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Competing proposals are working their way through the House and Senate to amend the Toxic Substances Control Act, the nation's primary law for managing chemicals in commerce. In this article, former senior Environmental Protection Agency officials Charles Auer and James Aidala and attorney Lynn Bergeson discuss making the bill clearer and how congressional direction can be provided on what EPA is to do with certain new provisions to implement them in the first years of any amended TSCA.

TSCA Reform Legislation and Its Workability: Thoughts on Steps to Help Ensure Successful Implementation at the Outset and Over Time

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Introduction

"Congress On the Verge of Amendments to TSCA," and headlines of similar ilk are not what those of us who daily engage with Toxic Substances Control Act (TSCA) issues thought we would ever see. At the same time, there is an element of "now what" since the legislative sausage grinder continues to churn and there are competing proposals for "TSCA reform" from the House and Senate.

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The views expressed in this article are entirely those of the authors.

This article is not an analysis of the politics between the House and Senate bills or a prognostication about which version of the legislation will be used to fashion final legislation or the prospects for ultimate passage. Instead, the authors are past senior officials in the U.S. Environmental Protection Agency (EPA) toxics regulatory program and an attorney with decades of experience as a TSCA practitioner. As such, we believe we can offer some additional perspective on what we believe is a missing element in the current TSCA legislative debate: given the legislative provisions on both sides of Capitol Hill, what are some of the key elements that perhaps could use more, or certainly clearer, congressional direction about what EPA is to do with certain new provisions to implement them in a timely and relatively efficient manner over the first years of implementation of any amended TSCA.

With all due respect to the dedicated members of Congress who have put serious time and energy into TSCA reform, and especially the staff of these members and committees, there appears to be somewhat of a missing perspective from those who have had past work experience in a federal regulatory agency. The lack of an Obama administration bill has also led to a void in offering detailed programmatic suggestions; although it appears that EPA has been active in offering regular "technical advice," often such advice has certain limitations in how much or how loud programmatic considerations can be made.

We offer here some thoughts for our EPA colleagues and other interested parties who now can and will be more actively engaged in the discussions about how best to move forward. We may have opinions about how

certain provisions should have been crafted, but we take as a starting point the House-passed bill (H.R. 2576) and S. 697 as reported by the Senate Environment Committee.

Given that those two proposals will drive the discussion between the two chambers, we pose some questions and offer some suggestions that we believe would enhance the chances for implementation success as the debate moves forward. Mostly, this can be summarized as a quest to determine ''how does it work'' when examining the competing proposals, and identify specific areas where Congress might offer more clarity, or where our EPA colleagues might benefit from more explicit provisions or definitions (or at least expectations).

Currently, many new terms, some with uncertain or missing definitions, along with what we see as impractical (yet perhaps politically important) directives could result in litigation, delay, and general hindrance to what appears to be shared hopes for programmatic success.

In addition, some of the authors here collaborated on an earlier August 2010 treatise requested by the American Bar Association Section of Environment, Energy, and Resources of laying out programmatically practical advice as a set of recommendations regarding TSCA reform.[1]

Discussion of Workability Issues

As discussed below, there are a number of what we refer to as ''workability'' issues that, in a perfect world, Congress would address and clarify, or EPA would suggest to Congress to make appropriate revisions and clarifications to ensure implementation success. While there are more that could be added to this list, we note key ones below.

Need for Greater Definitional and Legal Clarity

The bills use a number of new terms and concepts that lack clarity. While we understand the potential role of ambiguity to help legislators come to agreement, we are also alert to the potential for lawsuits challenging EPA's interpretation of the terms' meaning and intent in the absence of clear drafting or congressional clarification and explanation. Provisions of the 1990 Clean Air Act Amendments are hotly debated almost 30 years after Congress spoke; perhaps here Congress can speak more clearly. Regarding the current TSCA bills, examples include:

- ''Significant hazard'' and ''significant exposure'' as used in S. 697 Section 4A(b)(3) concerning EPA identification of high-priority substances. The former term is new and not further explained while the latter is somewhat similar to the term ''significant or substantial human exposure'' that appears in current TSCA Sections 4(a) and 5(e) regarding ''exposure-based actions.'' While EPA has released TSCA policy statements regarding its interpretation of ''significant or substantial human exposure,'' the different phrasing and the broadening of the term to encompass both human *and environmental* exposure raise questions about the intended meaning. It would be helpful if the legislative intent/meaning of these terms was better defined or at the least clarified.

