

## Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter

Vol. 19, No. 3

July 2018

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### FROM THE CO-CHAIR

Keith A. Matthews

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“Time flies.” “Time flees.” “*Tempus fugit.*” “Does anyone really know what time it is? Does anybody really care?”

It is hard to believe that it has been two years since I took on the responsibility of serving as chair, then co-chair, of this incredible committee. During that time, which coincides with the passage and initial implementation of the Lautenberg Toxic Substances Control Act (TSCA) amendments, the committee has been, consistent with the historical precedent, incredibly productive in so many areas. Although, admittedly, I have not conducted a formal analysis, I feel confident in stating that the Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee is at the top of the upper echelon of the Section of Environment, Energy, and Resources (SEER) committees in terms of the programming events that we sponsor and conduct—hosting multiple programs on Lautenberg, our annual joint symposium with CropLife America, an Endangered Species Act panel, the upcoming program on legal issues raised by state actions related to cannabis, our regular Friday Forums, and the annual “Meet the ABA” reception for summer associates. In addition, PCRRTK produces a top-notch newsletter and *The Year in Review*, and has a great social media presence on LinkedIn and Twitter.

All of the above is due to the tireless efforts of our outstanding group of committee vice chairs, which it has been my privilege to work with during my two years as chair. The vice chairs have made my job as chair incredibly easy, as my primary role in the functioning of the committee has been to make certain that the vice chairs know that they can reach out to me at any time for assistance, input, or support in whatever way could be helpful as they discharge their responsibilities. It is the roster of vice chairs, as well as our members, that make PCRRTK the truly outstanding committee that it is.

And, of course, this year I have had the privilege of serving as co-chair with the nonpareil Larry Cullen. Larry is a fellow EPA alum and truly one of the nicest individuals that I have ever met. (We also share the distinction of being UChicago parents (which, in truth, is a minor distinction compared to that of our UChicago offspring).) It has been great fun for me to team-lead the committee with Larry this year. It will be poignant for me to join Larry in welcoming the participants to our “Meet the ABA” event this year—my last official act as co-chair. But, as is ever true, in the words of the Nobel laureate, “the times they are a-changin’.” As I join the distinguished roster of past chairs of this committee, I look forward to supporting Larry and his new co-chair in any way that I can.

**Keith A. Matthews** is of counsel with Wiley Rein LLP.

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Pesticide, Chemical Regulation, and  
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Vol. 19, No. 3, July 2018  
Lynn L. Bergeson, Editor

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**AMERICAN BAR ASSOCIATION  
SECTION OF ENVIRONMENT,  
ENERGY, AND RESOURCES**

**CALENDAR OF SECTION EVENTS**

July 10, 2018

**The Administration's Regulatory Reform for  
Fuel Economy and Vehicle Greenhouse Gas  
Standards: Assessing the Significant Changes  
and Potential State Conflicts**

Committee Program Call

July 12, 2018

**DC Bar Environment, Energy and Natural  
Resources Community Annual Summer  
Reception**

Washington, DC

August 2-7, 2018

**ABA Annual Meeting**

Chicago, IL

August 10, 2018

**30th Annual Texas Environmental  
Superconference**

Austin, TX

Primary Sponsor: State Bar of Texas,  
Environment & Natural Resources Law Section

October 17-20, 2018

**26th Fall Conference**

Marriott Marquis San Diego Marina  
San Diego, CA

March 25-27, 2019

**37th Water Law Conference**

Grand Hyatt Denver  
Denver, CO

March 27-29, 2019

**48th Spring Conference**

Grand Hyatt Denver  
Denver, CO

**For full details, please visit  
[www.ambar.org/EnvironCalendar](http://www.ambar.org/EnvironCalendar)**

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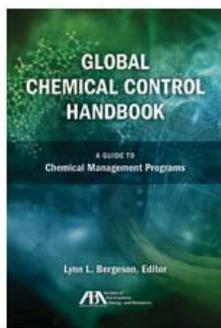
## FROM THE CO-CHAIR

Lawrence E. Culleen

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In light of Keith's wonderful missive, and his impending departure from the co-chair designation, I will add my thanks, on behalf of the entire membership of the committee, to Keith. Keith has been dedicated to our committee's success during an incredible whirlwind period of environmental news that affected every one of the agency's programs on which we focus as a committee. We will miss Keith's poise, charm, and willing friendship—which he displayed in each facet of his leadership; we should not plan to let him get too far from having important responsibilities as we embark on the summer and soon will begin planning for a new "ABA Year." I am excited to continue to serve for one more year as our co-chair, in part because of our sterling track record, as Keith has set out already above, and because of our considerable talent pool at the vice chair and general membership levels. I look forward to working with our membership and our current *and future* committee leaders to both maintain and enhance an energetic group which will, no doubt, continue to serve the "chemicals bar" (private, public, and nongovernmental) through stellar programming, exemplary publications, community service, and professional fellowship. Thank you all for your continuing interest, your talents, and considerable contributions to our committee's stature and bright future.

