Regulation, which will provide for a "Four-Step Process" to identify, prioritize, identify alternatives to, and regulate chemicals of concern. This regulation imposes compliance obligations on the entire product supply chain. In collaboration with DTSC, California's Department of Public Health oversees the California Environmental Contaminant Biomonitoring Program (CECBP), authorized by SB 1379. The program determines baseline levels of environmental contaminants in people, establish trends in chemical levels over time, and assesses the effectiveness of regulatory programs.

Massachusetts. Three state agencies implement the Toxics Use Reduction Act of 1990 (TURA): the Massachusetts Department of Environmental Protection (MassDEP) TURA program, the Office of Technical Assistance and Technology (OTA), and the Toxics Use Reduction Institute (TURI). All three organizations can help companies identify alternatives in order to comply with TURA. See Attachment B for more information on TURA.

Oregon. The Oregon Environmental Council (OEC) has green chemistry as one of its focus areas. In 2009, it convened the Oregon Green Chemistry Advisory Group, which sought to examine green chemistry opportunities in Oregon by bringing together leaders from academia, industry, and government agencies. Their four key recommendations on green chemistry were: 1) increase understanding and awareness of benefits, 2) provide education and training, 3) expand the public and private research and development capacity, and 4) commit state and local resources to support innovation. OEC has followed up on recommendations by hosting green chemistry promotion events and plans to partner with industry to raise awareness. In addition, Oregon's Department of Environmental Quality (DEQ) has a Toxics Reduction Strategy and associated program that focuses on the highest priority chemicals, reduces toxics at their source, establishes partnerships with other agencies, and measures the effectiveness of strategy implementation.

Washington. The Department of Ecology's Reducing Toxic Threats Initiative focuses on reducing the use of toxic substances in products and preventing toxic substances from entering stormwater. To address these goals, the initiative seeks to strengthen its ability to gather data on the presence of toxic chemicals and supports policy efforts at all levels.

Interstate Chemicals Clearinghouse (IC2). The IC2 is an association of state and local governments that seek to avoid duplication of efforts on chemicals, build capacity to identify safer chemicals, and ensure access to high quality data, information, and assessment methods. Their Safer Alternatives Assessment

method provides guidance on the development of alternatives assessment, with an associated wiki containing information and resources.

Industry

Green Chemistry and Commerce Council. The council is a business-to-business network that promotes green chemistry and design for environment, both nationally and internationally. This approach includes increasing supply and demand of green chemicals; developing and promoting approaches, tools, initiatives, etc.; and fostering collaboration among businesses, government, NGOs, and academia.

Pesticides, Chemical Regulation, and Right-to-Know Committee (PCRRTK). Part of the American Bar Association's Section of Environment, Energy, and Resources, PCRRTK is a forum that covers "legislative, regulatory, and judicial developments relating to the regulation and use of chemicals and pesticides" in various products. The committee seeks to keep members up to date on developments and encourage dialogue.

GreenWERCs. Developed by private company The Wercs, this tool allows companies to assess the composition of chemical intensive products and determines its health and environmental characteristics. The tool includes a scoring and weighting algorithm based on the composition of PBTs, CMRs, and potential hazardous wastes to aid in the comparison of different products.

NGOs

Healthy Building Network. Researches information on sustainable building materials and publishes results through tools such as their Pharos Project. The Pharos Project received an EPA award in 2008 as "a revolutionary on-line tool for evaluating and comparing the health, environmental and social impacts of building materials in a comprehensive and transparent way."

Clean Production Action. A small nonprofit that seeks to create tools and strategies for clean production using green chemicals and sustainable materials. They offer the GreenScreen method for comparative chemical hazard assessments, identifying chemicals of high concern and safer alternatives. This method incorporates the EPA's hazard assessment framework and criteria but also includes benchmarking. The method is used by industry, government, and NGOs, such as the Pharos Project.

Health and Environmental Sciences Institute (HESI). A nonprofit with a mission to engage scientists to identify and resolve global health and environmental issues. The subgroup "Frameworks for Alternatives Chemical Assessment and Selection of Safer, Sustainable Alternatives" seeks to identify key criteria and tools to help the selection of safer and more sustainable alternatives. Its members include scientists from government, industry, and academia.

