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PRODUCT STEWARDSHIP & SUSTAINABILITY REPORT

News and Analysis for Industry Marketers and Their Legal Counsel | March 2017

Public Comment Deadlines Near for EPA TSCA Framework Proposed Rules

By Tracy Heinzman, Martha E. Marrapese, and Keith A. Matthews

Last year, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg), which made substantial changes to the Toxic Substances Control Act (TSCA). These changes require the U.S. Environmental Protection Agency (EPA) to make substantive changes in the way that it regulates chemical substances in commerce. One major impact of Lautenberg is that it will substantially expand the agency's review of existing chemicals and bring more attention to their uses in consumer products.

Among the first actions required by the updated law by this June, EPA must promulgate a number of implementation rules that will establish new processes for the regulated community going forward. EPA recently proposed the three core "Framework" rules, which are now open for public comment:

- The first proposed rule is the "TSCA Inventory Notification (Active-Inactive) Requirements" rule, published on January 13, 2017. The public comment deadline is March 14, 2017. This rule would establish procedures to reset the TSCA Inventory of chemical substances used in commerce to identify those that are actually in use today (termed "active") to lay a foundation for EPA to identify chemicals for a more in-depth review for prioritization and risk evaluation. The technical aspects of this rule are discussed on page six of this Newsletter, but in summary: EPA proposes to require manufacturers and importers to notify EPA of any chemical substance manufactured or imported by that manufacturer or importer in the ten years prior to June 21, 2016. EPA would provide processors with a subsequent opportunity to voluntarily report active substances in U.S. commerce. EPA's proposal also includes instructions on re-activating an inactive TSCA Inventory chemical. Companies who need to report will need to be mindful of reporting the proper name for the chemical, documenting that the reported name is in fact on the Inventory, and providing up-front substantiation if they claim the substance name

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Walmart Settles $925,000 Plastics "Greenwashing" Lawsuit in California

By Joseph S. Kakesh

On January 31, 2017, Wal-Mart Stores, Inc. (Walmart) settled a consumer class protection lawsuit brought by 23 District Attorneys offices in California alleging that Walmart sold plastic products that were misleadingly labeled as "biodegradable" and "compostable." As part of the settlement, Walmart agreed to pay $875,000 in civil penalties and to pay $50,000 to CalRecycle, the state recycling agency, to support testing of plastic products that are marketed as compostable or degradable.[1]

This lawsuit is the latest brought by California since the state passed laws governing so-called "green marketing" claims for plastic products.[2] Green marketing, broadly speaking, is the marketing and advertising of products as environmentally safe or even environmentally beneficial. A product is deemed by some to be "greenwashed" if its environmental claims are false, fraudulent, or unable to be confirmed through an acceptable scientific or technical method. California's green marketing laws governing plastics initially were limited to plastic bags and containers, but effective January 1, 2013, they were expanded to include all plastic products, regardless of whether the product is made of plastic alone or in combination with any other material.[3]

California's green marketing laws are more prescriptive and demanding than those enforced by the United States Federal Trade Commission (FTC). The FTC has had regulations governing green marketing claims for all products since at least 1992, when it issued its first "Green Guide." The Green Guide was last updated in 2012. Notably, the Green Guide's regulations governing "compostable" and "degradable" claims are more general and less prescriptive than California laws governing such claims on plastic products. For example, the Green Guide requires only that claims regarding the compostable or biodegradable characteristics of products be based on "competent and reliable scientific evidence to support those claims." 19 C.F.R. §§ 260.7(b), 260.8(b). Relatedly, the Green Guides require that for a marketing claim regarding compostability and degradability not to be misleading, the products must be able to be broken down in a "safe and timely manner," *id.* § 260.7(b), or "within a reasonably short period of time after customary disposal, *id.* § 260.8(b).