**Lawrence Culleen** is a partner in the environmental practice group at Arnold & Porter.



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### GLOBAL CHEMICAL CONTROL HANDBOOK: A GUIDE TO CHEMICAL MANAGEMENT PROGRAMS

Lynn L. Bergeson Editor

Section Member: \$119.95  
Product Code: 5350252  
(c) 2014, paperback

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## EPA INCLUDES ACTIVE-INACTIVE DESIGNATIONS ON UPDATED TSCA INVENTORY

Richard E. Engler, Ph.D.

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The U.S. Environmental Protection Agency's (EPA) April 2018 Toxic Substances Control Act (TSCA) Chemical Substance Inventory is now available (<https://www.epa.gov/tsca-inventory/how-access-tsca-inventory>). For the first time, the Inventory includes a field designating substances that are "active" in U.S. commerce based on the following:

- Reporting from the 2012 and 2016 Chemical Data Reporting cycles;
- Notices of Commencement received by EPA since June 21, 2006; and
- Notice of Activity Form A's received by EPA through the February 7, 2018, deadline, per the TSCA Inventory Notification (Active-Inactive) Rule.

EPA states that it "carefully *processed* and conducted a quality check of the data to ensure duplicate entries and confidential business information were removed" from the large number of notices received under the Active-Inactive Rule. EPA also posted a list of substances reported in a Notice of Activity Form A from February 8 through March 30, 2018 (<https://www.epa.gov/tsca-inventory/list-substances-reported-under-tsca-inventory-notification-active-inactive-rule>). According to EPA, this list should assist processors in determining which of their substances on the Inventory have not yet been designated as "active." Based on our review, the Inventory lists approximately 38,303 total active substances, or about 44.5 percent of the substances listed on the Inventory. It is somewhat surprising that a greater percentage of the non-confidential substances were notified as active (45.6 percent of non-confidential business information (CBI) substances compared to 40.5 percent of confidential substances). Because most substances added to the Inventory through the premanufacture notification (PMN) process

were added with CBI identities (62.7 percent), we expected that a greater proportion of the CBI substances would be notified as active.

The deadline for voluntary submission of a Notice of Activity Form A by processors is October 5, 2018. Presumably, processors should only find substances in their supply chain that were notified as active by a manufacturer or importer. It is important, however, that suppliers verify that all chemicals in their supply chains are listed on the Inventory as active, exempt from listing on the Inventory, or excluded from TSCA. Substances that are declared inactive after the end of the processor reporting period may not be manufactured, imported, or processed without first submitting a “Form B” Notice of Activity to EPA.

More information on the TSCA Inventory rulemaking and TSCA Inventory issues is available on Bergeson & Campbell, P.C.’s (B&C®) blog under the key phrase “TSCA Inventory” (<http://www.tscablog.com/blogs/tagged/TSCA+Inventory>) and on B&C’s TSCA Reform News & Information webpage (<http://www.lawbc.com/knowledge-resources/tsca-reform-news-info>). More information on EPA’s Final TSCA Inventory Notification (Active-Inactive) Rule is available in B&C’s memorandum, “EPA Issues Final TSCA Framework Rules” (<http://www.lawbc.com/regulatory-developments/entry/epa-issues-final-tsca-framework-rules>). Specific information on changes in the Central Data Exchange (CDX) system is available in B&C’s blog item, “EPA Updates eNOA Template in CDX System” (<http://www.tscablog.com/entry/epa-updates-enoa-template-in-cdx-system>).

**Richard E. Engler, Ph.D.**, is director of chemistry with Bergeson & Campbell, P.C.

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## FDA GREENLIGHTS PRODUCTION OF GE SALMON AT U.S. FACILITY, BUT THAT IS NOT THE END OF THE STORY

Brian P. Sylvester

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Developers of genetically engineered (GE) species and crops should be paying careful attention to the saga of AquAdvantage Salmon®. It provides a good lesson in the complexity of obtaining necessary governmental sanction for new products.

### What Is AquAdvantage Salmon?

AquAdvantage Salmon is a variety of Atlantic salmon (*Salmo salar*) produced by AquaBounty Technologies, Inc. (AquaBounty) that has been genetically engineered to grow to market size in just 16 to 18 months—roughly half the time it takes the wild-type salmon to grow to market size. The accelerated growth of the AquAdvantage Salmon is mediated by a growth hormone-regulating gene from a Pacific Chinook salmon (*Oncorhynchus tshawytscha*). AquaBounty states that the AquAdvantage Salmon requires 25 percent less feed to grow to the size of wild salmon, and could have a carbon footprint of up to 25 times less. See AquaBounty’s sustainability claims, available at <http://aquabounty.com/sustainable/>.

In 2016, AquAdvantage Salmon became the first GE animal to be sold for food in the world when it received approval in Canada. See Government of Canada Announcement, Health Canada and Canadian Food Inspection Agency approve AquAdvantage Salmon, May 19, 2016, available at <https://www.canada.ca/en/health-canada/news/2016/05/health-canada-and-canadian-food-inspection-agency-approve-aquadvantage-salmon.html>. On April 26, 2018, AquaBounty obtained approval from the U.S. Food and Drug Administration (FDA) to produce AquAdvantage Salmon at a land-based contained facility near Albany, Indiana. But a provision in FDA’s current appropriations authorization prohibits AquaBounty from importing the eggs necessary for producing AquAdvantage Salmon in the United States.

