Testimony of

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On

H.R. 5820 - The Toxic Chemicals Safety Act of 2010

My name is Charles M. Auer. I was formerly an employee of the U.S. Environmental Protection Agency until my retirement in January 2009. While at EPA I gained experience in hazard and risk assessment, policy development and implementation, rule-writing, etc., and also participated as a U.S. negotiator in the development and final agreement on the Stockholm and Rotterdam Conventions. I started at EPA as a staff chemist in and spent my entire EPA career in the Office of Pollution Prevention and Toxics (OPPT) and its predecessors where, starting as a GS-5, I rose through the ranks in a variety of technical, policy, management, and executive positions. In 2002, I was selected as the Director of OPPT and held that position until my retirement. Over my career I developed an in-depth knowledge and an integrated understanding of scientific, technical, policy, and legal issues encountered in implementation of the Toxic Substances Control Act (TSCA). Following my retirement I formed a small consulting company to provide advice and analysis on, among other matters, chemical assessment and management. I also affiliated with Bergeson & Campbell, P.C., a Washington, DC, law firm specializing in TSCA and related areas. Since forming the consulting company I have worked with a variety of clients including chemical companies, trade associations, law firms, and international intergovernmental organizations. While I have had industry clients, I have not done any representational work before EPA or other agency.

I am pleased to have the opportunity to provide testimony on the Toxic Chemicals Safety Act of 2010 (TCSA; H.R. 5820*). The testimony I am offering is mine and I am not speaking for or on behalf of anyone else in offering it.* I have closely followed the debate about reforming or modernizing TSCA and have published several papers which outline some of my views. I share the concerns voiced by NGOs, grass roots organizations, and others that TSCA has failed to meet its goals and purposes and that a robust new approach is needed. I take heart from industry's statements that it too recognizes that problems exist and that a modernized approach is needed. TCSA is intended to strengthen and deal with the weaknesses in TSCA and, as such, TCSA is based on a discussion draft which was released on April 15, 2010, and subsequently taken through a stakeholder process. However, based on my long experience in this area and my understanding of the scale and complexity of this sector of the economy, I fear that the TCSA approach, if enacted without changes such as those outlined below, runs the risk of failing to deliver on its

goals and expectations despite imposing considerable burden on EPA and the industry or, more optimistically, taking so long to unwind that today's frustrations will continue almost indefinitely. Thus as discussed and explained in my testimony, I believe that further improvement is needed to provide a workable and effective approach to chemical testing, assessment, and management in the U.S. that, when implemented, will meet the needs and expectations of stakeholders and the public.

General Comments

TCSA proposes a dramatically different approach to managing chemicals from that which currently applies. TSCA for far too long did not did not provide adequate legal authority or receive sufficient oversight and the resources needed to do an adequate job of testing, assessing, and managing the tens of thousands of chemicals in commerce. While I welcome the spirit in TCSA to revise TSCA and address its weaknesses, I do not believe that TCSA as drafted provides a workable and effective approach to meeting the needs to protect public health and the environment from the risks of the tens of thousands of chemicals in commerce. While TSCA with its limited authorities and relatively cumbersome approach was insufficient to meet evolving needs and expectations, I believe that the approaches under TCSA are, in several areas, overly complex and unnecessarily broad and encompassing, and would present significant challenges and issues in their development and implementation, both as a general matter and within the timelines allotted, and prove inefficient in their application. In summary, although I agree with many of the goals of the bill, based on my experience, I fear that it would fail to adequately meet its stated goals and purposes.

Recognizing that the US must compete in a global economy, I have concerns that the approach in TCSA will overly and unnecessarily burden U.S. competitiveness in this critical sector and likely have important and undesired impacts on both the chemical manufacturing sector and the manufacturing sectors that rely on its products, and on innovation, both generally and particularly with regard to new chemical introductions. I believe it is essential that an approach be developed that can ensure timely and effective development of the hazard and exposure information needed to adequately inform and prioritize decisions regarding chemicals, enable needed actions to protect human health and the environment, and thereby gain greater confidence in the chemical industry and its products, and do so in a way that enhances the capacity for U.S. competitiveness and keeps innovation and market incentives within the U.S. economy. TCSA in my view does not provide that approach as currently drafted.

TCSA does include a number of useful and valuable concepts that, if appropriately structured and applied, could do much to meet the needs and expectations of the public regarding the safety of chemicals and products in commerce. I believe the central failing under TSCA was the inability to develop the hazard and exposure data needed to inform decisions on existing chemicals – TCSA would resolve this issue although I question if the approach provided is workable. TSCA did not provide adequate focus to several areas which TCSA has picked up including, in no particular order: addressing the needs of vulnerable subpopulations; encouraging the introduction of safer and greener new chemicals and providing help to industry's efforts, throughout the value chain, to move toward safer and greener chemicals; providing authorities whereby EPA could actually control existing chemicals; shifting the burden of proof from EPA to industry; providing a means which could obtain the resources needed for governance by EPA (including applying fees to claims for Confidential Business Information); giving recognition to the general societal interest in reducing and avoiding animal testing via encouragement of new approaches that can provide data adequate for the purposes of assessment; establishing a public data base containing test data, assessments, and decisions and their bases, and others. While the inclusion of

such concepts within TCSA is welcomed, the workability and effectiveness of the approaches proposed varies.

Specific comments

I am intimately familiar with the statutory provisions and requirements under TSCA and their application and operation. Based on that understanding and experience, I offer the following selected observations concerning possible issues and concerns associated with the approaches as proposed in TCSA. I also offer for consideration by the Subcommittee and stakeholders, several suggestions for possible improvement.

