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"Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact"

Introduction

My name is Charles M. Auer. I was formerly an employee of the U.S. Environmental Protection Agency (EPA) until my retirement in January 2009. While at EPA I gained experience in hazard and risk assessment, policy development and implementation, rule-writing, and related aspects of the Administrative Procedure Act, and also participated as a U.S. negotiator in the development of and final agreements on the Stockholm and Rotterdam Conventions. I started at EPA as a staff chemist 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 agencies.

I am pleased to have the opportunity to provide testimony at this hearing. *The testimony I am offering is mine and I am not speaking for or on behalf of anyone else in offering it.* Finally, my testimony includes several points that (and which I try to acknowledge) represent "my views;" I have no doubt that others will disagree to a smaller or larger extent with those views and I welcome that, in the hopes that such debate can lead to both understanding and improvements.

I. Overview of TSCA Authorities and EPA Rulemakings

After working with and trying to apply TSCA for over 30 years, I believe the law to be well and clearly drafted. It is a compact and almost elegant statute. TSCA Title I has never been revised, although additional Titles were added, since it was enacted in 1976 and, as discussed in this part of my testimony and beyond, there are issues that have arisen over the decades regarding certain of the provisions.

TSCA gave EPA authority in TSCA §8(b) to create an **Inventory** of existing chemicals in commerce (TSCA's definition of "chemical substance" does not include chemicals used as pesticides, drugs, etc. as such chemicals/uses are subject to other laws) and EPA completed this task by rule in the late 1970s (all Section ("§") references in this testimony go to Sections of TSCA unless otherwise noted and are intended to also reference the associated implementing regulations, where such exist). The so-called initial Inventory contained approximately 62,000 chemical substances, including "Class 1" and "Class 2" substances, and polymers. Class 1 substances have a discrete structure while Class 2 substances are complex mixtures of various types. The nonpolymer chemicals can be further subdivided into organic chemicals and inorganic chemicals, some of which are Class 2 "UVCBs" (chemicals of "unknown or variable composition, complex reaction products and biological" materials) or "statutory mixtures."

The Inventory having been created served to distinguish "existing chemicals" in commerce from "**new chemicals**" not on the Inventory that require advance notification under §5(a)(1) to EPA prior to their manufacture for commercial purposes ("manufacture" as defined under TSCA includes "import"). The so-called Premanufacture Notification (PMN) must also meet the reporting requirements under §5(d)(1). EPA reviews the PMN and evaluates the new chemical as a "gatekeeper" to assess potential risk or production/exposure concerns and based on this review can impose conditions to restrict or ban manufacture, uses, releases, etc., and/or to require testing. Formal regulatory action is generally implemented via a Consent Order under §5(e) and requires certain determinations by EPA that available information is insufficient to permit a reasoned evaluation of the chemical and that it "may present an unreasonable risk" or that it has substantial production and substantial/significant exposure/release. EPA has also relied on "voluntary" testing, including an informal "ban pending testing" arrangement to obtain testing that is relatively inexpensive to conduct (e.g., acute aquatic toxicity testing).

EPA can also impose Significant New Use Rule (SNUR) requirements (§5(a)(2)) on new chemicals that require advance notification to EPA prior to initiating the "significant new use." SNURs require consideration by EPA of a series of "factors" in taking the rulemaking and can be used to, in effect, extend the §5(e) consent order requirements to other companies beyond the notifier and/or more generally to require Significant New Use Notification (SNUN) for uses beyond those identified in the PMN.

Following the end of the 90-day review period (and which can be extended per §5(c)), PMN chemicals can be manufactured (subject to any conditions imposed by EPA); if manufacture occurs the PMN notifier is required to submit a Notice of Commencement (NOC) of manufacture to EPA after which the former new chemical is added to the Inventory. It is interesting to note that, historically, only ~50% of PMN chemicals actually commenced manufacture.

Finally, TSCA §5(h) includes several statutory exemptions (e.g., §5(h)(1) concerning "test marketing") and rulemaking authority for regulatory exemptions under §5(h)(4). Currently available

regulatory exemptions include ones for chemicals that meet "low volume" or "low release/low exposure" requirements, and for certain polymers. Under this section, EPA can "regulatorily exempt" companies from some or all of the PMN requirements upon an EPA determination that the manufacture, processing, etc. of the subject chemical "will not present an unreasonable risk." EPA has established eligibility criteria for the regulatory exemptions and, if granted by EPA, manufacture and use of the chemical is subject to the terms of the exemption and the chemical is not added to the TSCA Inventory.