## U.S. Regulatory Background

FDA's Center for Veterinary Medicine (CVM) regulates GE animals pursuant to the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), and must approve new products. To obtain FDA approval for AquaAdvantage Salmon, AquaBounty was required to comply with FDA's new animal drug requirements.

FFDCA defines a new animal drug as “an article (other than food) intended to affect the structure or any function of the body of . . . animals.” Subject to limited exceptions (in FDA-CVM Draft Guidance for Industry #236, “Regulation of Mosquito-Related Products,” FDA has proposed to clarify that the phrase “articles (other than food) intended to affect the structure or any function of the body of man or other animals” does not include articles intended to prevent, destroy, repel, or mitigate mosquitoes for population control purposes. Instead, such products are pesticides regulated by the U.S. Environmental Protection Agency (EPA)), FDA takes the position that altered genomic DNA intended to affect the structure or function of an animal meets the definition of an animal drug irrespective of whether the resulting GE animals are intended for food, or to produce pharmaceuticals (or any other substances). See FDA-CVM, Guidance for Industry #187, “Regulation of Intentionally Altered Genomic DNA in Animals,” noting that “altered genomic DNA” refers to the portion of an animal’s genome that has been intentionally altered, *available at* <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf>. FDA’s Draft Guidance for Industry #187 provides that “[a]ltered genomic DNA may result from random or targeted DNA sequence changes including nucleotide insertions, substitutions, or deletions, or other technologies that introduce specific changes to the genome of the animal. Non-heritable altered genomic DNA that is intended to affect the structure or function of the resulting animal . . . also meets the drug definition.” See *id.*

## FDA Approves AquaAdvantage Salmon for Human Food and Animal Feed

On November 19, 2015, FDA approved AquaBounty’s New Animal Drug Application (NADA) for AquaAdvantage Salmon. FDA Press Release, FDA Has Determined That the AquaAdvantage Salmon is as Safe to Eat as Non-GE Salmon, November 19, 2015, *available at* <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm472487.htm>. That approval specified, however, that only two facilities could be used for producing AquaAdvantage Salmon: AquaBounty’s facility on Prince Edward Island, Canada, where the salmon eggs are produced, and the company’s grow-out facility in Panama, where fish hatch from the eggs and grow to maturity. The 2015 approval specified that all production facilities for the product require separate site-specific approvals.

To expand upon its list of authorized production facilities, AquaBounty subsequently submitted a supplemental NADA requesting FDA approval to raise AquaAdvantage Salmon at a land-based contained facility near Albany, Indiana. This is the supplemental NADA that FDA approved on April 26, 2018.

## Import Alert Precludes U.S. Production and Sale of GE Salmon

Notwithstanding these approvals, due to legislative efforts spearheaded by Senator Lisa Murkowski (R-AK)—in whose state salmon fisheries play a significant role—FDA in 2016 issued Import Alert 99-40 ([https://www.accessdata.fda.gov/cms\\_ia/importalert\\_1152.html](https://www.accessdata.fda.gov/cms_ia/importalert_1152.html)). This alert prevents the production of GE salmon, including AquaAdvantage Salmon, in the United States until final labeling guidelines for informing consumers of such content are published. See Murkowski Statement on New U.S. Genetically Engineered Salmon Facility GE Salmon Import Ban In Place, *available at* <https://www.murkowski.senate.gov/press/release/murkowski-statement-on-new-us-genetically-engineered-salmon-facility->

FDA’s Import Alert responded to a provision in the 2016 Omnibus Appropriations Act. It prohibited

FDA from allowing the introduction into interstate commerce of any food that contains GE salmon, until the specified guidelines are published. The provision has also been included in the 2017 and pending 2018 Omnibus Appropriations Acts.

## Looking Ahead

Following FDA's issuance of Import Alert 99-40, Congress passed the National Bioengineered (BE) Food Disclosure Law. It mandates the U.S. Department of Agriculture (USDA) to promulgate regulations regarding the labeling of food derived from BE sources.

On May 4, 2018, USDA's Agricultural Marketing Service (AMS) published a proposed rule. It would establish the National BE Food Disclosure Standard (NBFDS) (<https://www.ams.usda.gov/sites/default/files/media/Final%20Bill%20S764%20GMO%20Discosure.pdf>). The proposed rule would apply to foods that are subject to the labeling requirements of the FFDCA. 7 C.F.R. § 66.3(b)(1). This includes, but is not limited to, "raw produce, *seafood*, dietary supplements, and most prepared foods, such as breads, cereals, non-meat canned and frozen foods, snacks, desserts, and drinks." 83 Fed. Reg. 19,860, 19,862.