Mixtures. *I found TCSA to be confusing and complex in its treatment of mixtures.*

The clarification provided by the July 28 technical correction to the legislation was welcomed in the way that it narrowed the scope of the requirements and resolved a number of fundamental questions about the treatment of and approach to mixtures as new chemicals. At the same time, and while I appreciated the deletion of the blunt and encompassing approach to mixtures found in the discussion draft, I question if the TCSA approach to mixtures is workable and effective. I found the concept of the mixtures survey at section 3(b)(3) a useful step but was at a loss to understand and attempt to apply the determination whether mixtures "have or may have substance characteristics that are different, in kind or degree." While I agree that dealing with mixtures is important, it is a difficult and complex area which will require more discussion and might best be dealt with via general requirements that would be implemented by EPA by rule once it has conducted and analyzed the results of the mixture survey and better understands the issue. Certainly EPA, and as is the case under TSCA, should have general authority under TCSA to deal with specific mixtures where needs or issues emerge in the interim.

Section 4. Minimum Data Set and Testing of Chemical Substances and Mixtures. *I found TCSA's approach to testing to be over-heavy and impractical, with the potential to impose unintended consequences on the introduction of new chemicals and to present potentially significant but currently unknown magnitudes of burden on the regulated industry given the number of existing chemicals in commerce and the scale of the testing that might be needed to satisfy TCSA's requirements. I believe that getting the provisions under section 4 right is the key to a workable and effective approach for dealing with chemicals.*

TCSA would require a minimum data set (MDS) for all chemical substances except those exempted per section 4(a)(3). EPA is given one year to develop and issue a rule implementing the MDS requirements as specified at section 4(a)(1)(A) and with the volume and timing triggers at section 4(a)(2)(A). I am supportive of the general concept of an MDS to be applied generally to existing chemicals although I oppose the requirement that new chemicals be subject to this requirement at the time of notification for the reasons given in my discussion of TCSA section 5 below. I also question if the exemptions allowed are sufficient to avoid unneeded or questionable testing, also as discussed elsewhere in my testimony.

I recommend for consideration by the drafters the discussion and analysis on "test data reporting" in my recent article (Auer, 2010) which explores issues of testing strategies and costs, production triggers and tiered testing menus, and other matters relevant to this section of TCSA. As noted previously, I view TSCA's central failing to be its inability to develop needed data and understanding and thus I attach great importance to the getting the approach right under any revised section 4.

While the testing that EPA would require to meet TCSA's MDS requirements can only be surmised, there are several models that can serve to outline, for purposes of discussion, possible approaches to designing the MDS that might be required. Given the TCSA requirement that the data set be "useful in conducting safety standard determinations" and the inclusion of the term "toxicological properties" with its broad statutory definition (section 3(24)) in the required elements of the MDS, I consider it *unlikely* that the Screening Information Data Set (SIDS) would suffice to satisfy these requirements (notwithstanding this statement, I note that the concept of "varied or tiered testing" in TCSA section 4(a)(1)(A) is useful and provides some flexibility in possibly using the SIDS menu although some clarity regarding how the concept relates to the other requirements for the MDS in section 4(a) and to section 4(b) concerning testing beyond the MDS would be helpful to understand) . The SIDS data set, which was developed by the Organization for Economic Cooperation and Development (OECD) and used by EPA in its "High Production Volume (HPV) Challenge" program and in HPV test rules, is intended to provide the basis for a *screening level assessment* that can initially assess a chemical and help to inform decisions as to needed higher tier testing. An MDS which both satisfies the definition of "toxicological properties" and meets the needs of a "reasonable certainty of no harm" assessment seemingly would require testing meeting or approaching a confirmatory data set for each chemical, such as that required for pesticide registrations under Part 158 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Tier 3 in EPA's Voluntary Children's Chemical Evaluation Program (VCCEP; note that this menu is limited to health effect testing endpoints and as such does not deal with environmental fate and environmental effects testing endpoints), or the "high volume" tier under the EU's REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) regulation (a table comparing several of these testing menus is available in Auer, 2010). If testing such as that found in these confirmatory menus is needed to satisfy the requirements for the MDS, it seems unlikely that TCSA's allowed time periods for developing the data sets will be sufficient. Furthermore, the costs required for such testing would be considerable. If, for example, EPA would determine that the SIDS is adequate for one or more of the volume tiers (although as noted above it is debatable whether the SIDS menus suffices to meet the requirements imposed), the estimated cost is approximately $200,000 for that battery, whereas the estimated cost of the high volume tier under REACH is 900,000 to 1.6 million Euros (see Auer, 2010); I do not have cost figures for the other test menus cited but estimates should be obtainable from EPA. To provide greater workability and flexibility, I suggest narrowing or softening the definition of "toxicological properties" per se or as applied under section 4(a) and an additional suggestion for consideration is noted in my discussion concerning TCSA section 6.

A basic question that would be very useful to have an answer to is "how many Inventory chemicals are actually in commerce and thus potentially subject to such an MDS requirement?" I am not aware of any vetted estimate of this number but applying available information, I guesstimate[i] that about 50,000 chemicals could be in commerce. Considering that tens of thousands of existing chemicals are potentially at play, with MDS test menu costs potentially ranging between $200,000 and more that $1 million per chemical (and even considering the potential reductions in testing afforded by the various exemptions at TCSA section 4(a)(3), the animal welfare considerations at section 34, and the potential for testing done under the EU's REACH regulation to meet some of the needs), the costs of such testing are likely to be prohibitive. I encourage the Subcommittee to carefully reconsider the approach proposed in TCSA and my 2010 paper provides some specific suggestions that might help to inform the debate.