- ''May present an unreasonable risk'' in H.R. 2576 Section 6(b)(3)(A), which concerns EPA's determination of chemicals requiring a risk evaluation. This term, which appears without elaboration in current TSCA Sections 4(a) and 5(e), is modified in H.R. 2576 by the addition of an explanatory ''because'' phrase:
  may present an unreasonable risk . . . *because of potential hazard and a potential route of exposure under the intended conditions of use*.
  The additional phrase changes the meaning of ''may present an unreasonable risk'' in ways that are likely to lead to legal challenges and would benefit from clarification and explanation should it be retained. To facilitate implementation, it might be preferable to eliminate it. We question in particular the legal and policy implications of the entirely open-ended phrase ''a potential route of exposure.'' By the fact of their presence in commerce, all chemicals have ''a potential route of exposure.'' The House Report on H.R. 2576[2] does not offer any additional explanation of the phrase but reinforces our concern when it states that ''[t]he standard for making this determination is broad and flexible because its application precedes the detailed scientific risk evaluation that it triggers.'' While we agree that the preliminary assessment needs to be ''broad and flexible,'' in our view this meaning would be assured by using the unadorned phrase ''may present an unreasonable risk,'' while perhaps also retaining ''under the intended conditions of use'' given the role this phrase plays in the text.
  Is it the intent of this change to devolve ''may present an unreasonable risk'' to a ''broad and flexible'' hazard-based requirement for the purpose of determining chemicals that are in need of a risk evaluation? This is one plausible interpretation, but the existence of many others suggests this language needs to be revised or clarified.

- Similarly mischievous is the definition of ''potentially exposed subpopulation'' in the H.R. 2576 definitions section that explicitly centers on those with ''greater potential exposure''—a definition which strikes us as quite broad. For example, a routine occupational exposure is likely to be ''greater'' such that normal worker exposures that are otherwise subject to oversight by the Occupational Safety and Health Administration (OSHA) seem to satisfy the definition. It is unclear whether the intent is that workers' exposure to chemicals is sufficient to trigger application of vulnerable population considerations found later in the bill, recognizing that this would apply such consider-

[1] *See* the American Bar Association Section of Environment, Energy, and Resources Special Committee on TSCA Reform, *Practical Advice for TSCA Reform: An Insider Perspective*, J. Aidala, C. Auer, L. Goldman, M.D., and J. Gulliford (Aug. 2010) (ABA Report), available at http://www.americanbar.org/content/dam/aba/administrative/nr/projects/tsca_reform/whitepapers/practical_advice_for_tsca_reform.authcheckdam.pdf.

[2] H.R. Report No. 114-176, at 24 (2015).

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ations in theory to all TSCA chemicals. Is this an intent to shift regulation of workplace exposure to chemicals from OSHA to EPA? Similarly, the definition here would incorporate any ''group of individuals within the general population'' with ''greater potential exposure'' as a special subpopulation, which strikes us as irrational since mathematically, in virtually all cases, some part of the population will have a ''greater'' exposure or otherwise exposures calculated as ''above average'' (the Lake Wobegon effect?). Somewhat mitigating our concern is the careful drafting elsewhere in the text where the term appears (Section 6(a)[3] regarding scope of regulation and Section 6(b)(6)[4] concerning determinations of no unreasonable risk) that can be read to suggest a more nuanced reading of the term. The House Report on H.R. 2576 also states that ''[i]t is the Committee's intention'' that EPA ''be clear about who is being identified and the basis for such a decision when invoking provisions involving subpopulations.''[5] We also note that the definition of this term in S. 697 expressly limits its application to groups ''identified'' by EPA, a somewhat different approach that we find clear and one that could also reduce the potential for legal challenges relative to the approach in H.R. 2576. It is clear that Congress recognizes the importance of ensuring consideration of vulnerable populations, but an overly broad application of the concept will inevitably dilute the provision's effect while also inviting legal challenges and other implementation hurdles.