Additional, more detailed discussion of the new chemicals program can be found below and in the Annex; also, several of the "Additional References" cited below discuss aspects of or the TSCA new chemicals program, in general.

Certain §5 authorities have not been used to any significant extent in my view by EPA or others (as appropriate), including: §5(b) Submission of Test Data; §5(f) Protection Against Unreasonable Risks; and §5(g) Statement of Reasons for Not Taking Actions. I do note that EPA has a pending matter before the Office of Management and Budget concerning a §5(b)(4) rulemaking and that there were a handful of actions that used §5(f) in the 1980s. I do not recall specific cases but §5(g) statements may have been published by EPA relating to SNUNs submitted under §5(a)(1) but for which no regulatory actions were taken, although in general few SNUNs were received during my time at EPA.

Existing chemicals on the other hand were essentially grandfathered under TSCA without any requirement for EPA review. TSCA §8(e) did mandate immediate reporting of "substantial risk" information to EPA by manufacturers, processors, and distributors and EPA in addition received broad TSCA authority to require by rule, inter alia, reporting of existing exposure and hazard information (§8(a) and §8(d)), to require testing (§4), and to regulate unreasonable risks (§6).

EPA has promulgated several types of §8 reporting rules, including:

- §8(a) rules, including the Preliminary Assessment Information Reporting (PAIR) rule, and §8(d) rules have been used to meet information needs identified by the Interagency Testing Committee (ITC) per §4(e) and by EPA more generally
- The Inventory Update Reporting (IUR)/Chemical Data Reporting (CDR) rules (§8(a)) have been in place since 1986 and have required regular periodic reporting (at intervals of four to five years) on production volume and, more recently, processing and use information. IUR reporting occurred in 1986, 1990, 1994, 1998, 2002, and 2006, and CDR reporting occurred in 2012, with the next report due in 2016. Basic production volume information has been required on chemicals meeting a production trigger (e.g., 10,000 or 25,000 pounds/year at a site) and the scope of subject chemicals included organic chemicals and, more recently, inorganic chemicals, but not polymers. Estimates of the numbers of workers reasonably likely to be exposed to such chemicals and maximum concentration information are also reported. Reporting of processing and use information is generally required only on higher volume chemicals meeting a trigger (e.g., production of > 300,000 lbs/yr at a site, and more recently >100,000 lbs/yr at a site, and dropping to 25,000 lbs/yr at a site in the 2016 reporting cycle). The 2016 cycle will also include reporting of the production volumes during the intervening years and other changes.

§8(a) includes a reporting exemption for small businesses which generally limits EPA's ability to require reporting from such entities. Notably the exemption did not apply in the development of the initial Inventory under §8(b), thus ensuring that reporting by small businesses contributed to that compilation.

Testing can be required by rulemaking (§4(a) if certain findings are made by EPA including:

- The chemical "may present an unreasonable risk" **or** is produced in substantial quantities and has substantial or significant exposure/release. Concerning the latter finding, EPA developed an

"exposure-based policy" via notice and comment, which in 1993 defined substantial production (as ≥1 million pounds/year) and several exposure and release terms (58 Fed. Reg. 28736);

- Insufficient data are available to determine the effects on health and the environment; **and**
- Testing is necessary.

EPA also developed an "enforceable consent agreement" (ECA) process for obtaining testing via a public negotiation process as an alternative to rulemaking.

TSCA §6(a) gives EPA authority to regulate existing chemicals if EPA finds that the manufacture, processing use, etc. of a chemical "presents or will present an unreasonable risk of injury to health or the environment." EPA in regulating such a chemical "shall by rule apply" any "one or more" of a number of regulatory measures at Subsections 6(a)(1) – 6(a)(7) "to the extent necessary to protect adequately against such risk using the least burdensome requirements." In taking the action, EPA is required by §6(c) to consider and publish a statement concerning a number of factors relating to "unreasonable risk," including the effects of the chemical and magnitude of exposure, the benefits and the availability of substitutes, and the reasonably ascertainable economic consequences of the rule. This section also imposes a number of specific procedural requirements on the rulemaking, including the possibility of an "informal hearing."

EPA can also use §5(a)(2) SNUR authority to require (by rule and considering a series of "factors") advance notification (i.e., a SNUN) concerning significant new uses of existing chemicals. Following review of a SNUN on an existing chemical, EPA can regulate the significant new use and/or require testing using authority under §5(e).