In stark contrast to the Green Guides, California's plastics green marketing law obligates the regulated community to meet what the state has deemed to be reliable technical standards before certain green marketing terms may be used. The legislature has identified standards for use of the term "compostable" but has yet to identify standards for the term "biodegradable." *See,* Cal. Pub. Res. Code §§ 42355, 42357(a), 42357(b). This means that marketing claims that plastic products are "biodegradable," "degradable," or "decomposable," or that "in any way imply that the plastic product will break down, fragment, or decompose in a landfill or other environment" are currently banned.[4]

In short, it will take another act of the California legislature before anyone may claim that a plastic product sold in the state is "biodegradable," regardless of whether there is "competent and reliable scientific evidence" to support such a claim. In light of strong consumer sentiment in favor of "green" products, and also in light of recent public attention to the automotive industry and elsewhere regarding green marketing claims,[5] it is unlikely that California will approve technical standards to allow such claims without significant scrutiny. We can likewise expect other states to continue to scrutinize green marketing claims under their own authority as well. ■

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[1] *People of the State of California v. Wal-Mart Stores, Inc. et al.* (Sup. Ct. Napa County, 2017, No. 89). *See also* "DA Announces Settlement with Walmart over 'Greenwashing' Claims," Alameda County District Attorney's Office Press Release February 1, 2017 (Press Release), *available at* http://www.alcoda.org/newsroom/categories/press_releases.

[2] *See, e.g.*, *People of the State of California v. Enso Plastics, LLC, et al*. (Sup. Ct. Orange County, 2011, No. 518091) (bringing claim against companies claiming their water bottles were biodegradable and recyclable).

[3] *See* California Senate Bill 567 (signed into law by Governor Brown on October 8, 2011).

[4] *Id.* § 42357(b); *see also* Press Release, *supra* note 1 ("California law imposes an outright ban on the sale of plastics labeled 'biodegradable' (or labeled with similar language . . . .").

[5] For example, the FTC filed a lawsuit under the Federal Trade Commission Act (FTCA) against Volkswagen with respect to environmental claims made by Volkswagen regarding its diesel emissions that proved to be false. That case resulted in billions of dollars in penalties against Volkswagen. *See Federal Trade Commission v. Volkswagen Group of America Inc.*, 16-cv-1534 (N.D. Cal.).

USDA Publishes Proposed Rule on Environmental Releases of Genetically Engineered Organisms

By Keith A. Matthews

On January 19, 2017, the USDA's Animal and Plant Health Inspection Service (APHIS) published a proposal to revise the 7 C.F.R. Part 340 regulations that implement APHIS's statutory authority under the Plant Protection Act (PPA)[1] to regulate the importation, interstate movement, and environmental release of genetically engineered (GE) organisms that may be plant pests.[2] This proposal represents APHIS's second attempt to overhaul these 30-year old regulations in the last decade. Given the significant deficiencies in the new proposal, it is not clear that the likelihood of this proposal going forward is much greater than the previous proposal. In any event, because the new proposal, rather than provide regulatory relief to innovative agricultural technology developers, likely will increase the unnecessary regulatory burdens that they face, interested parties should take the opportunity to comment on this proposed rule.

The APHIS regulations implementing its authority under the PPA were originally promulgated in 1987, and they have not been comprehensively revised since then.[3] APHIS states that its proposed rule would better enable APHIS to "focus its resources on regulating genetically GE organisms that may pose plant pest or noxious weed risks, and will enhance regulatory flexibilities that foster innovation." The new proposal, however, does not go far enough in providing the kind of meaningful regulatory relief that is needed by agtech developers – and, indeed, may actually unnecessarily increase regulatory burden.

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APHIS first proposed comprehensive revisions to the Part 340 rules in 2008. In response, APHIS received over 5,500 submissions containing 88,000 comments over a 9-month period. In 2015, in significant part based on the critical comments received, APHIS withdrew the proposed rule, pointing to substantive issues raised by some of the comments, "experience we have gained over the past 28 years," and "continuing advances in biotechnology."