CleanGredients. Developed by the nonprofit GreenBlue, CleanGredients is a cleaning ingredient database that includes information on environmental and human health and safety information. It also identifies alternatives and provides contact information for suppliers and MSDSs. In addition, the database allows users to participate in voluntary recognition or certification programs such as EPA's DfE. The database currently includes information of surfactants, solvents, fragrances, and chelating ingredients.

Sustainable Biomaterials Collaborative. A coalition of industry, government, academia, and NGOs that seeks to replace fossil fuel-based products with plant-based products that are sustainable from cradle to cradle. They create sustainability guidelines, encourage markets, and promote policy initiatives.

Other

United Nations' Environment Programme (UNEP). UNEP has several initiatives relating to green chemistry and toxic chemicals through the Chemicals Branch of the Division of Technology, Industry, and Economics:

- ***Strategic Approach to International Chemicals Management (SAICM).*** A policy framework to promote chemical safety. It promotes the lifecycle management of chemicals, with minimal impact on the environment and human health. SAICM's goal is that by 2020 "chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment". The World Summit on Sustainable Development adopted this goal in 2002.
- ***The Chemicals in Products Project.*** The project seeks to gather and publish reliable information on chemicals in products to inform consumers. To this end, it collects and reviews existing information, assesses the information to identify gaps, and develops recommendations to promote implementation of the SAICM. The project has published case studies on electronics, toys, building products, and textiles.

Attachment B

Key Statutory Requirements and Regulatory Actions Affecting Chemical Use and a Shift Towards Sustainable Alternatives.

Federal

Toxic Substances Control Act (TSCA). TSCA regulates the introduction of new or already existing chemicals, grandfathering in most existing chemicals in 1976 (not including PCBs). Prior to manufacturing or importing a new chemical for commercial purposes, companies must provide notification to the EPA, with some exceptions handled by other agencies (i.e., FDA or Agriculture). EPA reviews these notifications and may choose to regulate the chemical, from limiting production or use to a complete ban. In response to the over 84,000 chemicals now regulated under TSCA, in February 2012 EPA issues a new approach in its Existing Chemical Program Strategy to focus its existing chemical materials program on three areas: (1) risk assessment and risk reduction, (2) data collection and screening, and (3) public access to chemical data and information. In May 2013, an update to TSCA, the Chemical Safety Improvement Act (CSIA), was introduced in the Senate with bipartisan support. The new act seeks to address TSCA deficiencies and create a more streamlined, pragmatic approach by replacing many of the key provisions in TSCA. See TSCA text, Existing Chemicals Program, and CSIA text.

Additional summary of TSCA is available in Attachment C.

Pollution Prevention Act of 1990. This act aimed to reduce or eliminate waste at the source and includes provisions to promote the use of non-toxic or less-toxic substances. It also expanded the Toxics Release Inventory, which contains information on toxic chemical releases. See Pollution Prevention Act of 1990.

EPA New Chemical Consent Orders and Significant New Use Rules (SNURs). Issued by EPA under TSCA, Consent Orders are generally negotiated with the submitter of a premanufacture notice (PMN). While reviewing a PMN, EPA can issue a Consent Order that limits use under certain conditions and determines whether the chemical can be produced in substantial quantities, resulting in either a "risk-based" order or "exposure-based" order, respectively. SNURs are generally issued under TSCA as a "direct final" rule. Generally, TSCA section 5(e) SNURs are issued after a Consent Order that mimics the Consent Order for all other manufacturers. TSCA non-section 5(e) SNURs may be issued if a PMN does not result in a Consent Order and EPA determines that uses other than those in the PMN could result in unreasonable health or environmental risk. See Chemical Consent Orders and Significant New Use Rules.

National Environmental Policy Act (NEPA). NEPA established policy promoting the "enhancement of the environment" and established the President's Council on Environmental Quality (CEQ). Although not specific to chemicals, the NEPA process for Environmental Impact Statements includes evaluation of "all reasonable alternatives, including no action." See CEQ's website.