Authorities under §§4, 6, and 8 that have not, in my view, been used to any significant extent by EPA or others (as appropriate) include: §4(f) Required Actions (while there were several "4fs" in TSCA's early decades, the provision has not been used in some years); §4(g) Petitions for Standards for the Development of Test Data; of the TSCA §6 provisions only §6(e) on regulation of PCBs (polychlorinated biphenyls) has seen any significant use; EPA promulgated an §8(c) rule concerning records of "significant

adverse reactions" but last did a data call-in many years ago (although EPA more recently has expressed interest in using this section).

TSCA also includes **other provisions** relating to "imminent hazards" (§7), TSCA's relationship to other Federal laws (§9), exports (§12), imports (§13), confidential business information (§14), preemption (§18), citizens petitions (§21), etc. Concerning these sections, the following in my view have not been used to any significant extent by EPA or others (as appropriate): §7 Imminent Hazards; §9 Relationship to Other Federal Laws (other than "informal §9 referrals" and efforts to coordinate with other Agencies (§9(d)); and §18 Preemption (the limited number of TSCA §6 actions is likely a factor in few, if any, §18(b) exemption requests being received by EPA).

II. A Sampling of TSCA Statistics and My Impressions of TSCA's Footprint of Regulatory and Voluntary Actions

TSCA was enacted in 1976 and came into force in 1977. Since that time, EPA has taken a number of regulatory and voluntary actions to test, assess, and manage the risks presented by commercial chemicals. While it is clear to me that much more needs to be done to safeguard health and the environment than has been possible under TSCA, based on a fuller accounting of the actions taken and as discussed briefly below, I believe the chemical regulatory, management, and oversight actions taken by EPA have been more extensive and significant than has been generally recognized. **Note:** unless otherwise noted the statistics that follow were taken from a 2008 report by EPA's Office of Pollution Prevention and Toxics entitled "Overview: OPPT Laws and Programs" (http://epa.gov/oppt/pubs/oppt101-032008.pdf). The information and tables in the report range from approximately 2003 through 2006, and as such, may be considerably out of date.

How many TSCA chemicals are likely currently in production?

A straightforward answer to this question is not readily available; however, it may be possible to piece together an estimate, as follows. The initial TSCA Inventory contained about 62,000 chemicals and

through 2006, approximately 21,000 new chemicals were added by EPA following receipt of an NOC, yielding over 83,000 chemicals listed on the Inventory. In addition, as of 2006, EPA had received requests for TSCA §5(h)(4) regulatory exemption requests for over 11,000 new chemicals and polymers (recall that these are not listed on the Inventory) which, when combined with the Inventory count, totals over 94,000 chemicals. Based on the most recent (2012) CDR reporting, there were almost 7,800 nonpolymeric Inventory chemicals produced at or above 25,000 lbs/yr at a site; such information is not available on lower volume chemicals or on polymers. Nonpolymeric chemicals accounted for about 65% (53,400) of the 83,000 Inventory chemicals, while polymers represented about 35% (29,500); thus based on the 2012 CDR reporting about 15% of the nonpolymeric chemicals are in production at or above 25,000 lbs/yr at a site while 85% (or 45,390) are either produced below this level or are out of commerce entirely. It is not known how many of the ~30,000 Inventory polymers or the over 11,000 §5(h)(4) regulatory exemption substances are currently in production. If, however, one assumes that 50% of the non-CDR reported chemicals are *actually* in commerce at some level, this would yield, with the addition of the 2012 CDR chemical count (~7,800), approximately 51,000 chemicals in commerce. My suspicion is that this is an overestimate and that the actual number in commerce is lower, but as noted, there is no way of checking its accuracy at present.

How many new chemicals have been submitted to EPA and how many have been regulated by EPA? How much voluntary testing (e.g., "ban pending testing") has occurred?

The 2008 EPA report indicated that 36,600 PMNs were submitted to EPA as of 2003, and as of 2006 over 2,600 new chemicals were regulated using §5(e) consent orders and/or §5(a)(2) SNURs. An additional 1,700 new chemicals were withdrawn voluntarily by the submitter (this often occurs in the face of EPA regulation) and EPA obtained voluntary testing on over 300 new chemicals. In addition, all of the over 11,000 §5(h)(4) exemption chemicals are regulated and subject to the terms of the exemption (most such exemptions are granted, often with EPA conditions added; I do not have statistics on the ratio of

"grants" to "denials"). Thus, EPA has taken action (including withdrawals) on over 15,000 (or over 30% of) new chemicals based on these relatively dated statistics.

How many chemicals have been subjected to testing using §4 authority? How much voluntary testing of existing chemicals has occurred? Is it true that to require testing, EPA already has to have information showing the chemical is toxic or risky?

EPA reports (2008) that §4 testing has been required on 200 chemicals (note that this figure does not include testing required on new chemicals via §5(e) regulatory authority).