In its January 19, 2017 proposal, APHIS notes that "advances in genetic engineering have occurred" since the regulations were promulgated in 1987 and, importantly, that the evaluations associated with over 43,000 regulatory decisions under the 1987 regulations "have provided evidence that most genetic engineering techniques, even those that use a plant pest as a vector, vector agent, or donor, do not result in a GE organism that presents a plant pest risk." Notwithstanding this conclusion, the regulatory scheme proposed by APHIS still requires almost all new GE organisms potentially subject to regulation under the PPA to come to APHIS for a comprehensive assessment of whether the organism constitutes a potential plant pest risk. APHIS describes the proposed approach as follows: "APHIS is proposing a regulatory program in which it first assesses GE organisms to determine if they pose plant pest or noxious weed risks. If APHIS concludes that a GE organism does not pose a plant pest or noxious weed risk, then APHIS would not require a permit for movement of the GE organism. On the other hand, if APHIS determines, based upon the risk analysis that controls on movement are needed, APHIS will work with the requestor to establish appropriate permit conditions to manage identified risks to allow safe movement." APHIS touts this as a change from its current "regulate first/analyze later" approach, but it is not at all clear that moving to a "analyze first/regulate (or not) later" approach will have meaningful burden reduction impact for developers who, in the context of the current system, face a "regulate first/analyze second/deregulate third" approach.

Significant provisions of the proposal include: (1) a new regulatory risk analysis to evaluate GE organisms for noxious weed potential; (2) elimination of the notification process for certain GE organisms in favor of an affirmative permitting scheme; (3) a process for regulating GE organisms intended for use as biological control agents; (4) new criteria for regulation of plants genetically engineered to produce industrial chemicals and pharmaceuticals; (5) new criteria for regulation of small-scale field testing of new plant-incorporated-protectants (PIPs); and (6) a commitment to work with EPA to try to better coordinate regulatory decisions for herbicide-resistant plants and approvals of new uses for the associated herbicides.

That the proposal may not represent a meaningful burden reduction is demonstrated by the types of GE organisms that APHIS proposes to exclude from regulation, and by the fact that no products of gene editing would be presumptively excluded from regulation. First, APHIS proposes to exclude from the definition of organisms subject to regulation: (1) organisms in which the genetic modification consists solely of a deletion of genetic material, or a single base pair substitution that could otherwise be obtained by either chemical or radiation mutagenesis; (2) cisgenic transformations; and (3) organisms that are "the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny." In effect, the description of (3) confirms that "organisms that are not genetically altered will not be considered genetically engineered organisms."

Moreover, the preamble to the proposed rule explains that APHIS will continue to exclude from Part 340 regulation organisms created through chemical or radiation based mutagenesis (82 Fed. Reg. at 7015.2). This highlights a basic flaw in the APHIS regulatory scheme – that it is not

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risk-based, but instead is process-based. Indeed, in that same section of the preamble, APHIS describes mutagenetic modification and does not address at all the potential for risks that is entailed in the creation of "thousands of mutations in a single organism" (82 Fed. Reg. at 7015.3). Nor does APHIS contrast the comparative lack of risk entailed in the relatively precise genetic transformations now possible. Thus, the proposed rule represents a significant missed opportunity for APHIS to begin the transformation of its regulatory system to a risk-based system that is reflective of the near-universal consensus among scientists that agricultural products produced using the techniques of biotechnology do not entail any greater risk than conventionally developed foods. Similarly, the proposal does not meaningfully address gene editing techniques. APHIS thus also misses an opportunity to meaningfully address these significant advances in biotechnological techniques, and to propose what might constitute a rational regulatory approach to biotechnology techniques that entail a further diminution of risk in agricultural product development. It is critical that significant and substantive comments be submitted on the APHIS proposal highlighting these deficiencies.