- The requirements in S. 697 Section 4A(b)(4) that EPA must meet in identifying low-priority substances. The current text outlines a process whereby EPA, in identifying low-priority chemicals, must conclude ''[it] has information sufficient to establish that the chemical substance is likely to meet the safety standard.'' Report Number 114-67 prepared by the Senate Environment and Public Works Committee indicates that it ''intends that EPA adequately justify prioritization decisions, which it should fully describe'' when seeking comment on the proposed designation.[6] The ABA Report explored the issue of ''numbers'' starting with the observation that there are over 80,000 chemical substances listed on the TSCA Inventory. The ABA Report then suggests, following the application of several assumptions and facts, that as many as 4,300 chemicals may require some type of control action under an amended TSCA.[7] Even if this analysis is off by a factor of two or three, it suggests that somewhere around 30,000 chemicals are potential low-priority candidates. This rough analysis suggests that EPA could confront the almost impossible burden of satisfying the low-priority identification requirements for many thousands of chemicals, or be required to put them into the safety assessment and safety determination process, which would be a prodigious undertaking. If EPA cannot triage and thereby manage its work in the first and subsequent years of any revised program, the expectation that tens of thousands of chemicals need some significant level of assessment effort will continue to hinder program effectiveness for another 40 years.

In addition, the provisions in S. 697 concerning Section 8 exposure information reporting by manufacturers and processors and the ability to require (under Section 4) ''limited testing'' needed for prioritization would appear substantially to improve our knowledge of chemicals and their potential for risk. It is unclear to us, however, whether the exposure information and the level of testing that can be required for prioritization purposes are sufficient to meet the legal requirements inherent in ''*conclud[ing it] has sufficient information to establish* that the chemical substance is likely to meet the safety standard.'' If such test data and exposure information were insufficient to support the required conclusion, EPA would confront both a fundamental issue in its implementation of the bill's requirements and the possible need to take very large numbers of chemicals into some kind of Section 6 safety assessment and determination process. Couple this scenario with the fact that low-priority identifications would also be subject to judicial review, the combination could prove programmatically disastrous for EPA.

This is a huge workability issue. We encourage careful drafting to capture what Congress wants EPA to do to ensure that the legal requirements imposed on EPA in identifying low-priority chemicals are carefully matched with the types and level of test data and exposure information that are likely to be available for TSCA regulated chemicals under the new legislation.

These are but a few of the many areas that would benefit from greater definitional and legal clarity.[8] While we might have our own ideas about how such clarity might be achieved, our point here is to hope and encourage EPA to be actively involved, carefully evaluate the programmatic implications, and provide an explicit (and perhaps occasionally unpleasant) reality check with the congressional sponsors to help ensure that Congress is clear about what it expects of EPA and its toxics program. EPA officials could offer remedies in the form of suggested report language, recommended statutory clarity, or interpretative memoranda for the record in an attempt to avoid some of the likely implementation challenges posed by the existing language, among other options.

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[3] S. 697, Section 6(a) states: ''[S]o that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an *identified unreasonable risk* to a potentially exposed subpopulation.'' (Emphasis added.)

[4] S. 697, Section 6(b)(6) states: ''The Administrator shall not make a determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment if the Administrator *determines* that the chemical substance, under the intended conditions of use, presents or will present an unreasonable risk of injury to 1 or more potentially exposed subpopulations.'' (Emphasis added.)

[5] H.R. Report No. 114-176, at 22.

[6] S. Report No. 114-67, at 11-12 (2015).

[7] ABA Report at 6. The assumptions include that only 50 percent of the Inventory chemicals are currently in commerce and that EPA's regulatory experience with TSCA new chemicals offers some perspective on existing chemical actions, and the fact that, based on then current reporting (reference 2006 CDR), approximately 6,200 non-polymeric chemicals are in commerce above 25,000 pounds/year at a site.

[8] We offer much more information on pending TSCA reform bills and detailed critical analyses of these measures at the Bergeson & Campbell, P.C. website under TSCA Reform, http://www.lawbc.com/regulatory-developments/tsca-reform.