I note the inclusion at TCSA section 4(b)(3) of several considerations, including relative costs and the availability of facilities and personnel to perform the testing, that are to be applied by EPA in obtaining testing in addition to that in the MDS. I suggest, given the number of chemicals potentially at play and the potential scope of the needed testing, that these considerations should also be applied by EPA in the MDS rulemaking required under section 4(a)(1).

A final comment on this section concerns TCSA section 4(b)(3)(B) where EPA "may specify test protocols and methodology." While I am generally in favor of flexibility and discretion where appropriate, the provision as worded would not adequately ensure the enforceability of testing requirements imposed by EPA. To ensure the development of quality test data, I believe it is essential that industry conduct any newly required testing via enforceable test methods. From a somewhat different perspective, I know from experience that in some cases testing is needed in areas that do not have standard methods available and suggest inclusion of an approach based on the TSCA Enforceable Consent Agreement process for meeting such needs.

Section 5. Manufacturing and Processing Notices. *I found TCSA's approach to new chemicals to run the risk, in essence, of "throwing the baby out with the bath water." I question the need for and merits of an upfront MDS on all new chemicals. I believe it will have a detrimental effect on the rate and extent of introduction of new chemicals which, based on my experience at EPA, are generally safer and greener and over time provide important continuous improvement benefits to heath and the environment and to U.S. competitiveness and innovation. I believe there are better ways to approach meeting the needs presented in this section of TCSA and several concepts are discussed for consideration.*

TCSA would require a premanufacture notification from manufacturers and processors which includes a minimum data set on all new chemicals. I believe that this approach presents a strong bias against new chemicals and will dramatically reduce the introduction into U.S. commerce of new chemicals thereby having significant adverse impacts on innovation. Further I believe it has *not* been shown that the current approach to new chemicals under TSCA has failed to prevent unacceptable risks to public health and the environment. I encourage careful analysis of this situation to ensure that significant unintended adverse consequences are avoided in developing the regulatory approach to new chemicals under TCSA.

I offer these comments from the perspective of a former EPA staff scientist and official who participated personally in the review of thousands of new chemicals and was otherwise involved in the oversight of OPPT's efforts over several decades to assess and take needed actions on tens of thousands of new chemicals notified to EPA. I believe based on that experience that new chemicals are generally safer and greener than their existing chemical competitors and, over time, than their new chemical predecessors. EPA has made several efforts to "check its work" over the years and has consistently failed to turn up evidence of significant problems despite concerns voiced about the lack of a minimum data set on new chemicals and EPA's consequent reliance on (Quantitative) Structure/Activity Relationships ((Q)SAR) analysis in its review of new chemicals. New chemicals additionally often provide greater energy efficiency, product efficiency, or provide approaches that can help deal with existing health or environmental issues. Most of the time the improvements seen with an individual new chemical are incremental (however, there are exceptions to this rule of thumb), but over time a strong continuous improvement effect is not infrequently realized. An example, one of many, is what are called "100% solids" polymer coatings which have been developed and introduced as new chemicals since the 1980s and provided, over years of introduction as new chemicals, a breakthrough in solvent-free coating technology which combined heath benefits (from reduced solvent exposure and release, and which also

contributed to VOC (volatile organic compound) reductions) and greater energy efficiency (the coatings did not require evaporation of the solvent and curing could be obtained via radiation with, for example, electron beam technologies rather than heating or other energy-intensive processes). In my view, EPA has been appropriately cautious in its review of new chemicals, taking testing and control decisions on about 8% of new chemicals while an additional 5% were withdrawn by the notifier often in the fact of EPA action, such that significant risks were avoided while allowing the U.S. to benefit from the continuous innovation provided by new chemicals.

I raise concerns about a requirement for an MDS on all new chemicals at the time of notification because such up-front costs will have a dramatic and negative impact on the introduction of new chemicals. I encourage the Subcommittee to closely examine this issue and obtain the information needed to inform its understanding. Other countries which have required a minimum data set for new chemicals at the time of notification, such as the Minimum Premarket Dataset (MPD) in Europe, have seen dramatically fewer numbers of new chemicals introduced: over a 20-plus year period from the early 1980s until the entry into force of REACH in 2007, the European Union with its standing MPD requirement saw the introduction of approximately 4,000 new chemicals, while the U.S. over the same period saw the introduction into commerce of approximately 18,000 new chemicals corresponding to those notified in the EU (i.e., the U.S. figures have been adjusted[ii] to reflect the scope applied in the EU). As stark as these figures are, the impact would be even greater if, as discussed above under section 4, a more extensive and expensive data set is required. I specifically encourage that efforts be made to understand the experience in the EU regarding new chemical notifications since volume-based testing requirements were imposed on new chemicals following the entry into force of the REACH regulation in 2007. I suspect, but have not been able to confirm, that the testing requirements under REACH have further reduced the number of new chemicals introduced in Europe.

Despite my confidence in the historic performance of the U.S. new chemicals program, I do believe that the approach should be strengthened, particularly with regard to approaches that could enhance data submission requirements for new chemicals in a way that ensures the capacity for the U.S. to keep innovation and market incentives within the U.S. economy. One way to meet these goals is discussed in a recent publication (Auer *et al.*, 2009) which proposes to make the new chemical data requirements generally consistent with those on existing chemicals but recognizing the impact of up-front submission, allows for some delay in testing:

- new chemical notifications would be required to contain production, exposure, and use information plus any available hazard and environmental fate information on the chemical and EPA would have the ability to require early development of needed testing when it identifies concerns and to impose control measures as appropriate;
- the notifier would be required to undertake and complete the same data set that would be required for existing chemicals when the new chemical reaches certain production volumes, based on the time period allowed for submission of test data on existing chemicals.