Starting in the late 1990s, EPA implemented the voluntary High Production Volume (HPV) Challenge Program to obtain screening level data on the approximately 3,000 nonpolymeric organic chemicals produced at or above 1 million lbs/yr. Commitments were received on 2,200 HPV chemicals under the Challenge Program or a related effort by the Organization for Economic Cooperation and Development (OECD); EPA's report on the "Status and Future Directions of the HPV Challenge Program" (seemingly issued around 2004) presents interim information on progress made but does not provide final counts of the number of chemicals for which the HPV Challenge commitment was met. EPA has also used §4 test rules to obtain information on "orphan" or unsponsored HPV chemicals and this work continues.

Concerning TSCA's testing authority, as noted above, §4(a) allows EPA to require testing based on potential risk and/or exposure-based findings. Neither risk nor toxicity factor into the latter finding.

How many existing chemicals have been regulated? Were any voluntary risk management actions taken?

TSCA §6 rules have been issued and remain in effect for a number of chemicals, including PCBs (which is the subject of the bulk of the §6 regulations). The actual number of chemicals regulated depends on how one counts them and the 2008 EPA report cited earlier included a table which listed nine (9) proposed or final actions under §6 and, of these, four (4) rules which remained in effect. One of these

nine actions is a TSCA §6 rule to regulate asbestos, which was largely overturned in 1991 and today only a few asbestos items remain as banned products.

EPA has also used TSCA §5(a)(2) SNUR authority to regulate over 300 existing chemicals, including a number of "PBTs" (e.g., 6 PBBs (polybrominated biphenyls, the brominated analogue of PCBs), 2 PBDEs (polybrominated diphenyl ethers), and over 270 PFAS (perfluoroalkyl sulfonate) derivatives), known or suspected carcinogens (including 24 benzidine dyes, the flame retardant "tris" (tris(2,3-dibromopropylphosphate), and erionite (an asbestos-like fiber)), and other toxic and risky chemicals. The SNUR "triggers" for EPA notification range from "any use" for the PBBs to, in the case of the PFAS derivatives, uses other than specific ongoing low volume/low release uses for which alternatives are not available. EPA should be able to provide a comprehensive listing of such existing chemical SNURs and the concerns that resulted in the regulation, including the details of the SNUR triggers applied, if of interest.

In 2006, EPA and the eight major companies in the industry launched the "2010/2015 PFOA Stewardship Program," in which the companies committed to voluntarily reduce their global facility emissions and product content of PFOA and related long-chain perfluorinated chemicals (PFCs) by 95 percent by 2010, and to work toward eliminating such emissions and product content by 2015. According to EPA's Action Plan on Long-Chain PFCs, "most companies have reported significant progress in meeting" the goals of the Stewardship Program. Voluntary actions have been taken on other existing chemicals over the years (a prominent example was the chemical acrylamide when used in sewer grout), but I cannot do the subject justice with the information available to me.

III. What does or does not work well under TSCA? What legal gaps exist?

A number of TSCA issues and concerns as well as aspects that work well, are discussed in several papers cited as Additional References at the end of this testimony. I summarize my thoughts here.

What has worked well in TSCA? Creation of the TSCA Inventory under §8(b), the new chemicals program under TSCA §5 and the citizens petition process under §21.

Creation of the TSCA Inventory in the late 1970s was an unprecedented activity. No government had ever before attempted to compile an authoritative list of the chemicals in commerce and EPA's completion of this effort within 3 years of TSCA's entry into force was a prodigious accomplishment. The TSCA Inventory served as the standard and the model for other national inventories developed since then; many of the policies, approaches, and even terminology (e.g., UVCB) developed in the initial TSCA Inventory have been applied by other countries. Since that time EPA has done a good job of keeping the guidance and the listings current which is key given the way the Inventory serves as TSCA's "bedrock."

In my view, experience over the past 30+ years has shown that TSCA struck a good balance in its approach to new chemicals under §5 and that the program has been effective and efficient in its oversight of new chemicals. It has encouraged the introduction of safer and greener new chemicals while also working to move industry away from potentially problematic chemicals through both regulatory and voluntary efforts. The new chemicals program has been a driver for innovation in the U.S. More discussion on this important program and its successes can be found in the Annex.