Consumer Product Safety Act (CPSA). This act created the Consumer Product Safety Commission (CPSC) in 1972. CPSC regulates the sale and manufacture of many consumer products, which includes toxic chemical content. It has a review process that must balance health protective actions with cost to industry. CPSC also has limited capacity and by law must rely largely on voluntary industry standards. See CPSC's website.

Consumer Product Safety Improvement Act (CPSIA). Passed in 2008, this act mostly targeted children's products, focused on lead and phthalate content. It also imposed new testing and documentation requirements on CPSC as well as set new acceptable levels for substances already regulated by CPSC. In addition, CPSIA imposes stricter civil penalties for failing to report possible hazards and criminal penalties for noncompliance. See CPSC's About the CPSIA.

The Federal Food, Drug, and Cosmetics Act (FD&C). This act gave the Food and Drug Administration the authority to oversee the safety of foods, drugs, and cosmetics. This authority includes regulation of the chemicals in foods and drugs on a pre-market basis and cosmetics on a post-market basis. One example regulated under this act is the coloring additive "FD&C Yellow No. 5" (tartrazine), most commonly known as a food coloring but also used in other products including soaps, cosmetics, cleaning products, inks, and medications. FD&C has been amended over 20 times to expand FDA authority in areas such as bioterrorism and drug disposal. See the FDA's Reference Edition of the FD&C Act.

State

California. The California Safe Drinking Water and Toxic Enforcement Act of 1986 prohibits the discharge of chemicals that have carcinogenic or reproductive toxicity effects into drinking water sources. California's hazardous waste regulations are in Title 22 Social Security, Division 4.5, Environmental Health Standards and the Management of Hazardous Waste. In addition to providing criteria for identifying hazardous waste and their characteristics, this regulation contains up-to-date lists of substances classified as hazardous waste in California. It also provides standards for generators, transporters, and owners and operators of hazardous waste. California also has proposed Safer Consumer Products Regulation, which would require manufactures to report on high priority chemicals and replace some harmful chemicals with safer alternatives. See the California Office of Environmental Health Hazard Assessment, Department of Toxic Substances Control and Safer Consumer Products Regulations.

Massachusetts. The Toxics Use Reduction Act of 1990 (TURA) requires corporations that use large quantities of toxic materials to evaluate and plan for pollution prevention options, implement them if practical, and measure and report the results annually. The Massachusetts Executive Office of Energy and Environmental Affairs oversees the Toxics Use Reduction Program. See the Massachusetts Office of Energy and Environmental Affairs.

Oregon. Oregon's Toxics Use and Hazardous Waste Reduction Act of 1989 (revised in 2005) mandated pollution planning. The Department of Environmental Quality (DEQ) implements this act, which requires that Federal Toxics Release Inventory Reporters and hazardous waste generators to develop a Reduction Plan or Environmental Management System (EMS), submit a notice of completion, submit two implementation summaries, and update the plan or EMS when changes occur. To support this, DEQ maintains a list of high priority toxic chemicals (persistent or bioaccumulative) that it uses to prioritize pollution planning measures. Oregon is currently considering HB 3162, the Toxics Disclosure for Healthy Kids Act, which establishes a high priority chemical list that are of concern to children's health. The act would require manufacturers to notify health officials if their children's products contain these chemicals. The state then works with manufacturers to replace these chemicals with safer alternatives. See Oregon's DEQ Toxics Use and Hazardous Waste Reduction and Toxics Disclosure for Healthy Kids Act.

Washington. Title 70 of the Revised Code of Washington governs dangerous waste and pollution prevention. This is supplemented by the Dangerous Waste Regulations of the Washington Administrative Code (WAC) 173-303, which contains criteria for identifying dangerous wastes and up-to-date lists of substances considered dangerous wastes. Washington's Department of Ecology implements these laws by providing educational and technical assistance to businesses, enforcing and levying fees when necessary. However, chemicals can only be banned through the legislature. In 2008, Washington passed the Children's Safe Products Act. This act limited phthalates, lead, and cadmium in children's products (largely preempted by CPSIA) and also required the state to address chemicals that may put children at risk. To implement the latter portion, the Reducing Toxic Threats Initiative maintains the Reporting List of Chemicals of High Concern to Children, which manufacturers of children's products are required to report on. See Title 70 Public Health and Safety, WAC 173-303 Dangerous Waste Regulations, and the Washington Department of Ecology's Children's Safe Products Act.