The proposed rule defines a BE food to mean ". . . a food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding found in nature." 7 C.F.R. § 66.1 Bioengineered Food. This definition likely would cover the bioengineering technique used to produce the AquAdvantage Salmon, *though USDA is accepting stakeholder feedback to refine the definition of bioengineering through July 3.*

Odds thus are high that the guidelines required before AquAdvantage Salmon can hit American supermarket shelves will become available when USDA rolls out its final BE food disclosure requirements. Those currently are expected to come into force as early as January 1, 2020, for most manufacturers, or a year later for smaller companies.

## Labeling of AquAdvantage Salmon

But the pending proposed USDA BE food disclosure requirements are not the end of the story. Some are pushing for even more stringent labeling requirements for products like AquAdvantage Salmon.

Senators Dan Sullivan (R-AK), Maria Cantwell (D-WA), and Jeff Merkley (D-OR)—Washington and Oregon also have large salmon fisheries—have co-sponsored the Genetically Engineered Salmon Labeling Act, S. 1528, 115th Congress. It would require any BE salmon to be labeled as "genetically engineered" or "GE." This requirement differs from USDA's proposed requirement, which allows alternative labels: disclosure via (1) written text disclosure; (2) symbol disclosure; (3) electronic or digital link disclosure; or (4) a text-message disclosure. In all four cases, the disclosure uses a new acronym ("BE")—likely an attempt to move away from any negative associations consumers may incorrectly affiliate with the terms "GMO," "GE," or "genetically engineered."

Under a recent iteration of the now-delayed U.S. House Agriculture Appropriations Bill (May 16, 2018), an amendment had been proposed to ensure that disclosure requirements related to GE salmon and finfish be made in accordance with USDA's NBFDS. Although that version of the bill has since been defeated, it is possible that there will be a continued push to align disclosure requirements for GE salmon with the new USDA BE disclosure requirements. Doing so would serve to stem consumer confusion by ensuring that all BE foods are labeled in a uniform fashion.

While USDA works on releasing in final its BE disclosure requirements, FDA Import Alert 99-40 continues to remain in effect, and so AquaBounty cannot legally import AquAdvantage Salmon, including its eggs or any food from the salmon, into the United States.

**Brian P. Sylvester** *is special counsel with Wiley Rein LLP.*

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## EPA ISSUES DRAFT GUIDANCE ON EXPANDED ACCESS TO TSCA CONFIDENTIAL BUSINESS INFORMATION

Camille Heyboer

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The June 2016 amendments to the Toxic Substances Control Act (TSCA) expanded the categories of persons that may request access to TSCA confidential business information (CBI). In addition to federal employees, state, local, and tribal governments, health or environmental officials employed by federal, state, or tribal governments, and treating nurses and doctors may now request access to TSCA CBI. In the event of an environmental, medical, or public health emergency, treating or diagnosing nurses and doctors, agents of poison control centers, public health or environmental officials employed by state, local, or tribal governments, and first responders may also request access to TSCA CBI. In March 2018, the U.S. Environmental Protection Agency (EPA) issued guidance explaining the situations in which these categories of persons may request access to TSCA CBI, information that must be included in requests for CBI, and steps that these persons must take to protect the confidentiality of TSCA CBI.

### **State, Local, and Tribal Governments**

The draft guidance provides that state, local, and tribal governments will have the option of establishing in advance that they have legal authority and measures in place to protect CBI that is comparable to EPA's protection of CBI. If a government chooses to submit to EPA in advance information about the measures it has in place to protect CBI, EPA will review that information and, if appropriate, enter into an information-sharing agreement with the submitting government. If a government has an information-sharing agreement in place with EPA prior to requesting access to TSCA CBI, it must only submit a short written request to the agency for specific CBI when its need for that information arises. Alternatively, a government may submit information about its

legal authority and the measures it has in place to protect TSCA CBI in tandem with its submission of a request for specific CBI. EPA warned, however, that this option may delay the government's access to the requested CBI.

The guidance also provides examples of legal provisions and measures that could be included in a government's statement about the measures it has put in place to protect CBI. These include (1) exemption of TSCA CBI from disclosure in response to public information requests; (2) establishment of specific criteria for substantiating confidentiality claims; (3) providing businesses the opportunity to claim information as CBI before the information is released to the public; and (4) the chance to appeal the denial of a CBI claim. Examples of CBI-protective measures include controlling employee access to CBI documents, ensuring secure physical and electronic storage of CBI documents, and creating a process to ensure that CBI is not inadvertently disclosed in documents released to the public.

In addition to establishing that they have legal authority to protect CBI and have put into place measures to protect CBI, governments requesting specific CBI must cite the law for which the CBI is needed, and why the CBI is needed for the enforcement of that law. After such a request is received, EPA will provide a 15-day notice to the business claiming CBI, and allow the business an opportunity to object to disclosure.