The §21 petition process has proven useful as a means of bringing issues and concerns to EPA's attention. Under this section, citizens can petition EPA to take certain actions under TSCA §§ 4, 5, 6, or 8, and EPA is required to respond to the petition within 90 days. If EPA grants the petition, it is required to promptly commence an appropriate proceeding; if EPA denies the petition, the reasons for denial must appear in the *Federal Register*. EPA has received numerous petitions over the years (OPPT's web site provides a listing of 12 petitions received since 2007). In my view, these petitions have been effective in causing EPA to take a close look at the petitioned issue and to promptly consider whether the requested activity should be undertaken based on the information available to EPA as well as the requirements under §21. This type of petitioning opportunity, at its essence, is both useful and helpful in a participatory democracy. In addition, a number of activities which I consider to be useful have resulted --

directly or indirectly -- from such petitions, including, e.g., a recently proposed EPA regulation on formaldehyde emissions from composite wood products. More detail should be available from EPA on §21 petitions and their outcomes, if of interest.

One other effort that might appear on a future list of "successes" is the §8(a) IUR/CDR effort to collect volume, processing, and use information on existing chemicals. This effort has become more useful as it was expanded over time to include inorganic chemicals in addition to organic chemicals, added requirements for basic reporting on the number of workers "reasonably likely to be exposed to a chemical," maximum concentration, etc., and added reporting of processing and use information and then lowered the volume triggers for such reporting. It also made better efforts to distinguish commercial from consumer uses of chemicals and expanded requirements for substantiation of CBI claims. The 2016 CDR cycle promises to be even better with reporting on subject chemicals including productions volumes for each of the intervening years and with the trigger volume for reporting of processing and use information being further reduced to 25,000 lbs/yr at a site.

What hasn't worked well in TSCA? The testing program under §4 and risk management under §6.

The statistic that §4 has been required testing on about 200 chemicals says a lot about why this program is being discussed in this context. While TSCA §4 seemed like a reasonable approach to obtaining testing, in practice the §4 rulemaking requirements have proven cumbersome to implement and as structured did not allow EPA to obtain testing to the level and extent needed to inform assessment and regulatory decisions under TSCA. EPA found, for example, that satisfying the findings, particularly the "data insufficiency" finding, could be time-consuming. Other problems were associated with the generally slow and complicated nature of rulemaking, an issue which is not unique to §4 rules. However, part of the problem with the long duration of the rulemaking process was that it could (and did) force reconsideration of the findings and redrafting of the rule text and rulemaking support documents (findings document (especially the exposure assessment portions), economics report, etc.) to reflect new information which EPA received; an example is the ripple that would result from a new IUR/CDR report

which changed the information available to EPA concerning production volumes, number of manufacturers of record, number of workers, uses, etc. EPA also attempted to use multi-chemical rulemakings to obtain testing in the hopes that such "combined efforts" would be more efficient; unfortunately in many cases, EPA found that the test rule process could only go as fast as the most problematic of the chemicals and that dropping chemicals or breaking up the rulemaking was needed in many cases.

Because of the difficulties encountered in developing test rules, EPA developed an enforceable consent agreement process to obtain negotiated testing. While this proved helpful in some cases, in other instances, the negotiations were never able to result in an agreement.

As noted earlier, in the late 1990s EPA identified an interest in obtaining screening level testing on High Production Volume (HPV) chemicals and, recognizing the number of chemicals at play (~3,000) and the difficulties in using §4 rules generally and specifically for such a large number of chemicals, decided to attempt to meet the need through a voluntary testing program. While the HPV Challenge Program was successful in increasing both access to and the availability of test data on many but by no means "all" of the HPV chemicals, EPA ultimately had to shift gears and use §4 test rules to deal with unsponsored "orphan chemicals," a process that has been under way for over a decade and is yet to be finished.

TSCA §6 had surprising early success in efforts between 1978 and 1980 to regulate fully halogenated chlorofluorocarbons used as aerosol propellants, PCBs, and a site-specific rule regulating a storage facility in Arkansas handling dioxin-contaminated waste (the first and third of these rules were later superseded by actions taken under other statutes). Then in 1984, §6 was used to regulate three new chemicals used in metal working fluids. In 1989 EPA promulgated a ban and phase-out regulation under §6 on asbestos products. This rule regulated most of the use of asbestos but, following a legal challenge, was largely overturned, a decision which was not appealed. While much has been discussed and written about this rulemaking and the court decision, in my view, the requirements in TSCA §6(a) for a finding of

"will present an unreasonable risk" and the need to apply "the least burdensome" measures, combine to represent a largely unworkable legal standard for regulation.

Note that some number of my estimated "51,000 existing chemicals actually in commerce," are *actually* former new chemicals which were regulated when they came through the §5 program and, having been the subject of an NOC, were added to the Inventory. It is not possible to estimate this number for the reasons given earlier; it would nonetheless be interesting to understand how many former new chemicals have been the subject of reports under the CDR. EPA should be able to provide this information, if of interest.