International

Registration, Evaluation & Authorization of Chemicals (REACH)

The European Union (EU) issued the REACH Directive (Regulation (EC) No 1907/2006) in December of 2006 as an integrated system for the registration, evaluation, authorisation and restriction of chemicals, and established the European Chemicals Agency (EChA). REACH requires firms which manufacture and import chemicals to evaluate the risks resulting from the use of those chemicals and to take the necessary steps to manage identified risks. Under REACH, industry has the burden of substantiating that chemicals produced and placed on the market are safe. The stated purpose of the regulation is to ensure a high level of protection of human health and the environment, and to strengthen the competitiveness of the chemicals sector and promote innovation. The scope of the Regulation covers all substances (with some specific exceptions), whether manufactured, imported, placed on the market, or used on their own or in mixtures. The REACH system is complemented by Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures. This Directive integrates the classification criteria and rules on labeling of the United Nations' Globally Harmonized System (GHS) with Community legislation and includes the REACH provisions governing the inventory of classifications and labeling.

Restriction of Hazardous Substances (ROHS)

In 2003, the European Parliament issued a directive "on the restriction of the use of certain hazardous substances in electrical and electronic equipment." The RoHS directive became effective on July 1, 2006 and applies to new electrical and electronic equipment placed on the European market. The RoHS named six hazardous substances of immediate concern: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). It also provides for the addition of other hazardous substances, as soon as scientific evidence is available. The maximum concentration values tolerated for the RoHS substances are measured by weight at the homogeneous material level. The maximum concentration value tolerated for lead, mercury, hexavalent chromium, PBB, and PBDE is 0.1% by weight in homogeneous materials and for cadmium is 0.01%. Covered electrical and electronic equipment (EEE) includes any equipment that depends upon electric currents or electromagnetic fields for its operation (e.g., large and small household appliances; IT and telecommunications equipment; consumer equipment; lighting equipment/bulbs; tools; toys, leisure

and sports equipment; and vending machines). Exemptions may be granted to narrowly-defined applications when the elimination of a prohibited substance is technically or scientifically impracticable or when the only available substitution produces more negative than positive benefits to the environment, health, or consumer safety. The exemptions are temporary in nature and subject to review at least every four years, until such time as a reliable and safe substitution is available. Enforcement is by the EU member states, each within its own borders. In 2011, the EU adopted RoHS Recast (or RoHS 2.0) which replaced/repealed the original RoHS directive. Consistent with the EU's *New Approach* and *New Legislative Framework* policies, RoHS Recast uses annexes to specify covered EEE and restricted substances so that they can be more easily modified to account for technical progress.

Attachment C

The Toxic Substances Control Act (TSCA)

This attachment contains a more detailed description of TSCA, outlined in Attachment B. Chemicals regulated under TSCA are "any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical", which can include both traditional chemicals and microorganisms. TSCA consists of four titles:

I. Control of Toxic Substances
II. Asbestos Hazard Emergency Response
III. Indoor Radon Abatement
IV. Lead Exposure Reduction

Title I is the broadest and governs most of the TSCA regulatory process. Under Section 5, manufacturers and processors are required to notify EPA of all new chemicals, which are allowed into commerce after the 90-day review period. Through Section 8, the EPA has the authority to gather and update information on all chemicals in this Inventory. If the information is insufficient for a risk assessment, EPA may require manufacturers and processors to test a chemical under Section 4. EPA may then decide to issue regulatory restrictions or rules, as authorized under Sections 5, 6, and 7. Detailed outlines of these and other key sections are provided below, along with commentary.