Thus, for example, using the timeline proposed in TCSA, high volume new chemicals might be required to produce the data set within 3 years after introduction of the new chemical. Alternatively, consideration should be given to whether a somewhat longer time period or staggered data development approaches might make sense for new chemicals which, as such, have yet to actually establish a commercial market. I believe that an approach which does not as a general matter require up-front testing but provides for

flexibility in the timing of test data development will do much to continue to encourage the continued development and introduction of new chemicals in the U.S.

Section 6. Prioritization, Safety Standard Determination, and Risk Management. *I found TCSA's approach to regulation and management of chemicals to be over-heavy and ill-conceived. While I appreciate the desire to apply a safety-based approach to all chemicals and their uses, I question from several perspectives the merits of a "one size fits all" regulatory standard for all chemicals in all their uses when the pesticides law that is the source for the proposed standard only selectively applies such a standard to food use pesticides and otherwise applies a risk-based standard for other pesticide registrations. I also question the practical value of the critical use exemption procedure proposed in the bill. I believe that improvements to these and other parts of this section of TCSA are needed for the reasons explained and offer some suggestions in these regards.*

The concept in TCSA of creating a priority list to guide EPA's efforts is a strong addition which helps deal with the lack of guidance and direction to EPA under TSCA. I am cautious, however, about the concept of statutorily populated lists of chemicals (such as that at section 6(a)(1)(A)) and, if this approach is retained, encourage careful consideration of the entries to ensure they are appropriate for such a list.

TCSA's safety standard at section 6(b)(1), with its applicability to *all* intended uses, its *taking into account* of aggregate exposures, and the need to *ensure a reasonable certainty that no harm will result*, would in my view present considerable issues and challenges if applied against all TSCA chemicals and uses. I appreciate the significance of the changes made from the version in the discussion draft but believe that further refinement is needed to achieve a workable and effective regulatory standard and approach.

I question the practicality and need for applying a "reasonable certainty of no harm" standard to *all* intended uses. This standard derives from a similar standard developed for pesticides under the Food Quality Protection Act but applied *only* to the setting of food tolerances for pesticide residues. Other pesticide uses and exposures are subject to an "unreasonable risk" standard for pesticide registrations under FIFRA. Recognizing that

- pesticides are designed to be biologically active, all uses are specifically registered and subject to requirements per the relevant registration, and that the use of pesticides involves intentional exposure and/or release,
- while in comparison, chemicals are not designed to be biologically active, relatively few involve intentional exposure or release, and they have a broad diversity of uses encompassing industrial, commercial, and consumer applications,

it is difficult to square the public policy implications and see the practicability of the TCSA approach which proposes to apply a "reasonable certainty of no harm" standard to the myriad of all chemical uses, with the approach in FQPA, which applies a similar standard to only the narrow and targeted subset of food use pesticides. Put another way, from a public policy perspective I find it hard to understand why *all* uses of chemicals, especially given their characteristics as outlined above, should be subjected to a more stringent regulatory standard than that which is applied to non-food use pesticides. Recognizing these points, TCSA should at most be structured to apply such a standard to a narrow subset of uses which, following the FQPA approach, represent the greatest potential for exposure or concern, and to apply an appropriate risk-based standard to other uses.

One approach for consideration under TCSA is to possibly target an appropriate safety standard to use in products intended for consumers and children and to apply an appropriate risk-based standard to commercial and industrial uses. I base this suggestion on the recognition that there is at best limited ability to otherwise control exposures to chemicals at the point of contact with consumers and children and, furthermore, the available legal authorities are limited (while TSCA provides general authority, the effect of the Federal Hazardous Substances Act on chemical issues in consumer products is largely limited to acute effects while the recently enacted Consumer Product Safety Improvement Act covers only a limited subset of chemicals when used in children's products). This is not the case with exposures and releases associated with commercial and industrial uses of chemicals where other statutory schemes (Occupational Safety and Health Act, Clean Air Act, Clean Water Act, etc.) provide broad authority in conjunction with that available under TSCA, and where the application of concepts such as product stewardship and industrial hygiene provide an additional measure of assurance. For these reasons, and to provide an approach which can meet the test of being workable and effective, I encourage the Subcommittee to consider targeting an appropriate safety standard approach to an appropriate subset of uses while looking to an appropriate risk-based approach for other uses.

I note in passing that applying such a scheme would also have the benefit of focusing MDS testing: testing sufficient to meet a safety standard need would be required on only that subset of chemicals having uses relevant to the safety standard, while chemicals not having such uses would be subjected to an MDS that satisfies the needs for a risk-based determination; such as approach would save considerable MDS testing resources and animals.

I appreciate the inclusion of the concept of the "industrial hygiene hierarchy of controls" at TCSA section 6(2)(F) but suggest that some clarity or a definition is needed, given that a variety of such hierarchies can be found. More fundamentally, however, I raise a question whether it is good public policy to give EPA explicit authority to "prescribe specific control measures to reduce occupational exposures" without an explicit reference to TCSA section 9 or a requirement that the action be taken in consultation/concurrence with the Occupational Safety and Health Administration (OSHA), given the potential that independent EPA action could introduce conflicts with occupational exposure standards and related requirements established by OSHA under its authority.

Section 6(e) of TCSA provides a procedure for critical use exemptions to be requested and approved if EPA determines that the manufacturer or processor has demonstrated by clear and convincing evidence that a combination of requirements has been met. I believe that the exemption, while a good concept, will, without revision, find little practical applicability given the difficulty that will be encountered in satisfying the nested requirements articulated. Notwithstanding this concern, I suggest that consideration be given to providing the flexibility to also implement such exemptions by rule in the event that the exemption involves multiple manufacturers and processors.

Finally, I raise a question whether, in TCSA section 6(f) on PCBs, the references to section 37 on data quality are intended, or if one or both should reference section 36 on international cooperation?