Having acknowledged the success of the new chemicals effort and the lack of success of the existing chemicals program, it is nonetheless useful to take a step back and place that latter effort into a context *vis-a-vis* new chemicals. Certain aspects of new chemicals were in my view a factor in the success seen. These include the fact that EPA was typically dealing with only one company concerning a chemical with a generally limited spectrum of uses that were described in the PMN (along with exposure and release information, manufacturing process descriptions, etc.), and the production and uses of which represented future market potential. Existing chemicals, on the other hand, typically involved: several to many companies; uses that could be multiple and varied with possibly different exposures and releases associated with each; substantial gaps in the available understanding (IUR/CDR reports while helpful lack the detail found in a PMN); and the fact of an established market with in-place infrastructure involving production, processing, use, employment, etc. Without a doubt, for these reasons as well as other reasons discussed in this section, dealing with existing chemicals presents the greater challenge under TSCA.

What legal gaps exist in TSCA? While current TSCA §§4 and 6 may not rise to "legal gaps" in authority (although some might argue this point), there is need to strengthen and improve these authorities. Concerning legal gaps, in no particular order, I offer the following:

- EPA needs domestic authority to implement Convention obligations under Stockholm, Rotterdam, and LRTAP (Long-Range Transboundary Air Pollution) and open the door to

consider ratification of these treaties by the Senate; achieving these steps (among others) would enable the U.S. to join these Conventions as a Party;

- EPA should be allowed to share CBI with, and receive CBI from, States and possibly foreign governments that satisfy legal requirements and provide assurances of their ability to prevent disclosure of CBI. Note that both Canada (under the Canadian Environmental Protection Act of 1999) and the EU (under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation) allow for sharing/receiving of CBI with other governments that can adequately protect the CBI.

The 2009 and 2010 papers cited in the Additional References discuss a number of other areas where I believe TSCA could be improved.

IV. How does EPA currently set an agenda for reviewing chemicals? Does it need legal authority to do so?

EPA has developed and is currently using an Existing Chemicals Program Strategy to set an agenda for reviewing chemicals. A description of the approach can be found at http://www.epa.gov/oppt/existingchemicals/pubs/Existing_Chemicals_Strategy_Web.2-23-12.pdf. This is the most recent of numerous attempts by EPA over the decades to develop and implement an agenda to guide its work on testing and assessment of existing chemicals under TSCA. From my time at EPA, I can recall the so-called "15 Chemicals" strategy from the early years of TSCA (which was focused on risk assessment and risk management), the Master Testing List from the early 1990s (which was an attempt to create and publicize an "agenda" for §4 testing), an approach using preparation of "Risk Management 1" and "Risk Management 2" assessments (so-called RM1 and RM2 documents as part of an effort to focus risk assessment and risk management efforts) which, as I recall, dates from the 1990s, and the Chemical Assessment and Management Program (ChAMP) from 2007-2008. I am most familiar with ChAMP, an approach which involved, among other more traditional elements, efforts to

- apply the newly-received IUR reporting of processing and use information to assess exposures and
- use tools more generally associated with the new chemicals program (such as Structure Activity Relationships (SAR) analysis) to assess potential hazards

as part of an effort to screen and prioritize large numbers of existing chemicals for more detailed assessment and possible risk management, and thereby create an agenda for EPA. While TSCA is very broad in its authority, it is vague as to the important areas that EPA should focus on in dealing with the tens of thousands of existing chemicals and this "gap" has presented a long term and so far insolvable problem for EPA (the jury is still out on the latest effort; although, as EPA learns to use the CDR data and particularly the increased scope of reporting in the 2016 cycle, if the Agency, in setting its priorities, appropriately relies on the factual exposure information represented by the CDR data, that could make an important difference).

A great question is "why haven't these earlier attempts worked?" It is my view that this combination of "broad authority and vague priorities" never came together in a way that could yield an agreed set of program goals that would then be pursued in a disciplined manner over the longer term to sort, test, assess, and act, as appropriate, in managing the risks of the thousands of chemicals in commerce. Further, given this "gap," if you will, it is my view that EPA could do a better job and would be more effective in its work if it had some policy guidance that it could rely on as to what, among the many possibilities, the Agency should be doing, including ideally short and longer term goals. To elaborate on these critical points:

- In the case of new chemicals under TSCA, while there was not a statutory requirement for EPA to review the new chemical and take a decision, the fact of the PMN notices coming in to EPA on an almost daily basis, plus the discipline provided by the 90-day clock, served to create an agenda which EPA responded to very effectively. This kind of driver for shaping an agenda for existing chemicals does not exist in TSCA.

