



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

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FROM THE CHAIR

Charles L. Franklin

In early November, American voters will select a new class of federal, state, and local officials, a process likely to influence both the legislative and administrative agendas of federal and state governments over the next two years. Regardless of the electoral outcomes, however, the coming year promises exciting, if not tumultuous, times for Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) practitioners and their clients.

Chemical Control

On Capitol Hill, the 112th Congress will determine the fate of the most significant review of the Toxic Substances Control Act (TSCA) in over 30 years. During 2010, both chambers held hearings, introduced bills, and engaged stakeholder groups to explore opportunities to improve federal chemical control policy, but the issue lacked the political urgency needed to reach the top of the legislative agenda. (See Lynn Bergeson's article, *infra*, on TSCA reform. The conventional wisdom is that narrower margins in both Houses will make legislative action on TSCA even more difficult going forward. Of course, these are not conventional times, so do not rule out the potential for a TSCA comeback in 2010, particularly if advocates look to sneak more targeted changes or product-specific provisions into a bigger bill, as Congress did just last year with formaldehyde-treated wood products.

But even without new legislation, 2011 will be a busy year for TSCA practitioners. The U.S. Environmental Protection Agency (EPA) has signaled its intent to reassert, if not reinvent, its chemical control authority under the existing TSCA framework, promising to compel more data, take more focused action to manage risks from commonly used chemicals, and even develop a new "chemicals of concern" list. EPA may also be revisiting the prior administration's policy of regulating nano-scale versions of existing substances as "existing chemicals," a step that could increase the number of nanosubstances covered by TSCA's premanufacture notice requirements. In the meantime, EPA is already using TSCA's "significant new use" provisions to regulate higher-profile nanosubstances like carbon nanotubes.

Finally, with no clear time frame for TSCA reform ahead, expect more states to flex their own regulatory muscle as well. The Committee is well positioned to monitor and analyze such developments, and we will start by looking at California's leadership on issues such as green chemistry, nanotechnology, and mandatory disclosure.

Pesticide Control

While federal and state policymakers ponder the future of U.S. chemical policy, the judiciary will be the major driver for changes to federal pesticide policy in the coming year. After long treating the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as a self-contained legislative mandate, recent federal court decisions and related settlements are forcing EPA to

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Lynn L. Bergeson, Editor**

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integrate the Endangered Species Act's consultation requirements and the Clean Water Act's national pollutant discharge elimination system (NPDES) permitting requirements into the federal registration and reregistration review processes. Committee members are also awaiting major policy announcements from the administration regarding EPA's evolving approach to regulating nanopesticides under FIFRA. These policies will not only affect the next generation of new pesticide technologies, they could also affect hundreds of consumer and commercial products already in the marketplace.

Right to Know and Right to Confidentiality

During 2009 and 2010, congressional bills on TSCA reform, oil spill dispersants regulation, and even hydrofracturing chemicals regulation sought to reduce the business confidentiality protections available to substance and product manufacturers. The new administration, in turn, has initiated a number of proceedings to restrict business confidentiality claims and increase disclosure requirements under its current TSCA, FIFRA, and Emergency Planning and Community Right-to-Know Act (EPCRA) authority. But while regulatory transparency and the "public's right to know" constitute important social values, protecting private rights to intellectual property and encouraging research and innovation are also important social goals. This balance between the public interest in disclosure of sensitive substance and product information and the regulated community's interest in protecting its trade secrets and intellectual property will continue to be a prominent topic in the next year. The Committee offers an excellent forum for sharing perspectives and expertise on the issue.

International Developments

The United States is just one of many sovereign nations working to keep its domestic and international pesticide and chemical control policies in sync with the needs and demands of an innovative and evolving chemical sector. The European Union (EU) will continue to break new ground in late 2010 and 2011, as regulated companies reach one of the first major registration deadlines under the EU's Registration,

Other major trading partners like Canada, China, and Japan also have modified their chemical control policies recently. These policies will not only affect the competitiveness of U.S. companies in foreign markets, they will inform, if not alter, the political and economic calculus for many U.S. stakeholders weighing options for U.S. action on domestic chemical control issues as well as global initiatives like the Stockholm Convention on Persistent Organic Pollutants (POPs), the POPs Protocol to the Convention on Long-range Transboundary Air Pollution (LRTAP POPs Protocol), and the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The Committee includes some of the leading legal experts on these programs, and we welcome a dialogue on how the United States can learn from, and adapt to, the changing international regulatory landscape.

What Next for the Committee?

As illustrated above, the PCRRTK Committee may be small in terms of its membership, but the scope and import of the issues it follows are great. Today's PCRRTK practitioners must look well beyond the traditional bounds of TSCA, FIFRA, and EPCRA to understand the evolving chemical control landscape in the United States. The PCRRTK Committee provides professional networks, information resources, and communications platforms that can help you gain that understanding, and to share your expertise with others. With your active involvement in the Committee, we can be even more effective going forward.

It is an exciting time to be part of the PCRRTK community. We welcome your participation in the year to come.

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EPA'S PLANS TO MODIFY TSCA INVENTORY UPDATE REPORTING (IUR)

Irene Hantman

The goal of the U.S. Environmental Protection Agency's (EPA) proposal to modify the Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) is to improve EPA assessments of chemical risks to people and the environment. 75 Fed. Reg. 49,656 (Aug. 13, 2010). The proposed reporting requirement modifications will advance EPA's efforts to identify and manage risks associated with the production and use of chemical substances and mixtures (chemical substances). This action is one component of EPA's comprehensive effort to improve the agency's chemicals management program. (See, e.g., Enhancing EPA's Chemical Management Program, available at www.epa.gov/oppt/existingchemicals/pubs/enchanchems.html (July 23, 2010).)

The proposed changes affect all aspects of IUR. This article reports on likely modifications to various aspects of IUR. Also discussed is EPA's consideration of additional data elements to allow more comprehensive analysis of exposure during the manufacture, processing, and use of chemical substances.