### **Health and Environmental Personnel in Non-Emergency Situations**

This draft guidance also provides the requirements for health and environmental professionals employed by a federal, state, or tribal government, and treating doctors and nurses, to access TSCA CBI. Pursuant to the guidance, contractors of state, federal, and tribal agencies may not request access to CBI on behalf of the agencies. Persons eligible to request TSCA CBI pursuant to this guidance must submit to EPA (1) a request for the information needed for medical treatment

or to respond to an environmental release; (2) a statement that individual(s) have been exposed to the chemical substance at issue, or that an environmental release of this substance has occurred; and (3) an explanation of how the CBI will help the requester provide medical treatment or respond to the environmental release. Persons requesting TSCA CBI must specify the kinds of information they are requesting, including specific chemical identity and health and safety information.

Any information provided to a person pursuant to this guidance may only be used for the purpose for which it was requested—providing medical treatment or responding to an environmental release. Persons requesting CBI may also be required to sign a non-disclosure agreement. As with CBI released to state, local, and tribal governments, EPA will provide a 15-day notice to the business claiming CBI before releasing the information, and provide the business with an opportunity to object to disclosure. EPA noted in this guidance document that it is considering development of an electronic system for these requests.

## Health and Environmental Personnel in Emergency Situations

Finally, the draft guidance outlines access requirements for treating doctors and nurses, agents of poison control centers, first responders, and public health or environmental employees of state, local, and tribal governments. These persons may request TSCA CBI in the event of environmental emergencies, medical emergencies, and public health emergencies. Persons requesting TSCA CBI pursuant to this guidance must have “a reasonable basis to suspect” that an emergency situation exists and that the information will assist in the response to the emergency. In a request for CBI in an emergency situation, the requester must explain why the information being requested is needed to respond to the emergency situation. Any CBI disclosed pursuant to this guidance may only be used to respond to the emergency situation. EPA

will provide notice of the disclosure to the business claiming CBI, however, businesses claiming CBI will not necessarily be given notice of the disclosure before it occurs.

## Next Steps

Following the close of the comment period for this guidance in April 2018, EPA is set to begin developing final guidance for expanded access to TSCA CBI. EPA is careful to note in the guidance documents that the guidance is not “rulemaking” and “does not impose any legally binding requirements.” EPA also notes that it may revise the guidance documents at any time without further notice to and comment from the public. Entities that may be impacted by the expanded access to CBI provided for in the June 2016 TSCA amendments should keep an eye out for changes in the final guidance documents, as well as subsequent changes to the final guidance documents. If necessary, entities should also be prepared to, as EPA suggests, challenge the application of this guidance to their unique circumstances.

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## EUROPEAN UNION ACTS ON ARRAY OF NEW CHEMICAL REGULATIONS

Martha E. Marrapese and  
Marshall R. Morales

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The European Union (EU) is pressing forward with substantial new efforts under its Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. Companies with supply chains reaching Europe should stay abreast of REACH developments, especially to evaluate cost-effective strategies for compliance with both U.S. and EU regulations.

Under REACH, all manufacturers and importers of chemicals have a general obligation to register with the European Chemicals Agency (ECHA) each substance manufactured or imported in quantities of 1 tonne or more per year per company. May 31, 2018, marked the final deadline for registration under REACH. REACH registration requirements apply to European legal entities, not foreign exporters.

ECHA is considering new Substances of Very High Concern (SVHC) and has proposed new and expanded phthalate restrictions beyond the previous limits for children's products containing phthalates. The European Commission's REACH Committee also has advanced new rules on registering nanomaterials by 2020 and substance limits for textiles. Looking ahead, companies should be aware of upcoming biocidal registration deadlines that are staggered in groups of products over the coming years.

### New Substances of Very High Concern

In January 2018, ECHA added seven substances to its SVHC Candidate List, bringing the total to 181 SVHCs. (The full list is *available at* <https://echa.europa.eu/candidate-list-table>.) SVHCs are substances that ECHA has determined present serious hazards, based on carcinogenicity, mutagenicity, or reproductive toxicity or on persistence and bioaccumulation. Substances on

the Candidate List are candidates for inclusion in the Authorization List in REACH Annex XIV, which requires parties to apply for permission from ECHA to use those substances if there are no alternatives for their use.

The seven new substances are dechlorane plus, benz[a]anthracene, cadmium carbonate, cadmium hydroxide, cadmium nitrate, chrysene, and certain reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde, and 4-heptylphenol. ECHA also updated the SVHC listing for bisphenol A (BPA) to include endocrine disruption properties. BPA is already listed in the Annex XVII restricted substance list with respect to uses in thermal paper.

Suppliers of articles containing a Candidate List substance above 0.1 percent by weight, and totaling over 1 tonne per year in total manufacture or import, generally have obligations to notify commercial customers, consumers, and ECHA of that substance's use in the article. Any businesses using these or other substances on the Candidate List should be prepared to work with their supply chain on ECHA authorization or substitution of the substance if ECHA moves the substance to the Authorization List.

### Expanding Restrictions on Phthalates

In an ambitious round of compliance checks (including over 1000 mixtures and over 4600 articles), 18 percent of products were found not to comply with REACH in some respect. One of the most common categories of violations was the presence of phthalates in children's products. REACH Annex XVII limits certain phthalates to 0.1 percent by weight of the plasticized material in an article that can be placed in a child's mouth. Of the more than 460 children's products tested, almost 20 percent failed in some respect for phthalates.