<u>Section 8. Reporting and Retention of Information</u>. *I found the concept of periodic declarations to be a useful one that will do much to ensure that EPA's understanding remains current with commercial developments. At the same time, however, I suggest ways that might reduce the information collection burdens without adversely affecting effectiveness and also suggest retaining TSCA section 8(b)(2)*

concerning "Inventory categories" which had been deleted under TCSA, and suggest further development of the "categorized Inventory" concept at TCSA section 8(c)(3).

In considering the significant reporting burden of a declaration requirement being applied to all manufacturers and processors and noting the additional requirement for immediate updating when any one of numerous circumstances is encountered, I raise the question whether the requirement for updating every 3 years is more frequent, and thus more burdensome, than necessary. I also note that there would be value in requiring EPA to propose and publish a reporting rule specifying reporting requirements for declarations to avoid *ad hoc* submissions based solely on the statutory text at section 8(a)(2).

Concerning TCSA section 8(c) on the Inventory, I raise a question about the impact of not including or otherwise dealing with TSCA section 8(b)(2) which serves as the basis for the listing within the TSCA Inventory of numerous section 8(b)(2) categories (also known as "statutory mixtures") which comprise thousands or possibly tens of thousands of complex materials such as ceramics, frits, glasses, cements, and others. I note that the retained TSCA section 26(c) provides general authority to take actions with respect to categories of chemical substances and arguably could be applied by EPA as appropriate in this situation. Nonetheless, given the large number of materials at play which, depending on how or whether EPA chooses to address the issue without a specific statutory provision, could potentially result in thousands (or possibly tens of thousands) of additional Inventory entries leading potentially to tens of thousands of declarations from manufacturers and processors (and not forgetting the MDS requirement), I believe there would be great value in providing clarity in the statute by retaining section 8(b)(2).

I note the requirement at TCSA section 8(c)(3) that EPA within 5 years, and every 3 years thereafter, categorize the substances on the Inventory. The only action specified is that EPA publishes the results of its categorization efforts. I encourage that consideration be given to how such a categorized Inventory might be of value in developing prioritized approaches to assessing or setting aside chemicals from further review. I do not have an elaborated proposal to offer but note that the approach might be broadened and strengthened to operate as a key, if not the central feature in prioritization efforts under the act. For example, section 8(c)(3) could be set up to operate in a manner similar to that applied in Canada under the Canadian Environmental Protection Act for the "categorization" of chemicals to identify those that require further review and those which do not present such a need. Such as approach could thus serve to support continued development of the section 6 priority list and also provide an organized framework for efforts to identify persistent, bioaccumulative, and toxic (PBT) chemicals under TCSA section 32, and "safer alternative" and "intrinsic property" candidates for consideration under sections 35 and 39, respectively, among other provisions under TCSA.

Section 14. Disclosure of Data. *While I agree that, historically, industry has approached confidential business information (CBI) claims as a "blanket" need rather than as specific needs warranting protection against disclosure, I do not believe that the approach as drafted, while it represents an improvement over that in the discussion draft, provides an appropriate balance in addressing the competing interests. Without revision, I believe the approach's treatment of chemical identity runs the risk of adversely impacting innovation particularly as it relates to new chemicals. More generally, I have some concern that the approach proposed could have an effect of weakening the confidence that the business community will have in the ability of EPA to legally protect legitimate business confidential information from disclosure.*

I do not believe that the section affords adequate protection to intellectual property in the form of chemical identity, especially with regard to new chemicals where I believe such protection is needed to encourage and protect the investment made in research and innovation. While it is my guess that the "chemical identity" approach proposed would have a lesser effect generally on existing chemicals, I suspect that there nonetheless would be specific instances where the approach if implemented without greater balance and flexibility could have negative competitiveness impacts on companies doing business in the U.S. While I appreciate the difficulty in attempting to assess a health and safety study without chemical identity information, I do not believe it is sound public policy to see this transparency need as one that reflexively trumps the need for protection, for example, of new chemical identity at the time of notification and for some appropriate period thereafter.

I also have some concerns that the general approach, including the "rules of construction" with its "shall" requirements at section 14(b), the explicit statements of "Information not eligible for protection" at section 14(d), and other provisions, could have an effect of weakening the confidence that businesses have in the ability of EPA to legally protect legitimate claims of confidentiality under TCSA and encourage careful consideration of this possible issue.

Section 32. Persistent, Bioaccumulative, and Toxic Substances. *I appreciate and support the need for greater attention and authority to be applied to "PBTs" given the obvious issues that can be presented by exposure to and release of chemicals combining these properties. However, at the same time, I encourage careful consideration of the potential unintended consequences of the approach proposed.*

One particular area of concern is the requirement that new chemical PBTs will be evaluated subject to the critical uses exemption at section 6(e). As discussed above, I believe that, as a general matter, section 6(e) as drafted will rarely be satisfied and a likely consequence of retaining this requirement is that no – or at most very few – PBT new chemicals will successfully enter commerce. An experience I had several decades ago when EPA was developing its PBT policy for new chemicals may help to illustrate the potential for unintended consequences from such an approach.

> A new chemical was reviewed and determined to clearly meet the draft PBT policy based on EPA's review and it was teed up for a ban action. However, upon closer inspection the chemical was found to be manufactured in, as I recall, gram or milligram quantities for use as a liquid crystal dye in digital displays for watches. Based on the information in the new chemical notification, it was clear that well-controlled but tiny releases would occur during production of the chemical and during use by downstream digital display producers.