Reporting Threshold

IUR is now required for facilities that manufacture 25,000 pounds or more of reportable chemical substances in a calendar year at a site. Under the proposal, certain manufacturers will be required to report IUR data regardless of production volume. In addition, EPA plans to eliminate the 25,000 pounds threshold for chemical substances of high interest to the agency. Specifically, IUR data, regardless of production volume, will be required for those substances subject to

- rules promulgated under TSCA §§ 5(a)(2), 5(b)(5), and 6;
- orders issued under TSCA §§ 5(e) and 5(f); and
- relief granted under a civil action under TSCA §§ 5 and 7.

Because EPA has a strong interest in the manufacturing, processing, and uses of these chemicals, IUR will be required regardless of whether the substance might otherwise qualify for a reporting exemption under 40 C.F.R. § 710.46.

Modifications to Improve Data Quality

The proposed IUR modifications will modify selected definitions to improve data quality. The definition of "mixture" will be revised to mirror that used under TSCA section 3. "Manufacture" will be explicitly deemed to include the extraction, for commercial purposes of component chemical substances, from previously existing chemical substances. In addition, the definition will be modified to enable direct reporting by toll manufacturers. The revised IUR will also collect information about portable manufacturing units. Specifically, manufacturers will need to report the aggregated production volume for all portable manufacturing units dispatched from each distribution center.

EPA also anticipates that proposed modifications to data elements will clarify submitters' reporting obligations and improve the utility of IUR data. EPA plans to add data elements to capture

- whether imported chemical substances are physically at a reporting site;
- volume exported;
- whether a chemical substance is to be recycled, remanufactured, reprocessed, reused, or reworked (EPA notes that this information will be useful in assessing the effectiveness of various programs, such as EPA's Resource Conservation Challenge Program); and
- additional information on consumer and commercial use,
 - including identification of whether the use is a consumer or commercial use or both;
 - number of commercial workers reasonably likely to be exposed while using the substance; and
 - descriptive product information when product category "other" is selected.

EPA also proposed inclusion of Chemical Abstracts Service registry numbers and CA Index Names as a new data element. A significant number of prior IUR reports inadequately described chemical identity. Because "names" were too generic to allow EPA to identify the chemical substance, EPA reportedly was required to invest substantial resources in data retrieval and reanalysis.

Reporting Processing and Use Information

EPA expects to reduce the frequency of nonresponse for processing and use information by modifying the reporting standard for this data element. These data were missing from more than 40 percent of the 2006 IUR reports that should have included processing and use information. The low reporting rate limited the utility of these data in EPA's efforts to prioritize work on existing chemicals. EPA proposes to require reporting on processing and use where the respondent "knows or can reasonably ascertain the information." The "known to or reasonably ascertainable standard" is intended to extend to not only all information in a person's possession or control, but also to information that a similarly situated reasonable person could be expected to know, possess, or control. Because the "known to or reasonably ascertainable standard" has been used to report processing and use information in more than 30,000 TSCA section 5 premanufacture notifications (PMN), EPA believes that far more information about chemical substances processing and use is readily available to companies than is reflected in the 2006 IUR data.

By-product Reporting

The IUR modifications include a detailed discussion of by-product reporting which is intended to clarify reporting obligations, including the circumstances under which reporting is and is not required. For the purposes of IUR reporting, by-products are secondary chemical substances without separate commercial intent that are produced during manufacturing, processing, use, or disposal of primary chemical substances or mixtures. EPA believes that by-products are not inherently different from other manufactured chemical substances with respect to exposure rates

and risks. Thus, by-products manufactured at or above the 25,000 pounds threshold are subject to IUR requirements, unless the by-product is not used for commercial purposes. This requirement holds regardless of whether a substance is regulated by another EPA program (e.g., Resource Conservation and Recovery Act).

Requirements Concerning CBI

As with other ongoing EPA chemical regulation efforts, IUR imposes limits on confidential business information (CBI) claims for both chemical substance and processing and use data. EPA notes that often chemical substance identity information that is labeled as CBI is already published elsewhere (e.g., on the public portion of the TSCA Inventory). Because EPA believes that the information that could potentially be labeled CBI has already been disclosed, the agency asserts that publicly available information about substances and related processing that might otherwise be classified as CBI will no longer be treated as CBI. Furthermore, under the proposed IUR modifications, EPA may disclose this information without further notice to the submitter.

The proposed CBI constraints will require careful adherence to new procedures for asserting CBI claims. If a submitter fails to follow precisely the reporting procedures, EPA may release the information to the public without further notice to the submitter. Submitters must both check the CBI response box and sign a certification statement to claim information as confidential. And, by signing the statement, the submitter attests to the secrecy and value of his confidentiality claims.

The agency has also identified many instances of facilities claiming processing and use data to be confidential, while at the same time making similar or identical information publicly available on company Web sites and published material safety data sheets. Processing and use confidentiality claims have even been made when this information was submitted for publication on the agency's Web site (e.g., High Production Volume Information System). Under the proposed rule, to submit a claim of confidentiality for

processing and use information data elements, submitters will be required to both check the appropriate box and substantiate their CBI claims in writing. As with chemical substance composition data, if the submitter fails to substantiate properly his processing and use claims, EPA will not consider the information subject to confidentiality claims and may make the information publicly available without notice to the submitter.

(For more information on EPA's "new general practice" of reviewing CBI claims, see Trade Secrets in Chemical and Pesticide Law: Right-to-Know Meets Right-to-Innovate, in the June 2010 issue of this Newsletter; and Claims of Confidentiality of Certain Chemical Identities Submitted Under Section 8(e) of the Toxic Substances Control Act, 74 Fed. Reg. 68,215 (Jan. 21, 2010).)

Additional Data Elements Under Consideration

In addition to the new data elements proposed, EPA is also considering collecting additional exposure-related data elements to allow the agency to develop more comprehensive and complete exposure screening assessments. Data elements under consideration would capture information regarding

- manufacturing processes;
- storage and shipping containers;
- worker activities, personal protective equipment, and engineering controls;
- release control technologies and their efficiency; and
- destination of release, including, for aqueous releases, National Pollutant Discharge Elimination System permit number or name of publicly owned treatment works as appropriate; and
- quantity of chemical substance released directly to the environment or into control technology to the environment.