Section 4 (Testing of Chemical Substances and Mixtures). This section gives the EPA the authority to issue rules requiring manufacturers and processors to test new or existing chemicals or mixtures. In order for EPA to issue a rule, they must find that the substance "may present an unreasonable risk of injury to health or the environment" or it "will be produced in substantial quantities" which may enter the environment or result in "significant or substantial human exposure." The TSCA Interagency Testing Committee (ITC), an independent advisory committee to EPA, recommends which existing chemicals should be tested. Lowell (2003) comments that since EPA must first have data to prove that a substance may present a risk, they have enacted few test rules for existing chemicals. In contrast, Bergeson (2000) states that testing programs have "resulted in millions of dollars to testing and risk assessment by industry."

Section 5 (Manufacturing and Processing Notices). This section details the notices required from manufacturers and processors for regulated chemicals and provides EPA with the authority issue rules on new chemicals and significant new uses for chemicals. New chemicals are those not included under the EPA inventory maintained under TSCA Section 8. Significant new uses can include changes to the manufactured volume; type or form of human or environmental exposure; magnitude and duration of human exposure; or manner and methods of manufacturing and handling. The section also allows the EPA to keep a list of chemical substances whose "manufacture, processing, distribution in commerce, use, or disposal…may present an unreasonable risk of injury to health or the environment." Under this section, manufacturers and imports must submit premanufacture notices (PMN) at least 90 days before manufacturing or importing a new chemical or starting a new use. While PMNs do not require any

testing, they do require the manufacturer to submit any available testing results. EPA reviews the PMN during the 90 days and can either request additional data, prohibit or limit manufacture, or stop the review. However, Lowell (2003) remarks that "certain types of chemicals and chemical uses are exempted from the review process and EPA is authorized to make future exemptions.[1]" Despite these PMN restrictions and the fact that only about half of the PMN substances make it to the market, Bergeson (2000) notes that this program is "viewed by many in government and private sector as a premier pollution prevention program". Lowell (2003) agrees that the program has been a success due to the "low initial threshold for agency action" and the deterrence vs. guidance approach. This approach has allowed EPA to provide "strong signals to manufacturers" on which types of chemicals may be regulated in the future due to "unreasonable risks." However, Lowell (2003) also notes that "the new chemicals program applies to less than 1 percent by volume of the chemicals on the market today."

Sections 6 (Regulation of Hazardous Chemical Substances and Mixtures) and 7 (Imminent Hazards). Section 6 provides EPA the authority to regulate the "manufacture, processing, distribution in commerce, use, or disposal" of an existing chemical substance or mixture that "presents, or will present an unreasonable risk of injury to health or the environment." The resulting EPA rule must adequately protect against these risks while "using the least burdensome requirements." EPA can either (1) prohibit a particular use or use beyond a certain concentration or (2) limit the amount of a chemical for a particular use or use beyond a certain concentration. Section 7 authorizes actions following rules issued under Section 6. EPA can start a civil action for seizure of and/or relief against anyone manufacturing, processing, distributing, using, or disposing of an "imminently hazardous" chemical. This section is relatively controversial since it grants EPA broad authority while imposing strict requirements. According to Bergeson (2000), there is a "heated debate over the legal burden EPA bears in banning chemicals." Lowell (2003) notes that three requirements place a huge burden on the EPA: proving that a chemical "will present an unreasonable risk", that the proposed regulation is the "least burdensome", and that regulatory benefits outweigh industry costs. As a result, EPA has promulgated few chemical restrictions under TSCA. Lowell (2003) also indicates that this program "has been considered by many analysts and EPA officials to be a failure." In a testimony to the U.S. House of Representatives' Subcommittee on Environment and the Economy, Kathleen Roberts recommended that EPA implement a prioritization process to help address these issues (Roberts, 2013).

Section 8 (Reporting and Retention of Information). This section provides the EPA with the authority to promulgate rules that require each manufacturer and processor to maintain and submit reports for chemicals regulated under the above sections. These reports may require information on byproducts, environmental and health effects, and exposures. Rules issued under this section include the Preliminary Assessment Information Reporting (PAIR) rule and the Chemical Data Reporting (CDR) rule, formerly the Inventory Update Rule (IUR). The section also mandates that EPA keeps an inventory of all regulated chemicals and records of any "significant adverse reactions to health or the environment." Chemicals are never removed from the Inventory, even if they are no longer used. The chemicals reported under the CDR rule provide a better account of regulated chemicals still in use. In addition, EPA may require manufactures, processors, and distributors to submit health and safety studies and immediately notify