- As shown by the demise of ChAMP and all the other earlier EPA attempts to get its work organized, it has proven difficult for EPA to do this on its own. A TSCA advisory committee set up several years back under the Federal Advisory Committee Act (FACA) offered early promise in this regard, but that committee has ceased to exist.
- There is also the practical issue that in a bureaucracy with many claimants on resources, those programs that can point to strong drivers are the ones that get the resources. While the TSCA program has received more resources of late, this was not true for most of its existence, and especially for several decades after it was no longer a "new" statute.
- Another problem contributing to TSCA's difficulties in developing and implementing an agenda for existing chemicals, to be frank, has been the lack of Congressional interest and oversight for most of TSCA's history; hopefully this hearing is the start of ongoing and sustained interest by this Subcommittee.
- And, if I may continue to be direct, and with due respect, I believe, given the history I have reviewed in my testimony, that this situation is not likely to change appreciably until and unless the Congress debates and provides policy guidance if not requirements (along with any legal authority needed to implement the guidance or requirements) to enable EPA to focus on developing and then working to implement an agreed approach to dealing with existing chemicals over time.

The experience in Canada under the Canadian Environmental Protection Act and its 1999 revision (CEPA-1999) is, I believe, instructive as an example regarding the general question of the need for and value in an agenda and why such Congressional input is essential. This revision to Canada's "TSCA equivalent" law occurred after a period where the Canadian regulatory authorities also struggled to get their arms around the "problem of existing chemicals." Recognizing the issues, challenges, and needs, the Parliament debated and agreed to a legislative revision to their law which set in motion a process requiring that the government:

- screen and "categorize" the chemicals on the Canadian inventory to identify those presenting certain concerns, and then
- conduct screening-level risk assessments on all "categorized" chemicals to determine if they warrant consideration for further action, including controls.

By dint of hard work and resourcefulness, Environment Canada and Health Canada working together were able to complete the categorization process in 2006 and identified 4,300 chemicals (among the 23,000 on their inventory) needing further attention. This was by all accounts a remarkable achievement, especially considering the prior struggles. The Government of Canada in 2006 then swept up this accomplishment and announced a "Chemical Management Plan," which included several key "next step" actions and established a deadline of 2020 for addressing all of the priority chemicals. Progress has continued apace.

The clear goals and purposes of the Canadian "agenda" were, in my view, central to their success, as was the careful design of the other relevant parts of their CEPA-1999 authority. Note also that the approach in CEPA-1999 was broadly supported by Canadian stakeholders, and, as I understand it, that support continues to this day. Finally, please recognize that while I like elements of the Canadian approach, in citing this example, I am not necessarily suggesting anything specific regarding how the U.S. might approach the question of developing an agenda under TSCA.

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I thank you for the opportunity to have provided this testimony.

Additional References

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Annex

Additional discussion concerning "*What works well in TSCA?*" as it relates to the new chemicals program under TSCA §5.

Experience has shown that TSCA struck a good balance in its approach to new chemicals and that the program has been effective and efficient in its oversight of new chemicals:

(1) One of the major issues when TSCA was being debated in the 1970s concerned whether to require an upfront "base set of testing" on new chemicals. In the end, this testing was not required as part of the PMN notice, although EPA was given a flexible "may present an unreasonable risk" regulatory standard which essentially recognized the scientific uncertainties that a lack of test data would present to EPA in reviewing new chemicals. This standard encouraged EPA to regulate new chemicals that were a "potential problem" and led EPA to develop and rely on Structure Activity Relationships (SAR) analysis as a tool to assess and identify potentially hazardous new chemicals. I believe that these predictive assessment tools have worked reasonably well to identify potential problem chemicals, as shown in several EPA efforts to "check its work," including:

- a 1993 study conducted jointly by EPA and authorities in the European Union that compared the results of EPA's SAR predictions with the results of base set testing done on a set of new chemicals in the EU, and
- regular checks by EPA of §8(e) "substantial risk" submissions and §5(e) (and voluntary) testing done on new chemicals to compare the results of the testing with EPA's predictions.

While these EPA efforts are not dispositive of the question, the use of SAR approaches is now generally recognized by the OECD, Canada, and the EU (under the REACH program) as a valuable component in an initial assessment of chemicals.