The precise data elements would be based on those already included in PMN submissions. Alternatives to integrating these variables into IUR are promulgating a

new reporting mechanism under TSCA section 8(a) or using TSCA section 11(c) subpoena authority. EPA believes that including these data elements in IUR would result in the most complete data and best facilitate proactive identification of potential exposure-based chemical risk management issues. In addition, EPA asserts that adding these elements to IUR would also best ensure that manufacturers maintain relevant records.

Conclusion

The proposed IUR modifications suggest many changes to current reporting requirements. The full proposal comprises more than 50 pages in the Federal Register. In addition to the changes discussed above, the 2010 IUR will collect production volume information for 2006-2009. EPA plans to collect data electronically via an eIUR Web site. The agency anticipates promulgating the final rule during spring 2011. The next scheduled submission period is scheduled to run from June 1, 2011, through September 30, 2011.

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EPA'S THREATS TO USE MISBRANDING ACTIONS TO ENFORCE RISK MITIGATION: A CASE IN POINT

Lawrence E. Culleen

In a July 16, 2010, decision, a federal court of appeals issued a significant new ruling in litigation brought by the maker of the d-Con brand of rodenticides against the U.S. Environmental Protection Agency (EPA). *Reckitt Benckiser, Inc. v. EPA*, No. 09-1314 (D.C. Cir. July 16, 2010). The plaintiff, Reckitt Benckiser, Inc. (Reckitt), initially brought an action against EPA in federal district court challenging the manner in which EPA is implementing its risk mitigation decision (RMD) for 10 rodenticides (RMD). EPA had advised Reckitt that its registered rodenticide products containing certain active ingredients would be considered misbranded on June 14, 2011, if Reckitt declined to adopt all aspects of the RMD. Reckitt asked the district court to grant declaratory and injunctive relief on the ground that EPA could not bypass certain administrative proceedings and procedural safeguards available under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and treat registered products as misbranded for failure to comply with the RMD. The district court dismissed the complaint in a 2009 ruling for lack of subject matter jurisdiction. Reckitt appealed, and in July 2010, the court of appeals reversed the district court and remanded the case, holding that there was sufficient final agency action that was ripe for review, and that the district court had jurisdiction pursuant to FIFRA section 16(a).

The case is significant because a U.S. court of appeals found that a registrant may challenge, in a district court, EPA's use of threats of an enforcement action to attempt to compel the registrant to voluntarily cancel the registrations of its consumer-use rodenticide products following EPA's reregistration process.

The case is now back before the district court, where it has agreed to give the matter expedited consideration in light of the June 2011 deadline imposed by EPA's threat to bring a misbranding action.

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PROPOSED EU BIOCIDAL PRODUCTS REGULATION IS WORKING ITS WAY THROUGH THE EUROPEAN INSTITUTIONS

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In June 2009, the European Commission adopted a proposal for a regulation concerning the placing on the market and use of biocidal products (biocidal products regulation or BPR). The proposed BPR will repeal and replace current Directive 98/8/EC (current BPD) and is expected to enter into force on January 1, 2013. Adoption of the European Parliament's first-reading opinion is expected before the end of 2010, although many issues still remain unresolved.

Differences Between the Current BPD and the Proposed BPR

In October 2008, the Commission published a report on the implementation of the current BPD as statutorily required, and the report identified a number of weaknesses. The proposed BPR seeks to address these weaknesses and to take into account the comments made in the consultation procedure. Generally speaking, the proposed BPR broadly retains the same two-tier authorization process as established under the BPD, and the underlying legal framework regarding the regulation of biocidal products will remain the same. Depending on the amendments agreed upon within the European Union (EU) legislative process, however, the proposed BPR is likely to make some significant changes to, among other things, the following topics:

1. Scope

The proposed BPR will expand the scope of the current BPD. Significantly, the proposed BPR will be extended to include articles and materials treated with biocidal products such as textiles and furniture. This amendment is most likely to impact importers of treated articles. Under the current BPD, articles treated with unauthorized active substances outside the EU may lawfully be imported into the EU and placed on the EU market (i.e., the EU treated articles

exemption-which is not the same as the U.S. treated articles exemption). Under the proposed BPR, this perceived loophole will be closed and articles treated with unauthorized active substances outside the EU will not be able to be placed on the EU market. The proposed BPR also provides for specific labelling requirements as regards treated articles. The proposed BPR will also be extended to regulate the use of surface biocides in food contact materials, although questions remain regarding whether those materials would also have to continue to comply with current EU food contact legislation in the future.

2. Amendments Aimed at Improving the Functioning of the EU Single Market

Generally speaking, the proposed BPR will retain the two-tier authorization procedure established under the current BPD (i.e., approval of active at the EU level [Annex I inclusion regarding product types] and approval of the product at the Member State level). The proposed BPR sets out a number of changes with the goal of improving the functioning of the EU single market regarding biocidal products.

First, the proposed BPR establishes a new EU centralized system of authorization whereby the Commission, rather than the Member State authorities, will approve certain biocidal products. Those biocidal products include (1) products containing one or more new active substances; and (2) low-risk (as defined in Article 17) biocidal products (Article 33). At present, it is envisaged that most biocidal products will continue to be authorized at the Member State level under the proposed BPR, although members of the European Parliament reportedly are keen that a centralized EU system be also established for all other biocidal products, and therefore this issue is currently under review.

Second, the proposed BPR alters the rules on mutual recognition (i.e., the process whereby one Member State recognizes the product authorization of another Member State). The proposed BPR sets out a "mutual recognition procedure" whereby an applicant can either (1) apply for mutual recognition of a product authorization already granted in another Member State; and/or (2) apply for mutual recognition of a product authorization being granted at the same time and in

parallel to product authorization in another Member State. Lastly, the proposed BPR strengthens and brings into line labelling provisions relating to biocidal products with the Classification, Labelling, and Packaging Regulation (CLP) and the Dangerous Preparations Directive (DPD) (Article 58).