[1] Exemptions include "substances manufactured, processed, or distributed only for export; substances manufactured or processed only in small quantities for research and development, including product development; test marketing, if the substance 'will not present any unreasonable risk of injury to health or the environment' as a result of the test marketing activity; non-isolated intermediates (temporary intermediates with no exposure); polymers meeting specific requirements; and Low Volume and Low Release and Exposure, subject to restrictions on use"

EPA of any evidence of "substantial risks." According to Bergeson (2000), "Section 8 is often referred to as TSCA's most successful provision" since most TSCA enforcement actions have been for failure to comply with this section's requirements. Lowell (2003) points out its limitations since industry are reluctant to provide risk information and claimed information is business confidential. A 1998 EPA analysis concluded that "65 percent of the information in industry filings to the agency under TSCA was claimed as confidential." Roberts (2011) takes a moderate view on confidential information, noting that "…while there are very legitimate needs for EPA to have this type of information to achieve its statutory goals, there are also very legitimate needs for business to have that information remain confidential."

Section 9 (Relationship to Other Federal Laws). This section outlines TSCA's relationship to other federal laws. If the EPA concludes the use of a chemical presents an "unreasonable risk of injury to health or the environment" which may be prevented or "reduced to a sufficient extent" through a Federal law administered by another agency, EPA will submit a report to the other agency. Through this section, EPA has submitted some reports to the Occupational Safety and Health Administration (OSHA) to review worker's chemical exposure. However, EPA faced criticism for refusing to allow OSHA to handle occupational risks from acrylamide and N-methylacrylamide grouts (Bergeson 2000).

Sections 12(b) (Exports) and 13 (Entry Into Customs Territory of the United States). Section 12(b) provides EPA with the authority to require notification by any person who intends to export regulated chemicals. The EPA will then notify the foreign country of all available data on the chemical. Section 13 allows EPA to issue roles on the importation of regulated chemicals.

Sections 11 (Inspections and Subpoenas), 15 (Prohibited Acts), 16 (Penalties), and 17 (Specific Enforcement and Seizure). Together, these four sections allow EPA to inspect facilities for compliance, issue civil and criminal penalties for violations, and seize any chemicals that were manufactured, imported, processed, or distributed in commerce in violation of rules issued under TSCA.

Section 14(a) (Disclosure of Data). Section 14(a) limits EPA's public disclosure of information regarding trade secrets and certain commercial or financial information. However, when necessary, this information may be shared with government employees or contractors. It may also be released if it is required for court proceedings so long as it is "in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding." A chemical's health and safety data is not protected under the Freedom of Information Act (FOIA) exemption for trade secrets and so is publically available, though EPA cannot release any information on processes or mixture portions.

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APPENDIX IV – LETTER TO CALIFORNIA ATTORNEY GENERAL RE: PROPOSITION 65 SETTLEMENTS

California Manufacturers and Technology Association
California Chamber of Commerce
American Chemistry Council
American Coatings Association
California Paint Council
California Farm Bureau Federation
National Federation of Independent Business
California League of Food Processors
California Citizens Against Lawsuit Abuse
Association of Home Appliance Manufacturers
California Trucking Association
Pacific Legal Foundation

August 6, 2013

The Honorable Kamala D. Harris
Attorney General of California
1300 I St., Suite 1740
Sacramento, CA 95814

Dear Attorney General Harris:

The above listed organizations are writing to urge you to oppose settlements of Proposition 65 private enforcement actions that would ban or otherwise restrict the use of unlisted substances.

Private enforcement actions are brought "in the public interest." Cal. Health & Safety Code § 25249.7(d). Any settlement therefore must be in the public interest, and cannot be approved if it is not. *Consumer Advocacy Grp., Inc. v. Kintetsu Enter. of Am., Inc.* (2006) 141 Cal.App.4th 46, 62. Settlements of Proposition 65 private enforcement actions that attempt to ban the use of unlisted substances are an abuse of the private enforcement mechanism and are not in the public interest.