Need for a Transition Period

One approach to avoid some of the issues identified here could be to include some kind of ramp-up or transition period with carefully crafted deadlines for various phases of initial programmatic implementation. We have identified a number of potential timing conflicts or issues in the bills that should be considered and potentially revised to ensure a smooth and effective start and ongoing implementation of the new requirements. The issues we have identified include the following:

- S. 697 Section 3A(b) imposes a two-year deadline on EPA to develop through notice and comment rulemaking policies, procedures, and guidance (PP&Gs) as necessary to implement Sections 4, 4A, 5, and 6 (concerning testing, prioritization, new chemicals, and existing chemicals, respectively). H.R. 2567 Section 26(k)(1) also imposes a two-year deadline after enactment to develop PP&Gs needed to implement provisions affected by the bill.
- It is unclear how the two-year deadline for PP&Gs in S. 697 can be consistent with Section 4A(a)(1) that imposes a one-year deadline for establishing by rule a risk-based screening process for distinguishing between high- and low-priority chemicals, nor how either of these provisions squares with the requirement at Section 4A(a)(2) that EPA release an initial priority list within 180 days.
- These deadlines and requirements then flow into other S. 697 deadlines that, given the effort that will be required to meet the PP&G notice and comment requirements, raise questions whether it is reasonable that, within three years after enactment, EPA could also have started or completed safety assessments on 20 high-priority chemicals as S. 697 Section 4A(a)(2)(C) requires. Similarly, it is difficult to have confidence in meeting both the two-year deadline under Section 8(a)(4) for promulgating reporting rules to obtain information to carry out Sections 4 and 6 with the three-year safety assessment deadline.
- Regarding control actions under Section 6, H.R. 2567 requires that EPA propose a Section 6(a) regulation within one year after completing the risk evaluation with a final rule to be issued within two years. S. 697 would also give EPA two years to complete a Section 6(d) control rule. Even with the availability of extensions, the timelines strike us as tight, which invites litigation and/or seemingly random spasms of programmatic attempts to comply with difficult deadlines.

The ABA Report recommends six to 18 months to allow EPA to devise new policies and procedures and engage stakeholders and the scientific community. It also notes that standard Administrative Procedure Act (APA) notice and comment rulemaking takes at least two years and generally much longer. The ABA Report also states that one significant oversight in drafting the Food Quality Protection Act[9] was the absence of a transition time for EPA and industry in meeting requirements for pesticides under the old and new standards. Congress may wish to look carefully into these aspects and consider both an initial transition period or a phase-in period for the new requirements. Deadlines for specific requirements could be carefully crafted to impose measured and attainable demands on EPA and stakeholders during the critical early years of implementation. Deadlines should be designed to build the programmatic and regulatory infrastructure in a way that is logical, sustainable, and workable. In considering this question, it is important to recognize the scope differences between the two bills. Both bills offer different approaches and the selection of the most suitable approach should be guided by scoping considerations, not *ad hoc* ''picking and choosing'' indiscriminately. We offer our thoughts about a possible approach under a scenario including all of the major elements contained in both bills.

A ''transition period'' after enactment would allow EPA to begin to staff up, secure suitable contracts and get them in place, articulate clearly what the law requires and accordingly respond programmatically, and hear from and engage with stakeholders while beginning efforts to develop policies and approaches under new legislation. This ramp-up period is critically important in ensuring EPA's legal, policy, and organizational frameworks are solid and well grounded. As one example of how such a transition period might work, we have two specific suggestions to offer concerning aspects that would not come into force during this initial period, nor for some time afterward:

- The current approach to new chemicals in TSCA Section 5 should be retained for some period after enactment. This would avoid undue disruption and provide a transition period that could last until EPA had developed any needed rules and PP&Gs to apply the new Section 5 requirements. This transition period could be shorter or longer in duration. From our perspective, there would be value in a longer transition period that would free up EPA and stakeholder legal, technical, and policy resources to focus on other early implementation tasks.
- New requirements that appear in S. 697 Section 14 (such as those in subsections (f) and (g) regarding the development of a unique identifier and a 90-day deadline for EPA review of new confidential business information (CBI) claims, respectively) should be delayed and enter into effect at some later date. This date might coincide with the entry into force of the new Section 5 requirements. This delay would not affect the entry into force of the provision in both bills that requires substantiation of CBI claims for new submissions.

We recognize that the staging of requirements during a multi-year phase-in period could take a number of possible forms depending on the specific contextual needs and realities presented by final language approved by Congress. We encourage EPA to share its thinking to help inform Congress about what EPA believes would be workable and effective in ensuring a smooth launch of the new authorities available to it. For purposes of illustration, Table 1 offers one possible phase-in scenario that would help to build and apply the programmatic and regulatory infrastructure over time

[9] Pub. L. No. 104-170, 7 U.S.C. §§ 136 *et seq.*

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in a way that we believe is both workable and logical. In all cases, the deadlines suggested are after enactment. We fully acknowledge that ''it is easy for us to say'' from an external vantage point, but our message is that successful implementation in the long run will be much affected by successful early construction of any revised toxics program.