3. "Exclusion Criteria" and Substitution

The proposed BPR also introduces new requirements regarding the inclusion of substances on Annex I BPD. Most significantly, the proposed BPR is designed to phase out the use of substances classified as carcinogenic, mutagenic, and/or toxic for reproduction substances (CMRs) 1A or 1B under the CLP or considered as endocrine disruptors. It does this by way of the so-called exclusion criteria (Article 5). The exclusion criteria provides that active substances classified as CMRs 1A/1B or considered as endocrine disruptors can only be included on Annex I BPR if (1) there is negligible exposure to humans under normal conditions of use; (2) the active substance is necessary to control a serious danger to public health; and (3) not including the active substance in Annex I would cause disproportionate negative impacts when compared with the risk to human health or the environment and there are no alternatives.

In addition, even where an active is included on Annex I BPR, the BPR provides that the substance may be identified and considered as a "candidate for substitution" (Article 9). If or when a substance is considered as a candidate for substitution, products containing that substance may only be authorized/reauthorized after "comparative assessment" with products containing substances of lower risk (Article 21). If the product containing a candidate for substitution substance presents significantly higher risk than alternatives, its authorization will be refused or cancelled.

4. Other Issues

The proposed BPR sets out new reduced data requirements for product authorization. In particular, applicants will be able to waive requirements if data are not scientifically necessary, if they are technically impossible to supply, or if they are not relevant. To

prevent unnecessary testing on vertebrate animals, the proposed BPR also sets out mandatory information-sharing requirements similar to the Registration, Evaluation, Authorisation and Restriction of Chemicals data-sharing requirements. These provisions will only apply to substances/products evaluated after January 1, 2013.

The proposed BPR also provides that the European Chemicals Agency will play an active part in the Annex I inclusion process, the product authorization procedure, and in interparty disputes regarding data access. The proposed BPR also partially harmonizes fees payable both for Annex I inclusion applications and for product authorization applications.

Adoption of the Proposed BPR

In addition to these issues, there are a number of issues that are yet to be resolved before the BPR is adopted. For example, there is growing support in the European Parliament to ensure that provisions regarding the placement on the market and use of nanomaterials in biocidal products are assessed separately from active substances. Given the enormous impact the BPD has already had on the EU biocides industry and the weaknesses identified in the October 2008 Commission report on problems associated with data protection of information submitted under the BPD review program (free riding, among others), the provisions surrounding these issues in the proposed BPR may be further strengthened or amended to address these and related issues.

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SUMMARY AND COMPARISON OF HOUSE AND SENATE TSCA LEGISLATIVE EFFORTS

Lynn L. Bergeson

On July 22, 2010, Representatives Bobby Rush (D-IL), chair of the Subcommittee on Commerce, Trade, and Consumer Protection, and Henry Waxman (D-CA), chair of the Energy and Commerce Committee, introduced the Toxic Chemicals Safety Act of 2010 (H.R. 5820) (TCSA), which is intended to revise the Toxic Substances Control Act (TSCA). On April 15, 2010, Rush and Waxman released a discussion draft of their TSCA reform legislation, and Senator Frank R. Lautenberg (D-NJ) released the text of the Safe Chemicals Act of 2010 (S. 3209) (SCA), also intended to reform TSCA. Below is a summary of the key provisions of TCSA. Unless noted otherwise, the SCA includes similar provisions. Differences between the bills are noted, as well as differences between TCSA and the discussion draft of the House TSCA reform legislation.

No effort is made here to review these complicated bills in detail.

Definitions

TCSA amends several existing TSCA definitions and proposes several new definitions. The current definition of "chemical substance" is changed in both bills. While both the discussion draft and the SCA would broaden the definition to include "chemical substance contained in or formed into an article," this phrase has been dropped from TCSA. Both bills attempt to address nanoscale materials. TCSA would allow the EPA administrator to "determine different forms of a chemical substance with a particular molecular identity to be different chemical substances for purposes of this Act, based on variations in the substance characteristics. New forms of existing chemical substances so determined shall be considered new chemical substances for purposes of this Act." The SCA states, "Notwithstanding molecular identity, the Administrator may determine, under Section 5(a)(6), that a variant of a chemical substance is a new chemical substance."

Both bills change the definition of "new chemical" to tie it to chemicals "for which no declaration has been submitted." TCSA also clarifies that this provision does not apply for the one-year period after enactment and thus recognizes that declarations would not be available at the outset.

"Chemical identity" as defined in the discussion draft was largely retained in TCSA and reads "with respect to a chemical substance-(A) each common and trade name of the chemical substance; (B) the name of the chemical substance appearing in International Union of Pure and Applied Chemical nomenclature and 9th Collective Index format; (C) the Chemical Abstracts Service registration number of the chemical substance; and (D) the molecular structure and the molecular identity of the chemical substance."

"Substance characteristic" is defined in TCSA "with respect to a particular chemical substance, the physical and chemical characteristics that may vary for such substance, and whose variation may bear on the toxicological properties or the exposure potential of the substance, including-(A) structure and composition; (B) size or size distribution; (C) shape; (D) surface structure; (E) reactivity; and (F) other characteristics and properties that may bear on toxicological properties or exposure potential." Importantly, TCSA has added the concept of "exposure potential" to the definition.

The SCA does not define "substance characteristic," but instead defines "special substance characteristics" as such "physical, chemical, or biological characteristics, other than molecular identity, that the Administrator determines, by order or rule, may significantly affect the risks posed by substances exhibiting those characteristics." In determining the existence of special substance characteristics, the administrator may consider size or size distribution; shape and surface structure; reactivity; and any other properties. The Senate definition focuses on "risks posed," whereas the House definition focuses on "toxicological properties."