This report comes as the EU considers a proposal to expand some phthalate restrictions from children's products to other articles with plasticized materials. The proposal would add diisobutyl phthalate (DIBP) to the list of restricted phthalates.

And the proposal would broadly expand the bis (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and DIBP restrictions to apply to articles in general with certain exclusions provided. The limit level of 0.1 percent by weight for plasticized material would remain, and other phthalates restrictions in toys and childcare articles would be unchanged. The new restrictions would apply 18 months after the regulation enters into force, if the regulation is approved.

This focus on phthalates is not new as phthalates have been previous targets in the EU, with a Restriction of Hazardous Substances (RoHS) Directive amendment in 2015 providing 0.1 percent by weight limits for DEHP, DBP, BBP, and DIBP in electrical and electronic equipment, effective in July 2019. Nonetheless, the revised Annex XVII restricted substance list would represent a substantial restriction on phthalates in articles on the EU market.

## Nanomaterials

New nanomaterial regulations are under review that would amend several REACH annexes to clarify the registration requirements for nanomaterials. Under the new draft regulation, nanomaterials are defined as nanoforms of substances with particles between 1 and 100 nanometers in size, in at least one dimension.

How to distinguish one nanoform from another is not entirely clear from the proposal. Characterization will be needed, however. The existing REACH tonnage bans will apply for data requirements, but detailed notes are being added to the annexes to explain the considerations and parameters to be followed. Chemical safety plans for the macroforms will need to include detailed information on exposure and handling of the nanoforms identified. The proposed deadline for filing registrations is 2020.

Manufacturers or importers of a nanomaterial that manufacture or import over 1 tonne of

that nanomaterial in a year will need to pursue registration. The proposal is under a draft review by the European Parliament and Council, after which the regulations will be considered by the European Commission for adoption.

## Clothing and Textiles

New limits on 33 substances have been proposed for clothing and textiles through amendments to Annex XVII. The list of substances includes a range of metals (e.g., arsenic, lead), phthalates, and other organic chemicals. The rule would apply to chemicals remaining on products from production processes or added intentionally to products to enhance textile properties (e.g., wrinkle resistance).

Exemptions from the restrictions include products entirely made of natural leather, fur, or hide; occupational personal protective equipment; and products used as medical devices. If approved in its current form, the restrictions would apply 24 months after the regulation enters into force. The proposal has been approved by EU Member States and is awaiting review by the European Parliament and Council.

## Biocidal Approvals

Deadlines are advancing for EU authorization to keep certain biocidal products on the market. EU authorization supplants the need for any national authorization in the EU market. Those with deadlines in the remainder of 2018 are 2-methyl-1,2-benzisothiazol-3(2H)-one (MBIT), peracetic acid, piperonyl butoxide, azoxystrobin, silicium dioxide, and silicon dioxide.

ECHA recommends that applicants make a pre-submission to ECHA for biocidal products at least six months in advance of the relevant deadline for a free-of-charge consultation to identify any potential issues.

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## EPA HOLDS SUMMIT ON PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

Lawrence E. Culleen

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In late May, the U.S. Environmental Protection Agency (EPA) held a two-day “summit” on per- and polyfluoroalkyl compounds, following through on a March 2018 promise to bring together state, local, and tribal officials to discuss concerns with regard to the substances. The “National Leadership Summit” was an outgrowth of EPA’s December 2017 announcement of its “cross-agency effort to address PFASs.” Governors of 56 U.S. states and territories were invited to attend the summit. Ultimately, approximately 200 persons attended, including persons from 40 states, tribes, and territories, 20 federal agencies, as well as congressional staff, trade associations, and various nongovernmental organizations. The public was also able to join portions of the meeting through an online webcast. The objectives of the summit were to (1) allow participants to share information about the risk characterization of PFASs and techniques to monitor and remediate PFASs; (2) identify short-term actions needed to address PFAS contamination; and (3) develop strategies to discuss PFAS contamination with the public. During the summer of 2018, EPA officials plan to visit PFAS-contaminated sites across the country. Additionally, in the fall of 2018, the agency plans to release a “PFAS Management Plan.”

Convening the National Leadership Summit was intended to reflect Administrator Pruitt’s pledge to “restore power to the states through cooperative federalism.” Notably, a recently released report by the Department of Defense called upon EPA to take more control of regulation of perfluorinated substances rather than relying on the states. The Department of Defense report, “Addressing Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA),” identified the lack of a maximum contaminant level (MCL) for PFOS and PFOA at the national level as a barrier to cleaning up PFOS and PFOA contamination at military installations. In early 2016, the governors of New York, Vermont, and New Hampshire also called upon EPA to set a federal standard for PFOS

and PFOA in drinking water. EPA has already indicated that it will provide groundwater cleanup recommendations for PFASs in September 2018.