The case caused me to take another look at the draft policy and to recommend adjusting the approach to consider the nature and magnitude of the exposures and releases to ensure that such reflexive unintended consequences could be avoided. To be clear, this is not to say that this situation alone needs to be addressed, rather the point is the importance of recognizing the diversity of the chemical products and uses which are in commerce and the future uses which the Subcommittee can't anticipate. Accordingly, I encourage development of a more flexible approach that gives EPA more discretion than that provided by the language in section 32(a) in identifying PBTs and by the requirement to apply section 6(e) to new chemical PBTs in determining the need for and nature of the actions required. Black-and-white requirements can be useful if carefully applied but I believe that section 32 presents a situation that requires and would benefit from the application by EPA of both judgment and discretion to make decisions that are protective but avoid unintended - and undesired - consequences.

Section 34. Reduction of Animal-based Testing. *I appreciate and generally support the concepts outlined in this section and offer a few suggestions and cautions.*

I suggest that it may be useful to articulate an appropriately worded longer-term goal for EPA to work towards in this area; as suggested in Auer *et al.* (2009) such a goal might be framed to achieve by 2020 the testing vision set forth by the National Research Council of the National Academy of Sciences in its 2007 report "Toxicity Testing in the 21st Century: A Vision and a Strategy."

As noted above in the discussion under section 4, I have raised concerns about the possible lack of enforceability concerning testing conducted under TCSA. Regarding section 34(b) and the need to periodically publish a list of methods, I raise a question about the need to carefully consider the effect of the failure to include and apply a definition of "standards for the development of test data," a term that was defined in TSCA at section 3(12) and applied under section 4. The discussion of methods in section 34 is focused on "demonstrated testing methods that reduce the use of animals in testing" and, while this is a worthy goal, the loss of the concept of "test standards" and the relatively general nature of the discussion in section 34(b) may lead to a weakening in the level of scientific rigor that is required to be met by the test methods applied under TCSA. An important point to consider is that whatever approach is selected in this regard must also allow the U.S. to continue to meet the terms of the OECD's Council Decision on Mutual Acceptance of Data which ensures international acceptability of testing conducted in accord with OECD test guidelines and Good Laboratory Practices. I question whether the approach in TCSA provides adequate assurances in the areas discussed in this paragraph.

Section 35. Safer Alternatives and Green Chemistry and Engineering. *I generally support the concepts outlined in this section and believe that TCSA and its future orientation is improved by virtue of their inclusion. At the same time, some suggested improvements are offered.*

A general comment is to note that the section, with its emphasis on the concept of "safer alternatives," might be strengthened and improved via a somewhat broadened and elaborated concept that also allowed recognition of factors like energy efficiency, product efficiency, and others that can also be valuable contributors to developing safer and greener alternatives. Based on my experience at EPA in development and implementation of the Design for the Environment (DfE), Green Chemistry, Green Engineering, Pollution Prevention, "Sustainable Futures," and "New Chemical Pollution Prevention Recognition" efforts, I believe that such a broadened approach can be invaluable in developing and applying analyses that reflect an *integrated optimization* of the properties, relative hazards and exposures, performance needs and attributes (including "functional use" considerations such as those applied in the DfE program), costs, and other factors that are key to developing alternatives that will provide commercial value and find application.

I note the requirement under TCSA section 35(a)(2)(B) which has the Administrator determining that the proposed alternative "is effective for the proposed use or uses." I question if this is something that EPA can do or if such a "determination" is actually better left for the markets to decide. I believe that such consideration might better be applied as a "factor" rather than a determination by EPA.

Section 39. Exemption for Chemical Substances or Mixtures Based on Intrinsic Properties. *While I liked the concept of an exemption based on intrinsic properties, I found the exemption approach contained in this section to be overly cautious such that, at the end of the day, it would not serve its purposes of exempting chemicals for which there is little need or value in applying the close scrutiny that otherwise would be required by TCSA. I recommend that a more flexible approach be developed that could meet*

the purposes of exempting chemicals from some or all requirements as warranted and offer a few suggestions in this regard. I also raise what I believe is an important issue concerning polymers and whether it makes sense to treat them in the same manner as nonpolymeric chemicals under TCSA.

TCSA proposes authority to exempt certain chemical substances and mixtures based on intrinsic properties. If EPA can determine that "*scientific consensus exists* that the intrinsic properties of a chemical substance or mixture are such that it *does not and would not pose any risk of injury* to health or the environment *under any current, proposed, or anticipated levels of production, patterns or use, or exposures arising at any stage across the lifecycle*" (emphasis added), EPA may by order exempt the substance or mixture from one or more requirements under sections 4, 5, 6, or 8 of the act. While the concept of the exemption is a welcome addition, it is difficult to see that it will be useful for many chemicals. As indicated by the italicized points in the determination text, the multiple requirements, all of which must be met, conspire to make it virtually impossible for a chemical to be determined to satisfy the requirements. Consider the example of water -- could it satisfy the requirement for "not posing any risk…under any…anticipated… exposures…at any stage across the lifecycle" when this substance, while essential for life, can cause intoxication or drowning under exposures that are known to occur? Even high molecular weight polymers, that are eligible for production under the current TSCA section 5(h)(4) polymer exemption, could be found ineligible for the section 39 exemption insofar as the reactive or toxic monomers used in their manufacture might not satisfy the "across the lifecyle" requirement. Finally, the fact that all such chemicals would not be eligible for CBI protection seems to detract further from the appeal of the exemption.