Section 4—Creation of a Minimum Data Set

TSCA section 4 authorizes EPA to issue rules requiring manufacturers, importers, and processors to test

certain new or existing chemical substances or mixtures for their effects on human health and the environment. Both TCSA and the SCA would require manufacturers and processors to submit to EPA a "minimum data set." For existing chemicals, companies would be required to submit data on chemicals and mixtures 18 months after EPA's listing of the substance or mixture on the section 6(a) priority list, and for chemicals depending on the production volume of the chemical substance (high volumes within three years; moderate volumes within four years; and low volumes within five years of enactment of TCSA).

This is a change from the House discussion draft, which would require data on existing chemicals and mixtures within five years of enactment. The determinations of high, moderate, or low volumes would be made by the administrator and, recognizing that EPA has one year to establish the minimum data set, the time period available to manufacturers and processors for completing the minimum data set for such chemicals would be reduced by one year to two, three, and four years, respectively. Manufacturers of new chemicals would be required to submit data when submitting the premanufacture notice (PMN).

Section 4—Additional Test Rules

Under TSCA, to require testing, EPA may issue a rule if it finds that "there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted," and "testing of such substance or mixture with respect to such effects is necessary to develop such data." EPA must also find that the chemical substance or mixture "may present an unreasonable risk" to human health or the environment, or is produced in substantial quantities that could result in substantial or significant human exposure or environmental release. TCSA would broaden EPA's authority to require additional testing by allowing EPA to (1) issue orders in addition to rules to require data; (2) require the submission of data "as necessary for making a safety standard determination under Section 6(b) or carrying out any provision of this Act"; and (3) impose penalties or by order impose conditions,

including prohibitions on manufacturing, processing, or distribution of any chemical substance or mixture for which minimum data set or testing requirements are not met by a given manufacturer or processor.

Section 5—New Chemical Substance and New Use Review

Under TSCA, manufacturers and importers must submit a PMN for any chemical substance to be manufactured or imported that is not listed on the public or confidential versions of the TSCA Inventory and that is not eligible for an exemption from PMN requirements. The PMN form seeks information on the submitter's identity, the chemical substance's identity, production volume, uses, exposures, and environmental fate. TSCA does not require a submitter to test new chemical substances before submitting a PMN. Health and safety data relating to a new chemical substance's health or environmental effects that are in a submitter's possession or control, however, must be submitted with the PMN. EPA has certain authorities to control and require testing on PMNs. TSCA also includes several statutory and regulatory exemptions.

Both bills appear to require a PMN from each person who manufactures or processes a new chemical. Currently, TSCA limits the manufacture of a chemical not listed on the Inventory. TCSA would change several aspects related to the submission and review of notices on new chemicals and on new uses. First, manufacturers and processors would be required to submit a minimum data set when the PMN or new use notice is submitted, unless the minimum data set requirement has already been met for an "equivalent chemical substance" as determined by EPA.

Second, the SCA would also require the submission of a minimum data set and PMN for new chemical substances (but not mixtures) and new uses of chemical substances. Unlike the current TSCA, which requires a significant new use rulemaking to trigger such a notification requirement, "new uses" under the SCA are determined based on revised declarations under section 8(a) received from the manufacturer or processor.

Under the SCA, EPA must find that the manufacturers and processors have established that the chemical substance meets the safety standard, or EPA must find that the new chemical substance is not, and is not expected to be

- (I) manufactured in a volume of more than 1,000,000 pounds annually or released into the environment in a volume of more than 100,000
- (II) a known, probable, or suspected reproductive, developmental, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or has other toxicological properties of concern;
- (III) persistent and bioaccumulative;
- (IV) found in human cord blood, or otherwise found in human blood, fluids, or tissue, unless the chemical substance or metabolite or degradation product is naturally present at the level commonly found in that medium; or
- (V) found in food, drinking water, ambient or indoor air, residential soil, or house dust, unless the chemical substance or metabolite or degradation product is naturally present at the level commonly found in that medium.

Both the SCA and TCSA include the current TSCA section 5(h) exemptions for (1) test marketing purposes; (2) equivalent chemical substances; (3) substances manufactured or processed in small quantities; and (4) substances that exist temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and to which there is no, and will not be, human or environmental exposure. Of these, numbers 1 and 2 are available upon application. Neither the SCA nor the discussion draft includes the current section 5(h)(4) regulatory exemption provision. This means that substances currently in commerce based on such exemptions would be subject to the PMN, the minimum data set, and other provisions discussed above.

TCSA includes a provision regarding such prior regulatory exemptions. Under TCSA, within one year after the date of enactment, EPA would review exemptions granted under TSCA section 5(h)(4) to

determine if they satisfy the requirements regarding "intrinsic properties" under section 39(a). The prior exemptions will continue in effect "until such date as the Administrator determines, by order, that (1) the exemption is not authorized or not appropriate under this section, at which time the exemption shall cease to be in effect; or (2) the exemption is authorized and appropriate under this section, at which time the Administrator may issue an order to modify or continue in effect the exemption pursuant to subsection (a)."

Section 6—Development of Priority List for Safety Standard Determinations

While the discussion draft included a provision requiring expedited action for a set of 31 chemicals and categories of chemicals, this provision has been dropped from TCSA. In its place, the bill establishes an initial priority list of 12 chemicals plus a seven-chemical category of phthalates for which safety standard determinations shall first be made. The initial statutory priority list would include bisphenol A; formaldehyde; n-hexane; hexavalent chromium; methylene chloride; trichloroethylene; vinyl chloride; certain phthalates (benzylbutyl phthalate, dibutyl phthalate, diethylhexyl phthalate, di-isodecyl phthalate, di-isononyl phthalate, di-n-hexyl phthalate, and di-n-octyl phthalate); perchlorate; tetrachloroethylene; tris (1,3-dichloro-2-propyl) phosphate; tris (2-chloroethyl) phosphate; and tris (2,3-dibromopropyl) phosphate.