EPA Administrator Pruitt opened the National Leadership Summit on PFASs by announcing certain steps that the agency plans to take following the summit. The four-step action plan can be distilled as follows:

1. EPA will initiate steps to evaluate the need for a MCL for PFOA and PFOS. EPA will convene exchanges with federal partners and examine everything they know about PFOA and PFOS in drinking water.
2. EPA is beginning the necessary steps to propose designating PFOA and PFOS as “hazardous substances” through one of the available statutory mechanisms, including, potentially, Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 102.
3. EPA is currently developing groundwater cleanup recommendations for PFOA and PFOS at contaminated sites and will complete this task by fall of this year.
4. EPA is taking action in close collaboration with its federal and state partners to develop toxicity values for GenX and perfluorobutane sulfonic acid (PFBS).

During the summer months, the agency is planning “direct engagement” with communities by traveling to a number of states impacted by PFAS. As locations and dates become available, EPA will post materials on this website: <https://www.epa.gov/pfas/pfas-community-engagement>. The event also gained some notoriety in the national media when some journalists were excluded due to what were described as space limitations. Following the event, EPA issued a press release, <https://www.epa.gov/newsreleases/historic-epa-summit-provides-active-engagement-and-actions-address-pfas>, which reiterated the plans discussed during Mr. Pruitt’s opening remarks.

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## BEYOND REGULATORY COMPLIANCE: MANAGING THE BUSINESS RISKS FROM UNANTICIPATED CONSEQUENCES

Kathleen Sellers, PE

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Consider this paradox: to mitigate substantial business risks and the resulting headlines, we must often anticipate the sometimes unforeseen consequences of our actions. Resolving this paradox requires us to expand the boundaries of analysis of consequences and risks beyond regulatory compliance. Four basic principles apply; they are as follows:

- Define corporate risk tolerance
- Anticipate developments
- Communicate clearly
- Establish risk management practices

The best lessons come from case studies, but client confidentiality limits our ability to share those details. And so to explore these principles we can turn back to 1945, to events of striking relevance to today.

This story begins with a publication by a scientist in the Ministry of Agriculture in Great Britain. Despite the dry scientific prose and the passage of six decades, we can still hear Dr. Taylor's excitement as he wrote: "I have recently had the opportunity of carrying out a few trials with a substance temporarily designated '666.' . . . This substance, which may now openly be referred to as hexachlorobenzene . . . is a very remarkable compound in [its] extraordinary insecticidal properties . . ." As he wrote this passage, Dr. Taylor anticipated that hexachlorobenzene (HCB) would benefit society by eradicating lice and scabies. The uses of HCB soon grew to include treatment of the seeds of food crops to prevent the growth of fungus, and as a component in synthetic rubber production, graphite electrode production, and the manufacture of other chemicals. (E. L. Taylor. 1945. Acaricidal property of a new insecticide, hexachlorobenzene. *Nature* 155:393–94. For more information about HCB as described herein, see K. Sellers. 2015. *Product stewardship: Life cycle analysis and the environment*. ch. 4. CRC Press.)

A decade after Dr. Taylor's optimistic pronouncement, thousands of children were horribly crippled or died from eating HCB-treated wheat during a famine in Turkey. Some 15 years after that, scientists began to realize that HCB could be transported long distances by air, persist in the environment, and bioaccumulate in mammals. Many countries now ban many uses of HCB as a "dirty dozen" chemical under the Stockholm Convention. Despite such bans, the long-range transport of HCB to Arctic regions continues, and biomonitoring data have not yet shown consistently decreasing concentrations in the tissues of mammals.

Dr. Taylor and the companies that found myriad uses for HCB worked under laws with few requirements for pesticides, chemical regulation, and right-to-know; the U.S. government, for example, did not require toxicity testing of pesticides until 1954. Consequently, this case study illustrates the need to go beyond regulatory requirements to anticipate and manage the consequences of bringing a product to market.

### Define Risk Tolerance

The word "risk" in this context can have two meanings. From the scientific perspective, it refers to risks to human health or the environment. From a business perspective, it can include risks to market access or more broadly the risks to a company's reputation due to gaps in product stewardship. Regardless, understanding risk tolerance is a fundamental aspect of product stewardship.

Writing in 1945 about the miraculous new compound 666, Dr. Taylor implicitly addressed risk tolerance. He noted that application of HCB to rats treated notoedric mange "apparently, without any danger to the treated animals" (Taylor 1945). He contrasted this with the results of a parallel experiment in which DDT did not treat mange but killed some of the test animals after inducing neurotoxicity. Dr. Taylor also noted that HCB was

highly toxic to aquatic organisms. His publication conveys the conclusion that the benefits of using HCB outweighed the potential risks.