I encourage that careful consideration be given to developing an approach that would prove workable and effective in exempting chemicals for which data development or other requirements might not be warranted. Although I appreciate the desire for what amounts to an almost "absolute and comprehensive" standard based on intrinsic properties for making such determinations, I believe that such an approach runs a considerable risk of defeating the purposes of the exemption. I believe that to serve and meet its purposes the exemption must allow an appropriate role for judgment and discretion in applying the exemption. Thus, for starters, I encourage the Subcommittee to gain a good understanding of EPA's approach in implementing the TSCA section 5(h)(4) exemptions. I believe these exemption approaches have been effective in encouraging the introduction of new chemicals under appropriate conditions of volume and use (such as the low volume exemption and the low release/low exposure exemption) or where polymers meet conditions of high molecular weight and other factors. I encourage the Subcommittee to consider ways that such approaches, in addition to a revision of the "intrinsic properties" approach, might be incorporated into revised legislation.

Relatedly, I draw attention to the issue of polymers and whether and to what extent the revised law should treat the tens of thousands of polymers which are likely in commerce (the TSCA Inventory lists approximately 30,000 polymers) in the same manner for MDS and declaration purposes as the nonpolymeric chemicals on the Inventory. While some polymers are of concern many, perhaps most, are generally considered to present low hazard, especially those that have high molecular weights such that absorption is limited. Polymers also present practical difficulties. For TSCA Inventory purposes, polymers are named based on the monomers which are used in their production. Thus, an Inventory polymer can be named as "Polymer of A, B, C, and D" where A to D are monomers used in producing the polymer and the chemical name does not otherwise provide any details on the reaction sequence or conditions, the ratio of the monomers, the molecular weight, or other information critical in determining

the nature of the resultant polymer. In fact it is possible to make multiple, distinctly different polymers from a given Inventory listing by adjusting factors such as these. (In reviewing new chemical polymers, EPA principally considers the polymer that the submitter intends to produce, an approach which gives a specific focus to EPA's assessment task.)

Because of such considerations and practical complexities, polymers were not subject to the reporting that EPA required by regulation under the Inventory Update Reporting rule and polymers were also not included in EPA's HPV Challenge program. In Europe, the approach to polymers has differed historically from that in the U.S., in that polymers were generally not subject to the legal regime which preceded REACH (e.g., polymers were not included on the European inventory nor were they generally subject to new chemical notification requirements). Under REACH, polymers are generally exempted from the registration requirements that otherwise apply to chemicals. The Subcommittee should consider these points carefully given the large number of Inventory-listed polymers which could be subject to testing and declaration requirements, and also recognizing some of the practical issues briefly noted in this section. One alternative approach to consider is to continue to apply requirements under section 5 to new chemical polymers, to generally exempt new and existing chemical polymers from the MDS requirements, and to obtain exposure and use information under section 8 needed to support an EPA review of the issue similar to the approach envisioned under TCSA section 3(b)(3) for mixtures. Based on that analysis, EPA could, as suggested above for mixtures, develop general requirements for testing and assessment of polymers that would be implemented by EPA by rule once it better understands the issue. During the interim, EPA should have authority to require appropriate testing and impose controls on specific polymers or classes of polymers when there is a need for such action.

Regulatory procedures and need for adequate due process. *I welcome and support the broadened order authority provided to EPA under TCSA, however, recognizing the nature of and the limitations in orders, I encourage careful consideration of whether the authority is workable and effective in all of the areas where it is mentioned.*

In particular, I question the approach of developing and applying CBI guidance via order authority at section 14(e) and the requirement at section 24(d) that all actions on single chemical substances or a single category of substances "shall be made through an order." Regarding the first, it is difficult to understand how order authority, both generally and particularly without a requirement for proposal and comment, would be used to implement CBI "guidance." The second appears difficult to implement effectively. Consider the chemicals on the section 6(a) initial priority list where, from my perspective, it would prove very difficult to implement needed requirements on formaldehyde, methylene chloride, the phthalates category, and others via order authority considering the number of manufacturers, processors, users, distributors, disposers, etc. that are involved with such chemicals. Furthermore, since most actions under section 6(c) will likely involve single chemicals or a single category (are the PBTs under section 32 a "single category of chemical substances?"), it appears that order authority would be the required approach in almost all instances. I encourage that greater flexibility to use rulemaking be provided.

I also question whether TCSA as drafted provides the appropriate balance between an ability to take more prompt action by order versus the due process afforded by rulemaking. Although I am not a big fan of rulemaking, given the time required and the difficulty encountered in proposing and promulgating an action, I have to say that in my experience at EPA virtually *every* rule and guidance document was improved following EPA's consideration of the comments. I grudgingly came to the conclusion that notice and comment is a necessary and valuable step which serves to improve the rulemaking process and

ultimately make Executive branch regulations workable in a participatory democracy. I think this is an important issue to get right and I encourage the drafters to think carefully about the appropriate role for rules versus orders in the bill.

Timelines and Deadlines. *I believe based on my experience that a number of the timelines and deadlines in TCSA will prove very difficult to realize, while others might not be sufficiently responsive. While I appreciate the desire by the Subcommittee and stakeholders for prompt progress to be realized after the failings under TSCA, the reality is that sorting through the issues and developing workable and effective approaches that satisfy statutory requirements is, in an area as complex as this, difficult to do and the result will not be improved by unrealistically short deadlines which not infrequently have been superimposed on each other. I offer a few suggestions for consideration.*

One of the practical challenges that EPA will encounter in implementing any revision to TCSA is the need to staff up (despite the challenges and delays encountered in the Federal hiring process) and to develop and implement support contracts (which itself can be a time-consuming and complex process) that would allow it to apply such resources in meeting the requirements under a revised law. Even as EPA is attempting to expand its staffing and extramural capabilities, it will at the same time need to work to understand, interpret, and apply the new statutory requirements, develop options and get Agency decisions and potentially inter-Agency clearance on required actions, establish the bodies called for under the law, develop policies required per the statute or ones that EPA determines are needed to guide its future efforts, and so on. The first several years will be quite challenging to say the least. I note, for example, the following overlapping timelines/deadlines and other considerations that might benefit from more realistic timeframes and other changes in approach:

- Whether the 1 year allowed under TCSA section 4(a) provides sufficient time for EPA to propose and promulgate the MDS requirements given the issues and complexities at play and as discussed above in the relevant section. Relatedly, I note also the requirement at section 35(a)(2) that within 1 year EPA establish by rule the "safer alternatives data set" and, within the same period, establish a program to create incentives for the development of safer alternatives (section 35(a)(1)).
- Whether TCSA should continue to require "premanufacture" notices from new chemicals or, based on EPA's experience under TSCA with new chemicals, if the trigger should be shifted to "premarketing" (i.e., notifications would be required after manufacture but before commercialization has occurred). The key statistic prompting this suggestion is that only about 50% of the new chemical premanufacture notifications received by EPA actually commence manufacture (Auer, 2009), which represents considerable wasted effort by both EPA and the industry.
- Section 5(b)(2) under TCSA essentially requires that all new chemicals be taken through the section 6(b) safety standard determination, unless otherwise exempted. Per section 5(b)(5) EPA has 90 days to determine whether a safety standard determination is required and 9 months later EPA is required to have completed such required determination (although there is no consequence or relief provided if EPA is late), which means that EPA could take as much as a year to render the determination on each new chemical. In comparison, under TSCA EPA has 90 days (extendable to 180 total days) to take its decision on new chemicals and historically decisions have been completed on the great majority of new chemicals within the initial 90-day

period (in the case of exemption requests under TSCA section 5(h)(4), decisions to grant or deny such requests are typically made within 30 days of receiving the exemption notification). I question if a new chemicals decision process that could require 1 year for a decision to be rendered, appropriately balances the competing needs between sound decision-making and being adequately responsive to commercial needs and realities. I encourage careful consideration of shortening the timeline, noting in particular that, in my experience at EPA, it is generally simpler to assess the situation associated with a single notifier of a new chemical, than it is to assess and understand a situation involving an existing chemical with multiple commercial entities at play.

- TCSA section 6(a)(1)(B) requires that EPA, within 1 year of enactment, update the priority list to a total of not fewer than 300 chemicals. While I can appreciate the value of having such a list developed promptly, I question if the deadline makes good sense considering, among other aspects, that EPA would not have the first set of declarations available when it is making these initial additions to the priority list
- Other TCSA requirements that come due within 18 months following enactment, include, for example: section 8(d)(1) on establishing a public database; section 14(e) on guidance for CBI claims; section 32 on establishing criteria for PBTs; section 37 on "data quality;" section 38 on "hot spots;" section 39(d) on "prior regulatory exemptions;" and so on.

I think you for the opportunity to have provided this written testimony.

References

Auer, Charles M., Blake A. Biles, and Lawrence E. Culleen, "Fundamental changes could be in store for regulation for commercial chemicals," BNA Chem. Reg. Reporter (Vol. 33, No. 40), Oct 12, 2009 (pp 1008-1012).

Auer, Charles M., "Periodic Reporting of hazard data, exposure information on existing chemicals," BNA Chem. Reg. Reporter (Vol. 34, No. 16), April 19, 2010 (pp. 384-392).

[i] The 2006 Inventory Update Reporting rule received reports on a total of approximately 6,200 non-polymeric chemicals produced above 25,000 pounds per year at a site (http://www.epa.gov/iur/pubs/2006_data_summary.pdf, page 2). It is not known how many of the polymers on the TSCA Inventory are currently in production, nor is it known how many of the lower volume non-polymeric Inventory chemicals are presently in commerce (such chemicals were not subject to the 2006 IUR rule). It is known that there are approximately 30,000 polymers listed on the TSCA Inventory and EPA reports additionally over 4,500 TSCA section 5(h)(4) "polymer exemptions" for a total of 34,500 polymers potentially in commerce (an additional unknown number of exempted polymers is also likely to be in commerce based on the terms of the revised TSCA section 5(h)(4) polymer exemption). There are 45,000 non-polymeric Inventory chemicals that did not meet the volume reporting trigger under the 2006 IUR rule plus an additional approximately 8,900 TSCA section 5(h)(4) "low volume exemptions" that have been approved by EPA (http://www.epa.gov/oppt/pubs/oppt101-032008.pdf, see pages 6 and 12) yielding an estimated total of 53,900 lower volume nonpolymeric chemicals potentially in commerce.

Assuming that half of each of the 34,500 polymers and the 53,900 lower volume chemicals are currently in production, and adding in the 6,200 higher volume chemicals which are known to be in production based on the 2006 reporting under the IUR rule, yields an estimated total of slightly over 50,000 substances currently in commerce and for which EPA would possibly receive MDSs under TCSA section 4(a)(2) and declarations under TCSA section 8(a)(1) (the math is as follows: (53,900 + 34,500)/2 + 6,200 = 50,400).

[ii]Historically, the U.S. and the EU have taken somewhat different approaches to the chemicals that are covered under their respective new chemical notification requirements and the figures reported have accounted for those differences. A key difference is that new polymers are treated as new chemicals in the U.S. (where they represent about 55% of the new chemicals notified to EPA) whereas polymers are generally not subject to notification in the EU. The U.S. also has a regulatory exemption procedure for low volume new chemicals under TSCA section 5(h)(4). Thus, considering these points, the U.S., through approximately 2006, has seen over 9,200 nonpolymeric new chemicals added to the Inventory and over 8,800 low volume exemption requests granted by EPA for a total of approximately 18,000 nonpolymeric new chemicals introduced into U.S. commerce (http://www.epa.gov/oppt/pubs/oppt101-032008.pdf, see pages 7-12).