Table 1. Illustrative Multi-Year Phase-in Approach

Deadline	Phased-in Requirements
15 months	■ Promulgate S. 697 Section 8(b)(4) Inventory reset reporting rule. Although the involvement of processors as proposed in S. 697 brings challenges, the scope of reporting is limited and straightforward. Assuming a six-month reporting period and electronic reporting, the information should be available to inform the first prioritization as proposed below.
18 months	■ Issue final PP&Gs for S. 697 Section 4A prioritization screening process for high- and low-priorities.
24 months	■ First implementation by EPA of the prioritization screening process to create an initial priority list using available information. ■ Promulgate S. 697 Section 8(a)(4) reporting rules and issue any needed PP&Gs. This provision relates to information needed to carry out Sections 4 and 6; we note that S. 697 Section 4A should also be referenced in this provision, recognizing the role of exposure information in prioritization screening.
30 months	■ Promulgate Section 4 and Section 6 PP&Gs. ■ Promulgate any needed Section 5 reporting rules and PP&Gs after which the new regulatory regime would apply to Section 5 notifications and exemption requests. ■ S. 697 Section 14 requirements for timely EPA review of CBI claims and development of a unique identifier could enter into effect at the same time as the new Section 5 requirements.
36 months	■ EPA releases second prioritization list. This timing should allow EPA to consider the results from early actions to require limited testing for prioritization under S. 697 Section 4(a)(2) as well as Section 8(a)(4) reporting by manufacturers and processors.

After urging Congress to exercise restraint in its deadlines, we offer one suggestion that goes against this advice. We see merit in requiring that the Science Advisory Committee on Chemicals (SACC; as proposed in S. 697 Section 3A(j)) be established by EPA six months (rather than one year) after enactment. From our perspective, this would ensure that the SACC is available as an early resource to advise EPA in developing PP&Gs and needed rulemakings. We note that EPA's recent announcement of the formation of a Chemical Safety Advisory Committee (CSAC) offers a potential starting point upon which these efforts could be built.[10] The June 12, 2015, announcement of the CSAC encouraged us to suggest the earlier deadline.

The bills would impose a number of complex and overlapping requirements on EPA that unless carefully staged would challenge both the agency and stakeholders. Recognizing that, politically speaking, ''speed is of the essence'' to those seeking to revitalize the toxics program, suggestions for transition periods and phased-in requirements might seem undesirable. While we support our suggestions as being consistent with the desire for early implementation success, another avenue of acceleration for the numerous rulemakings and requirements for PP&Gs about many new definitions and program components could be explicit legislative truncating of the rulemaking process. Congress could explicitly remove some or all early program activities from the Office of Management and Budget (OMB) review requirements (and the underlying legislative mandates) either on a selective basis or for some defined initial period of time (such as the first three years after enactment to ease early implementation). We raise what some might see as an alarming suggestion only to illustrate how difficult the current legislation will be to implement unless more attention is paid to the programmatic meshing of the underlying wheels and bearings (and, metaphorically, to avoid the program from grinding to a halt).

Establishing Fees

As OPPT has no experience with fee setting and collecting (except for the $2,500 premanufacture notification (PMN) fee), the provisions in Section 26 for establishing a TSCA fee system seem unrealistic. The promulgation deadline is one year from enactment to establish fees, after having met with parties potentially subject to fees, and to meet every three years thereafter regarding fees. Much greater direction from Congress is needed to have this rather critical component of a new TSCA program get off the ground smoothly.

At least two suggestions can be found from the pesticide program. First, there is in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) a requirement for a ''maintenance fee,'' which is a fee imposed on each registered product in EPA's system. The fee is uniform, but capped for companies with large numbers of products, and exemptions are made for small businesses. Such a fee might be imposed by anyone required to submit certain reports under Section 8 (such as reports of ''active'' chemicals under the Inventory reset provision (S. 697 Section 8(b)(4) and manufacturer/processor reporting under S. 697 Section 8(a)(4)). Second, there is a fee for those who submit applications for pesticide registration; here the concept is that fee rates

[10] 80 Fed. Reg. 33,517 (June 12, 2015).

reflect some measure of the differing need for more scientific review and evaluation by EPA depending on the nature of the submitted application. The more review needed, the higher the fees that are imposed.