Newly listed substances include di-isononyl phthalate, di-n-octyl phthalate, and perchlorate. EPA would then have 12 months to update the list, "which shall consist of not fewer than 300 chemical substances." EPA would have discretion in listing these chemicals, based on "available scientific evidence and consideration of their hazard, exposure, or risk relative to other chemical substances, aggregate or cumulative exposure, evidence of exposure to humans including presence in human or animal biological and environmental media including in the workplace, use, volume of manufacture, toxicological properties, persistence, bioaccumulation, or other properties indicating risk." EPA can remove a chemical substance only after a safety determination has been made, and

must periodically add chemical substances to the list so that the list never has fewer than 300.

Section 6(b)—Safety Standard Determination

TCSA proposes that EPA apply a safety standard that "takes into account aggregate exposure to a chemical substance or mixture and ensures that, for all intended uses: (i) with regard to public health, there is a reasonable certainty that no harm will result, including to vulnerable populations; and (ii) the public welfare is protected." The TCSA standard differs in several critical ways from that proposed in the discussion draft.

Key changes include dropping the need to take into account cumulative exposure, the strengthening of the standard with use of "ensures," and the narrowing provided by "for all intended uses" and the specification regarding public health in applying the "reasonable certainty of no harm" provision. TCSA goes on to require that the administrator in making determinations "shall consider, among other relevant factors," the life cycle of the chemical substance or mixture and "available information concerning the cumulative effects of exposure to chemical substances or mixtures."

Significantly, under the SCA, a determination by EPA that a manufacturer or processor has not established that the chemical substance meets the safety standard "shall not be subject to judicial review." The SCA would require manufacturers and processors to submit, not later than 15 years after enactment, the minimum data set and indicate whether the chemical substance, including specified uses to be evaluated and any proposed conditions on the specified use, meets the safety standard. The SCA would also allow any person to petition EPA for a redetermination of whether a chemical substance continues to meet the applicable safety standard. The petition must include "a description of the basis for requesting the redetermination." EPA would have 180 days after receipt of the petition to publish its decision, and the basis for its decision, in the Federal Register.

Section 6(c)-Risk Management

Under TSCA section 6, EPA is authorized to restrict or ban the manufacture, processing, or distribution in commerce of chemical substances or mixtures upon

showing that the activity "presents or will present an unreasonable risk of injury to health or the environment." EPA currently must select the least burdensome of the regulatory options available to it that is adequate to achieve its regulatory objectives. Because of the restrictions on EPA's authority to regulate existing chemicals, EPA exerted its section 6 authority sparingly and was never successful in using it. The perception of inaction has been the source of repeated EPA criticism.

With the new safety determinations proposed in TCSA, significantly more chemicals would be assessed by EPA. EPA would have significantly greater discretion to take action for chemical substances or mixtures that are determined by EPA not to meet the safety standard. If EPA determines that the safety standard has not been met for a new chemical substance or mixture or new use, then that chemical substance or mixture cannot be manufactured, processed, or distributed in commerce. If EPA determines that the safety standard has not been met for an existing chemical substance, then that chemical substance or mixture cannot be manufactured, processed, or distributed in commerce, effective one year after publication of that determination, "or as quickly as feasible and in no case later than 3 years after such publication."

Actions EPA can take if it finds that conditions must be imposed to ensure that the chemical substance or mixture meets the safety standard include (1) prohibiting the manufacture, processing, or distribution in commerce of a chemical substance or mixture, a particular use of a chemical substance or mixture, or a particular use in a concentration in excess of a level specified by EPA; (2) limiting the amount that can be manufactured, processed, or distributed in commerce of a chemical substance or mixture, a particular use of a chemical substance or mixture, or a particular use in a concentration in excess of a level specified by EPA; (3) requiring clear and adequate warnings and instructions with respect to the use, distribution in commerce, and disposal of a chemical substance or mixture; (4) imposing record-keeping requirements; (5) prohibiting or limiting any manner or method of manufacture, processing, commercial use, or disposal; and (6) requiring the development of a risk reduction management plan to achieve a risk reduction specified by EPA.

TCSA would also provide explicit authority to regulate occupational exposure provided the requirement "reflect[s] the industrial hygiene hierarchy of controls." This term is not defined nor is it linked to the Occupational Safety and Health Administration approach that starts with engineering controls. Other available hierarchies of control start with "prevention" approaches.

Section 8(a)—Reporting-Declaration of Manufacturing or Processing

Both bills propose a new requirement that each manufacturer or processor, within one year of enactment, provide a declaration of current manufacturing or processing of a chemical substance. The discussion draft had extended this requirement to mixtures but the scope has been limited in TCSA in a provision allowing EPA to require "additionally" a declaration from any manufacturer or processor of a mixture "determined by the Administrator to have substance characteristics different from the substance characteristics of the constituent chemical substances, in kind or degree." TCSA section 8(a)(2) added or clarified numerous of the data requirements under the declaration.

Under TCSA, a manufacturer or processor also can declare that it has permanently ceased, or will permanently cease within 180 days of submission of the declaration, all production, importation, processing, and export of the chemical substance (the discussion draft and the SCA did not limit this provision to permanent cessations). Manufacturers and processors would have to update these declarations every three years, or immediately when certain information is obtained.

Section 8(c)—Reporting-Inventory

While the House discussion draft would require that all chemical substances and mixtures in commerce be compiled and maintained in the Inventory, the SCA would require the Inventory to include each chemical substance that is manufactured or processed in the

United States, as well as new chemicals entering commerce and declarations under the new section 8(b). TCSA establishes an Inventory consisting of chemical substances and mixtures for which declarations are received under section 8(a)(2) and new chemicals or mixtures. Neither TCSA nor the SCA include the provision at current TSCA section 8(b)(2) concerning Inventory categories (sometimes referred to as "statutory mixtures"). Insofar as both draft bills retain the TSCA section 26(c) "category" provision, this might provide a means to retain such Inventory categories, although an explicit reference would be helpful. TCSA would allow EPA 24 months to first publish the list, while the SCA provides EPA only 18 months.