The Attorney General's Proposition 65 private settlement guidelines identify as contrary to public policy the resolution of "any claim concerning chemicals that are not on the list of chemicals known to the state to cause cancer or reproductive toxicity." Cal. Code Regs. tit. 11, § 3204(a). This is appropriate. Private plaintiffs should not be allowed to use the threat of Proposition 65 enforcement actions to seek restrictions on the use of unlisted substances, thereby bypassing (or possibly even overriding) evaluation of candidate substances by the State's qualified experts or other authoritative bodies.

Private enforcement of Proposition 65 *supplements* public enforcement by the Attorney General or other prosecutors. Just as it would be inappropriate for the Attorney General to use the threat of Proposition 65 penalties to obtain bans or restrictions on unlisted substances, it is equally inappropriate for private plaintiffs to do so. The private enforcement mechanism is not a vehicle for private groups to pursue their own policy agenda with respect to chemical substances. The purpose is to enforce the law as it is, not as private parties wish it to be.

California courts have rejected "shakedown" settlements that serve the plaintiff but not the public interest. *See Consumer Def. Grp. v. Rental Hous. Indus. Members* (2006) 137 Cal.App.4th 1185, 1219. Settlements that use the cost and burden of defending a Proposition 65 action to coerce private bans on unlisted chemicals are nothing short of such a shakedown.

Courts also have rejected Proposition 65 settlements where the settlement, "rather than resolving a dispute between the parties, purports to act like legislation, in that its function is to regulate the acts which may be undertaken by nonparties, at some speculative time in the future." *See Consumer Cause, Inc. v. Johnson & Johnson* (2005) 132 Cal.App.4th 1175, 1187. This is exactly what is happening when plaintiffs attempt to ban or restrict unlisted chemicals. Private plaintiffs can have no valid claims concerning unlisted chemicals. Seeking private bans on such chemicals is outside the scope of proper enforcement.

If this abuse of the private enforcement mechanism is allowed, we could see a tremendous surge in Proposition 65 private enforcement actions brought not to enforce the statute, but to obtain restrictions on unlisted chemicals that could not be obtained through proper regulatory channels. This was never intended when voters approved Proposition 65, and would represent an extraordinary abuse of the private enforcement mechanism.

It does not matter that the private bans are embedded in proposed settlements. "[T]he Legislature expressly required judicial review of a Proposition 65 settlement brought by a private plaintiff in order to safeguard the rights of the public. The parties' agreement to a mutually beneficial set of terms does not ensure that the policies underlying Proposition 65 or the public's interest in the litigation were considered." *CAG v. Kintetsu*, 141 Cal.App.4th at 63. Review by the Attorney General's office is required for the same purpose.

For all the reasons stated in this letter, proposed settlement terms that ban or restrict unlisted substances constitute an abuse of the private enforcement mechanism, are contrary to the public interest, and should be opposed by the Attorney General, in court if necessary.

Thank you for your attention to this important matter. Any questions or follow-up comments can be directed to Tim Shestek at 916-448-2581; tim_shestek@americanchemistry.com

Sincerely,

Mike Rogge
California Manufacturers & Technology Association
916-498-3313

Mira Guertin
California Chamber of Commerce
916-444-6670

Cynthia Cory
California Farm Bureau Federation
916-446-4647

Kevin Messner
Association of Home Appliance Manufacturers
202-872-5955

Ken Devore
National Federation of Independent Business
916-448-9904

Trudi Hughes
California League of Food Processors
916-640-8150

Michael Shaw
California Trucking Association
916-373-3500

Tom Scott
California Citizens Against Lawsuit Abuse
916-989-9665

Lauren De Valencia y Sanchez
American Coatings Association/California Paint Council
916-443-5301

Tony Francois
Pacific Legal Foundation
916-419-7111

cc: The Honorable Jerry Brown, Governor
Secretary Matthew Rodriquez, California Environmental Protection Agency
Dr. George Alexeeff, Director, Office of Environmental Health Hazard Assessment
The Honorable Ted Lieu, Member of the Senate
The Honorable Mike Gatto, Member of the Assembly
Deputy Attorney General Susan Fiering