The maximum fee for a submitted package, one which requires review of an extensive data set of more than 100 health and environmental toxicity studies, is close to $1 million. What this also reveals is that the pesticide program has a refined estimate of what it takes for EPA personnel to review various toxicity studies and exposure/use information according to EPA procedures and risk assessment guidelines. That information could be used to craft a fee scheme that could be presented to Congress for consideration as a way to facilitate the establishment of a fee system to more rapidly supply the resources to the chemical assessment program.

Recognizing that it will take time to set up a fee schedule by rule, another concept is to establish an interim fee scheme. This could include additional fees on chemical notification submissions under Section 5. Alternatively or in addition, Section 4 or Section 8 submissions could include a fee requirement to offset program costs to whatever extent Congress requires that fees contribute to EPA's program needs.

Addressing Persistent, Bioaccumulative, and Toxic Chemicals (PBT)

Both bills address PBTs, but in very different ways. S. 697 Section 4A(a)(2)(B)(iii) requires that EPA, in identifying high-priority substances, ''shall give preference to chemical substances scored as high for persistence and bioaccumulation,'' while Section 6(d)(2)(B) requires that EPA select prohibitions and other restrictions for PBTs that EPA determines ''are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.''[11] H.R. 2576 Section 6(i) outlines a more elaborate and focused program mandating that no later than nine months from enactment, EPA must publish a list of chemicals that the ''Administrator has a reasonable basis to conclude are persistent, bioaccumulative, and toxic,'' excluding metals and chemicals subject to Section 6(e) critical use exemptions. No reference or guidance is provided in statutory text regarding the criteria to be applied in developing this list, although the Committee Report states that the Committee ''hopes'' EPA will rely on the 2012 Work Plan Chemicals Method Document.[12] Within two years of enactment, EPA is to designate as a PBT chemical of concern chemicals ''with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other,'' pursuant to the 2012 TSCA Work Plan Chemicals Methods Document, *and* ''exposure to which is likely to the general population or to a potentially exposed subpopulation.'' Section 6(i)(3) then requires ''expedited action'' within two years of designation (subject to the availability of appropriations) to ''reduce likely exposure to the extent practicable'' (an off-ramp is available if certain steps occur following publication of the initial list). The ''availability of appropriations'' language seems to be a tacit acknowledgment of the impossibility of meeting these strenuous deadlines.

The Senate version strikes us as a more sensible deployment of resources and avoids the ''death by listing'' that could arise under H.R. 2576. Fears of market deselection pressure would also provide an incentive for any manufacturer to pursue continuous litigation over each step of any selection or evaluation proposal. We are also concerned about the effect of the somewhat open-ended concept of ''likely exposure'' in designating a PBT chemical of concern and in mandating control requirements for the reasons noted above as the lack of clarity in this standard could both invite unnecessary restrictions and lawsuits.

Emerging Technologies and Other Issues

Neither bill addresses the growing problem of how best to support and regulate chemicals that are products of emerging technologies such as biotechnology, nanotechnology, or synthetic biology. This issue crystallized with ironic clarity on July 2, 2015, when the White House Office of Science and Technology Policy (OSTP), OMB, the U.S. Trade Representative, and the Council on Environmental Quality issued a memorandum directing EPA, the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) to update the Coordinated Framework for the Regulation of Biotechnology. Last updated in 1992 and first rolled out in 1986, the Coordinated Framework outlines a comprehensive federal regulatory policy for products of biotechnology. The July memorandum directs the federal agencies to develop a long-term strategy to ensure that the regulatory system for biotechnology products is prepared for future products, and commissions an expert analysis of the future landscape of biotechnology products. A July 2, 2015, OSTP blog[13] item notes that the complexity of the array of regulations and guidance documents developed by EPA, FDA, and USDA ''can make it difficult for the public to understand how the safety of biotechnology products is evaluated, and navigating the regulatory process for these products can be unduly challenging, especially for small companies.'' The memorandum states that the objectives ''are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.''

The Coordinated Framework describes the federal regulatory policy intended to ensure the safety of biotechnology products. The 1992 update to the Coordinated Framework ''sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment.'' Accord-

[11] It is noteworthy that the Senate bill references in Section 6 (prioritization screening) the ''October 2014 TSCA Work Plan and subsequent updates,'' which suggests to us that Congress expects EPA to issue both Work Plan *and* prioritization lists.