Section 18—Preemption

Neither TCSA nor the SCA contains provisions that clearly address the concerns identified by chemical manufacturers concerning the plethora of state and local requirements that make interstate marketing, sale, and distribution of chemical products challenging. TSCA section 18 preempts states and political subdivisions of a state from enacting requirements applicable to a chemical substance or mixture that is regulated under TSCA section 5 or 6, unless the state requirement is identical to the federal requirement, implements another federal law, or prohibits use of the substance or mixture within the state. A state or political subdivision may ask EPA to allow a requirement that provides a significantly higher degree of protection from risk than does the federal requirement. Under TCSA, states, political subdivisions, and tribes would have the ability to adopt or enforce requirements that are different from or in addition to requirements established under TCSA, unless compliance with both TCSA and the state or political subdivision requirement "is impossible." The SCA states that neither the SCA, nor any rule, regulation, or order issued or promulgated pursuant to the SCA, would "preempt, displace or supplant any provision of any law, including common law, of any State or political subdivision of a State relating to any chemical substance or mixture, or any article that

contains a chemical substance or mixture, which is more stringent than is provided for under this chapter."

Section 19—Judicial Review

TSCA section 19 sets forth the circumstances when a party can seek judicial review. TSCA proposes to remove the definition of rulemaking record and to remove the TSCA exception from general Administrative Procedures Act (APA) requirements regarding the standard of review. A court would have jurisdiction to "grant appropriate relief," including interim relief, and to review such rule or order in accordance with chapter 7 of title 5, United States Code. Under TSCA, courts would no longer be directed to hold unlawful and set aside rules where the court finds that the rule is not supported by substantial evidence in the rulemaking record. Instead, courts would use the APA standard of review, and would invalidate EPA's rules or orders only where the court

finds that EPA's action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

The bills are very detailed and contain many, many more provisions than those covered here. Care should be taken to review both bills carefully. Further legislative action is not expected in 2010. Watch for developments in 2011.

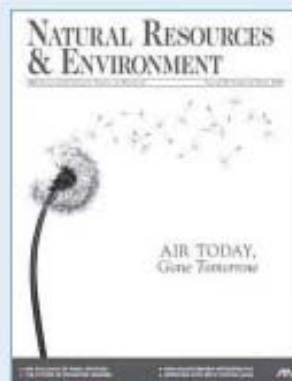
Lynn L. Bergeson is managing director of *Bergeson & Campbell, P.C.*, a Washington, D.C., law firm focusing on conventional and engineered nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues; and president of *The Acta Group, L.L.C.*, and *The Acta Group EU, Ltd.*, with offices in Washington, D.C., and Manchester, UK.

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NANO: SIZE MATTERS FOR METALS

Joel Davidson

Nanoscale substances, including metals and metal oxides, often have different properties than their bulk, conventionally sized counterparts. "It's like you shrink a cat and keep shrinking it, and then at some point, all at once, it turns into a dog." Jennifer Kahn, Nano's Big Future, NAT'L GEOGRAPHIC, June 2006, at 98, 103. Unlike the repositioned carbon in carbon nanotubes, bulk metals can simply be cut down until a unit of the same basic molecular identity is incredibly small. While the increased surface area and unique properties of nanoscale substances may aid countless applications, safety-and therefore regulatory concerns-also arise.

A May 2010 letter from U.S. Environmental Protection Agency (EPA) Assistant Administrator Stephen A. Owens to the U.S. Government Accountability Office noted that "[t]he same special properties that make nanoscale materials useful are also properties that *may cause some* nanoscale materials to pose *potential* risks to humans and the environment." Anu Mittal et al., Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk, GOV'T ACCOUNTABILITY OFFICE (May 2010) at 55, available at <http://www.gao.gov/new.items/d10549.pdf> (emphasis added). Regulators desire more information. According to EPA nano expert Jim Alwood, "[t]here is so much uncertainty about the questions of safety. We can't tell you how safe or unsafe nanomaterials are." Andrew Schneider, Amid Nanotech's Dazzling Promise, Health Risks Grow, AOL NEWS (Mar. 24, 2010), available at <http://www.aolnews.com/nanotech/article/amid-nanotechs-dazzling-promise-health-risks-grow/19401235>. In part, that is because scientists "generally do not have access to data . . . needed to detect patterns in the relationships between toxicity and other characteristics of various nanomaterials." Linda-Jo Schierow, Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges, CONG. RES. SERVICE, Jan. 22, 2008, at 9.

This article summarizes applications of four nano metal oxides and suggests that regulatory bodies will likely

seek additional information-gathering and regulatory authority over these and other nanoscale metals.

State and Federal Concern

One could reasonably anticipate the regulation of nanoscale metals under EPA's upcoming proposed significant new use rule (SNUR) for nanoscale chemical substances under the Toxic Substances Control Act (TSCA). The SNUR is "expected to identify existing nanoscale substances that share the same molecular identity as their conventionally sized counterparts listed on the TSCA Inventory as a 'category' of chemical substances." Lynn L. Bergeson, What's New in Nano?, 2010 TRENDS, July/Aug., at 4. Last year, California's Department of Toxic Substances Control requested information on nano versions of titanium dioxide, aluminum oxide, zinc oxide, and cerium oxide, in addition to nano silver and other non-oxidized metals. That could be "the first step in a process that leads to state regulation of these nanomaterials." Laura Duncan, Mark Duvall, Phil Moffat & Alexandra Wyatt, Nanometal Oxides Targeted for Review by California Department of Toxic Substances (June 18, 2009), <http://www.bdlaw.com/news-597.html>.