(2) Augmenting the "may present" standard and EPA's use of SAR, TSCA also provided "exposure-based" and SNUR regulatory authority. The former can be thought of as an encouragement for EPA to obtain greater scientific certainty on higher volume/higher exposure new chemicals. It can also help improve EPA's approach as a check on "false negative" new chemicals (chemicals which EPA does not identify as a potential problem in initial review, but which are subsequently found to be toxic based on testing; §8(e) reports, unless they consist of §5(e) testing, can also be thought of as a check on false negatives). SNURs, on the other hand, provided a flexible regulatory authority that allowed EPA where indicated to get "another bite at the apple" for new chemicals that exceeded their SNUR triggers.

(3) EPA has used its TSCA regulatory tools to control new chemicals presenting risks or uncertainties and this can be seen in the regulatory action counts discussed earlier. EPA has also used its assessments and regulatory outcomes over time to communicate understandings to industry about potential problem chemicals and to encourage them to shift away from some chemistries, while at the same time encouraging industry to consider safer new chemicals. Specifically, EPA has:

- released a "PMN categories" document that discusses groups of new chemicals that EPA has typically identified as presenting possible concerns,
- made its SAR and exposure estimation tools available on-line,

- encouraged industry to discuss, as part of the PMN, the pollution prevention (or "P2") benefits that may be associated with a new chemical,
- has implemented an informal "P2 recognition" program that highlights noteworthy new chemicals, and
- has also used the "Sustainable Futures" program to encourage industry to use EPA's assessment tools to identify potentially risky new chemicals early in the development process and use that understanding to develop safer alternatives that also meet performance requirements.

(4) I believe, based on my experience as a former EPA staff scientist and official who participated directly in the review of thousands of new chemicals, that new chemicals are generally "safer and greener" than their existing chemicals competitors and, over time, than their new chemical predecessors. New chemicals also often provide greater energy efficiency or product efficiency, or provide approaches that can help deal with known problem chemicals by offering alternatives that reduce risks while meeting performance requirements. 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. Thus, I believe that the TSCA new chemicals program has been an important contributor to innovation in the chemical industry.

(5) The decision not to require upfront testing in TSCA also had the effect of reducing the economic impacts and time delays (due to the time required for testing) in introducing new chemicals, recognizing that regardless, such chemicals had to compete with existing chemicals and demonstrate their commercial value in the marketplace (recall that only ~50% of new chemicals actually commence manufacture and it is not known how many or how long commenced new chemicals remain in the market, although some of this turnover is likely "creative destruction" along the lines of the "continuous improvement" discussion, above).

(6) A review of available information indicates that the EU has seen dramatically fewer numbers of new chemicals introduced into commerce in comparison to the U.S. experience:

> over a 20-plus year period (from the early 1980s until the entry into force of REACH in 2007), the EU with its requirement for base set testing saw the introduction of "about 3,000" new chemicals,[1] while the U.S. over approximately the same period saw the introduction into commerce of a corresponding ~17,000 new chemicals (see further explanation of this number below). These figures thus indicate that *relative to the EU's experience, there were approximately six (6) times as many new chemicals introduced in the U.S. over this period,* put another way, the EU's total number of new chemicals notified represents about 18% of the U.S.'s corresponding total.

The U.S. figure, taken from the 2008 EPA report cited earlier, includes commenced PMNs and §5(h)(4) regulatory exemption requests submitted during this period and have been adjusted to reflect the regulatory scope applied to new chemicals in the EU; for example, the U.S., unlike the EU, required notification on all new chemical polymers. The U.S. figure thus includes both commenced nonpolymeric

[1] Van Leeuwen, C.J., B.G. Hansen and J.H.M. de Bruijn, "The Management of Industrial Chemicals in the EU," in *Risk Assessment of Chemicals: An Introduction,* 2nd ed., Springer, The Netherlands, 2007 (pp. 511-551; see p. 512 for the information cited).

PMNs (8,200 "as of 2006") and §5(h)(4) regulatory exemption chemicals (8,826 Low Volume and 33 Low Release/Low Exposure regulatory exemptions through September 2006; most of these are nonpolymeric substances (given the separate regulatory exemption that is available for certain polymers) but there could be some polymers included as well; a more careful analysis would need to be done by EPA to determine the actual number of nonpolymeric regulatory exemption chemicals if this question is of interest).

Conclusions. I believe that the U.S. over time has greatly benefited, both competitively and environmentally, from the increased number of new chemicals introduced into commerce because of the flexible and less burdensome approach under TSCA, and the appropriately measured response by EPA in its regulatory efforts and in working as an advocate for environmental stewardship in the development of new chemicals. As discussed above, I believe that new chemicals notified to EPA are in general safer and greener than the chemicals they have substituted for, while also, particularly over time, being more energy efficient and delivering higher technical and commercial performance. For reasons such as these, it is my belief that the new chemicals program has been one of TSCA's great successes.