[12] TSCA Work Plan Chemicals: Methods Document (Feb. 2012), available at http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf.

[13] *See* ''Improving Transparency and Ensuring Continued Safety in Biotechnology,'' available at https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology.

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ing to the memorandum, the update affirmed that federal oversight should focus on the characteristics of the product and the environment into which it is being introduced, rather than the process by which the product is created.[14] This last point appears to reaffirm one of the central tenets of the 1986 Coordinated Framework—that the premise is to ''regulate the risks of the product, not the process'' used to derive novel substances.

Modernizing the Coordinated Framework is as critically important as modernizing TSCA. Despite the significant role TSCA plays in the U.S. regulatory system for products of biotechnology, curiously there has been virtually no discussion of or attention given to TSCA's application to products of biotechnology during congressional deliberations on either bill. That the modernizing of the Coordinated Framework will occur on a separate trajectory perhaps in parallel with implementing TSCA reform legislation should it happen this year poses both risks and opportunities.

That the Coordinated Framework needs a do over is clear. A number of recent reports have convincingly outlined the reasons why the Coordinated Framework can no longer nimbly, clearly, or comprehensively regulate products on biotechnology and call for exactly what the Administration is undertaking.[15]

The Administration's decision to modernize the Coordinated Framework is welcome news. If TSCA reform legislation is enacted this year, the tricky part will be ensuring the modernizing of TSCA and the modernizing of the Coordinated Framework are aligned. If TSCA reform legislation does not advance this year, it will be interesting to see how the two initiatives progress in tandem.

Similar issues and questions arise with regard to the treatment of the products of nanotechnology under a modernized TSCA. While there is no ongoing review of the government's approach, the fact that EPA has received over 170 TSCA new chemical notifications for new nanoscale chemical substances in the past ten years is noteworthy of significant innovation in this area. Similarly, the fact that EPA has been struggling with a TSCA Section 8(a) rule with respect to nanoscale versions of existing chemical substances for over seven years indicates that this is an area of intense agency attention and considerable legal and policy challenge.

While we do not wish to delay or complicate the current progress being made in advancing bills to modernize TSCA, we believe that it is *important* that Congress consider the issues associated with emerging technologies in the context of revising TSCA so as to ensure protection of health and the environment while also ensuring that the U.S. continues its global leadership in the science and commercial development of the products of these technologies. We would also lend our voice to that of others who have recommended that Congress not forget about changes to TSCA that are needed to meet legal obligations under the Stockholm and Rotterdam Conventions concerning persistent organic pollutants (POP) and prior informed consent (PIC), respectively, thereby resolving one of the issues preventing the U.S. from achieving Party status under these international agreements.

Conclusion

Taking steps such as those suggested above would help to address some of the issues and conflicts embedded in the current bills and increase the workability of the bills as proposed. At the same time, Congress needs to ensure that EPA receives adequate resources to do all that would be required for a successful launch while ensuring that EPA can develop an adequate infrastructure to meet all that the bills would require. If this can be done, it would go a long way to ensuring the long-term success of TSCA modernization.

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[14] The memorandum states that federal agencies regulating biotechnology products ''should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements.'' Improvements must:

- Maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- Establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
- Promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

The memorandum initiates a process to help advance these aims, beginning with the following one-year objectives: (1) development of an updated Coordinated Framework to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology; (2) formulation of a long-term strategy to ensure that the federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens; and (3) commissioning an external, independent analysis of the future landscape of biotechnology products.

[15] Last year, the J. Craig Venter Institute issued a landmark analysis of the domestic biotechnology regulatory system in which it highlighted the critical need for modernizing the Coordinated Framework. J. Craig Venter Institute. *Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options* (May 2014), available at http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-biology-and-the-us-regulatory-system/full-report.pdf. More recently, the National Research Council of the National Academies issued on March 13, 2015, *Industrialization of Biology: A Roadmap to Accelerate the Advance Manufacturing of Chemicals*, available at http://www.nap.edu/catalog/19001/industrialization-of-biology-a-roadmap-to-accelerate-the-advanced-manufacturing. The report, prepared by the Board on Chemical Sciences and Technology, Board on Life Sciences, Division on Earth and Life Studies, identified the challenges and opportunities posed by the current regulatory system relating to biotechnology and synthetic biology.