Nanoscale Properties

Titanium Dioxide

Titanium dioxide has been used in surgical procedures, pigments, and plastics. At the nanoscale, it is commonly used in cosmetics and sunscreen, and to remove arsenic from water. UCLA scientists, however, who exposed mice to nanoscale titanium dioxide through drinking water found an increased cancer risk; the metal bioaccumulated and its larger surface area led to systemic genetic damage. Nanoparticles Used in Common Household Items Cause Genetic Damage in Mice, SCIENCEDAILY (Nov. 17, 2009), <http://www.sciencedaily.com/releases/2009/11/091116165739.htm>. The National Institute for Occupational Safety and Health has recommended an occupational exposure limit 15 times lower for nano titanium dioxide than for its conventional counterpart. Andrew Schneider, Obsession with Nanotech Growth Stymies Regulators, AOL NEWS (Mar. 24, 2010),

Aluminum Oxide

Consumers may most readily recognize aluminum from its use in kitchenware, as aluminum foil, and in some baseball bats. If they could see nano aluminum, though, consumers probably would not recognize it, because it becomes explosive at approximately 20 to 30 nanometers. Nano aluminum might be used in rocket fuel or explosives, or even as an environmental filter. EPA intends to propose a rule that would require the generation of test data on nano aluminum, among other nanoscale substances. Anu Mittal et al., *supra* at 37.

Zinc Oxide

Zinc oxide is used in the manufacture of rubber, in soothing calamine lotion, and, like titanium dioxide, in sunscreen. Experiments have found nano zinc oxide particles twice as toxic to colon cells as conventional sized particles. Evidence That Nanoparticles in Sunscreens Could Be Toxic If Accidentally Eaten, SCIENCE DAILY (Apr. 7, 2010), <http://www.sciencedaily.com/releases/2010/04/100407110824.htm>. Scientists say this could be cause for concern if a child were to ingest the sunscreen, though more research is needed to study the passage of the nano particles through the digestive tract. *Id.*

Cerium Oxide

Cerium oxide is used in metallurgy, mirrors, and televisions. An EPA hazard assessment of cerium

exposure found adverse lung effects. Particle size appeared a "more important factor" than particle number or total surface area. Martin Gehlhaus et al., Toxicological Review of Cerium Oxide and Cerium Compounds, ENVTL PROTECTION AGENCY (Sept. 2009) at 40, available at <http://www.epa.gov/iris/toxreviews/1018tr.pdf>. Nano cerium oxide has been used in England as a diesel additive to increase fuel efficiency. This application is not currently authorized in the United States.

Conclusion

Even though a conventional metal may share a molecular identity with its diminutive nano counterpart, it may sometimes exhibit more toxic properties. State and federal regulatory bodies can be expected to seek additional data on nano metals and metal oxides and, potentially, to regulate their production, importation, and use.

Joel Davidson is a third-year student at the William & Mary School of Law. This past summer he clerked for the U.S. EPA's Office of Enforcement & Compliance Assurance, Office of Civil Enforcement, Waste and Chemical Enforcement Division. His opinions do not reflect those of EPA.



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CALIFORNIA RELEASES PROPOSED REGULATIONS FOR SAFER CONSUMER PRODUCTS

Lynn L. Bergeson

The California Department of Toxic Substances Control (CDTSC) released its proposed regulations for safer consumer product alternatives. Under the proposed regulations, CDTSC would create a list of chemicals that it deems toxic and believes could harm people or the environment. CDTSC would prioritize products containing those chemicals based upon such factors as the volume in commerce, the extent of public exposure, and how the product is eventually disposed. Manufacturers of those products would be required to perform an "alternatives assessment" to determine if a viable safer alternative is available. CDTSC will hold a public hearing on November 1, 2010. CDTSC intends to complete the formal process to adopt the proposed regulations by the end of 2010. More information is available at <http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/Proposed-Regulation.cfm>.

CDTSC released a draft proposed regulation on June 23, 2010, and received comments from more than 90 stakeholders, legislators, and the public. According to CDTSC, the comments contained "widespread support for pursuing the basic principles of the Green Chemistry Initiative," and focused on a few remaining issues. In considering comments and potential changes to the June 23, 2010, draft regulations, CDTSC states that it consulted scientists, alternative assessment professionals, and life-cycle analyses practitioners in academia, industry, and private consulting firms. The proposed regulations, which CDTSC has submitted to California's Office of Administrative Law, include changes made as a result of that consultation. According to CDTSC, the changes

- address criticism that the initial scope of chemicals list was too narrow. CDTSC has "significantly broadened" the proposed scope by expanding the lists of authoritative bodies that could be consulted for establishing the chemicals of priority list;

- respond to concerns that the previous draft regulation's lack of deadlines could cause unintended delays. Proposed deadlines are now included for both chemicals and products lists along with specific timelines for various regulatory steps;
- Additionally, CDTSC has added a tiered process for alternative assessments intended to reduce the time for identifying safer alternatives and provide more specific performance targets to move manufacturers through the regulatory process;
- address comments regarding the complexity of the process. CDTSC has simplified the process and clarified what information would be required and how it would be submitted; and
- respond to requests to have public comments on regulatory actions. CDTSC now proposes to allow public comment on any regulatory responses that are triggered by a CDTSC ruling or determination.

The proposed regulations are intended to (1) establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered to be a chemical of concern; (2) establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by priority chemicals; and (3) specify the range of regulatory responses that CDTSC may take following the completion of the alternatives analysis. The proposed regulations include the following timelines:

- (1) The proposed initial list of Chemicals under Consideration shall be issued for public review and comment no later than June 1, 2011;
- (2) The final initial list of Chemicals under Consideration shall be issued no later than March 1, 2012;
- (3) The proposed initial list of Priority Chemicals shall be issued for public review and comment no later than July 1, 2012;
- (4) The proposed initial list of Products under Consideration shall be issued for public review and comment no later than March 1, 2013;

- (5) The proposed initial list of Priority Products shall be issued for public review and comment no later than September 1, 2013; and
- (6) The final initial list of Priority Products shall be issued no later than December 1, 2013.

In preparing the initial list of Priority Chemicals, the proposed regulations state that CDTSC shall consider only chemicals that are one or more of the following:

- (1) Chemicals that are carcinogens or reproductive toxins, or both;
- (2) Chemicals that are listed as having mutagenic properties in the European Union Category 1A or 1B under Annex VI, part 3 of the Regulation; or
- (3) Chemicals that have been determined by the U.S. Environmental Protection Agency to be persistent bioaccumulative toxic chemicals.

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