Current regulations in many countries now limit the manufacture and use of chemicals to scenarios that meet specified risk limits. But the companies that make chemical-based products must still define their risk tolerance. That often depends upon the product end use and resultant exposures. An executive of Johnson & Johnson, for example, has described its name as a “trust mark” and not a trademark; the company’s approach to managing risks to human health and the environment through actions that exceed regulatory compliance reflects that philosophy. Hoffmann-La Roche Ltd. reflects its risk tolerance in a commitment to stop the use of “substances of very high concern,” where technically feasible, after they are put on the European Union Candidate List. In contrast to these companies that make medical devices and pharmaceuticals, some manufacturers of heavy equipment are far more tolerant of incorporating hazardous chemicals into their operations and products in light of the potential exposures and controls. (A. Iannuzzi. 2018. *Greener products: The making and marketing of sustainable brands*. 2nd ed. ch. 3; [https://www.roche.com/sustainability/environment/our\\_she\\_goals\\_and\\_performance.htm?tab\\_id=tab1](https://www.roche.com/sustainability/environment/our_she_goals_and_performance.htm?tab_id=tab1).)

## Anticipate Developments

Hindsight reveals early warnings about HCB. Although its use was essentially unregulated when brought to market, scientists anticipated potential negative consequences of exposure from the very beginning. Dr. Taylor himself reported that HCB was “exceedingly toxic to the freshwater crustaceans *Cyclops*, *Daphnia* and particularly to *Diatomus*” (Taylor 1945). (Toxicity testing to *Daphnia* is now a relatively routine task when bringing a new chemical to market.) A 1948 editorial in the *Journal of the American Medical Association* cautioned, “The brands of new insecticides, fungicides and herbicides . . . number several thousand. . . . The Council on Pharmacy and Chemistry and the Council on Foods and

Nutrition are deeply concerned over this situation because so little is known about either the acute or chronic pathologic effects on man” (N. O. F. Blood. 1948. Pesticides: Chemical contaminants of foods. *JAMA* 137 (18):1604–05).

Regulatory compliance is obviously the first and most important step in managing business risks; but regulatory requirements typically lag behind the warnings of scientists and the issue-driven outrage of the public. Recently, scientists have identified potential hazards of endocrine disruption that are not yet broadly embedded in regulatory schemes, and consumer outrage drove the removal of water bottles containing bisphenol A from store shelves when no regulation required such action.

Consistent reconnaissance of emerging issues can enable companies and their advisors to anticipate and manage the consequences of bringing products to market. Prudent practice includes:

- Systematic review of indicators
  - Leading indicators include social media, nongovernmental organization (NGO) activity, and scientific research
  - Lagging indicators include trends in research, lawsuits, and listing of a chemical on a “watch list” by a retailer or NGO
- Defining and assessing evolving issues
- Prioritizing issues for response, considering the potential business risks, speed of evolution of the issue, and level of uncertainty

(For additional perspective on surveillance principles, see G. Hart, R. L. White, and K. Sellers. 2018. Chapter 13: Maintaining awareness of and responding to requirements. In *Professional practices of product stewardship*, ed. G. Hart (Falls Church, Va.: Product Stewardship Society). See also A. Iannuzzi. 2018.)

## Communicate Clearly

The results of consumption of HCB-treated wheat in Turkey during the 1950s illustrate the potential

for tragic consequences of poor communication regarding chemical risks. Current regulations in many countries mandate hazard communication. But those warnings are not always effective; pesticide poisoning from eating treated seed happens even now. Looking beyond required hazard communication to potential exposures throughout a product life cycle can help a company to minimize risks to human health and the environment, and consequently to the business (J. G. Schier et al. 2012. Consumption of pesticide-treated wheat seed by a rural population in Malawi. *Journal of Exposure Science and Environmental Epidemiology* 22(6): 569–73).

More broadly, some communications about a product, its uses, and benefits can inadvertently increase business risks. Anecdotal discussions among product stewards suggest that it is not uncommon for the marketing division of a company to write copy or create videos that suggest inappropriate product uses or make inappropriate claims. Without effective risk management practices that mandate review by counsel, such materials create business risk.

### Establish Risk Management Practices

Defining risk tolerance, anticipating developments, and communicating clearly occur most effectively in a program of deliberate risk management practices. Many companies, particularly those that have experienced rapid growth by merger and acquisition, lack a programmatic structure in which to anticipate consequences beyond regulatory compliance. The Responsible Care® Product Safety Code of Management Practices

offers one framework (<https://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Product-Safety-Code/Responsible-Care-Product-Safety-Code-PDF.pdf>). Other companies may choose to anchor their risk management practices in an ISO 14001 program (ISO 14001:2015(E): Environmental management systems—requirements with guidance for use. For additional perspective, see K. Brewer and G. Thompson. 2018. Design, implementation, and evaluation of a product stewardship program. In *Professional practices of product stewardship*, ed. G. Hart. (Falls Church, Va.: Product Stewardship Society).

The HCB parable related here provides strikingly relevant insights into thoughtful management of business risks resulting from actions taken within regulatory boundaries but perhaps without full consideration of their potential consequences. Some companies fail to articulate and communicate effectively risk tolerance internally; separate teams working in functional silos may make decisions without aligning on the appropriate level of risk. Prudent product stewards anticipate scientific developments and the public reactions that can catalyze new regulations or consumer deselection of a product; prudence should also extend to communications about a product’s uses. These actions occur most effectively within established risk management practices embedded in a company’s routine operations. Working “beyond compliance” affords an increase in business resilience and limits business risk.

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