The APHIS proposal, if promulgated as proposed, would at the very least constitute a missed opportunity for meaningful regulatory relief, and, at worse, could in fact increase regulatory burden. APHIS states that "[t]he rule is likely to result in a broader range of GE organisms being required to come in for review, but fewer would be subject to regulatory controls." APHIS does not expound on the wisdom of requiring "a broader range" of presumptively less risky products to undergo review, when it has already concluded that fewer of those presumptively less risky products will actually be subject to regulatory controls. This begs the question of whether this approach can conceivably be considered a rational regulatory choice.

Individuals and companies that intend to release, move interstate, or import any genetically engineered organism not intended for pesticidal use should carefully review the APHIS proposed rule and consider submitting comments on relevant provisions. It is important to provide APHIS with substantive input, both to possibly influence the final rule, and to preserve important issues for possible judicial challenge. ■

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[1] 7 U.S.C. §§ 7701 – 7786.

[2] On February 10, 2017, APHIS published a notice extending the comment period for the January 19, 2017, proposed rule to June 19, 2017.

[3] 7 C.F.R Part 340, Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests.

EPA Seeks Comments on TSCA Reform Inventory Notification Proposed Rule

By Saskia Mooney

By June of this year EPA must finalize three separate rule packages that will set the ground rules for the agency's review of several thousand chemicals over the coming years and decades. These rules are mandated by 2016's Lautenberg Chemical Safety Act (Lautenberg), which substantially revised the Toxic Substances Control Act for the first time in nearly 40 years. These first three rules will implement the LCSA's mandate to (i) "reset" the TSCA Inventory to identify chemicals actually in use today; (ii) create the prioritization process by which EPA will choose chemicals for review; and (iii) create the risk evaluation process under which EPA will review the chosen chemicals. These proposed rules and areas for comment are discussed in the article on page one of this newsletter.

On January 13, 2017, EPA issued the first of these proposed rules, the "Inventory Reset" rule. The Inventory was initially published in 1979 and now lists 85,000+ chemicals, most of which have never been subject to a risk-based review. The purpose of this proposed Inventory Reset rule is to focus EPA's limited prioritization and risk evaluation resources only on chemicals that could potentially pose a risk to human health or the environment.

The proposed Inventory Reset rule would require chemical manufacturers, importers and, in certain cases, processors to submit electronic notifications to EPA to establish which chemicals on the TSCA Inventory are commercially "active" in the U.S. 15 U.S.C. §§ 2607(b)(4) and (5) and 82 Fed. Reg. 4255. Comments on the proposed rule are due on or before March 14, 2017. EPA must finalize the rule by June 22, 2017.

Overview

For reportable chemicals, EPA is proposing to break the commercial activity notification obligations into two categories: "retrospective" and "forward-looking" activity notification, with each type reported on yet-to-be developed "Notice of Activity" (NOA) forms: Form A and Form B. These forms will require information on chemical identity, type of activity (manufacture, import or processing), dates of manufacture or processing, and whether existing confidential chemical identity claims are to be maintained.

Retrospective Commercial Activity Notices

Mandatory for manufacturers (a term which, under TSCA, includes importers), "retrospective" reporting on NOA Form A would establish which chemicals have been active and inactive in the recent past. But Lautenberg requires EPA to focus its energies by requiring retrospective notification only on chemicals manufactured between June 21, 2006 and June 21, 2016 (the "look back period"), which EPA has proposed.

EPA also is proposing to allow chemical processors to file "retrospective" reports on a voluntary basis. Processors might choose to do so as a protection, for example, in case all of a chemical's manufacturers fail to report their chemical(s) to EPA. This would preclude future forward-looking reporting and possible related business delays for the processor.

Manufacturers and importers would have 180 days after the final rule is published to file the retrospective NOA Form A. Processors would have 360 days. This provides processors additional time to assess manufacturer reporting and avoid unnecessary duplicate reporting. Inactive chemicals will remain on the Inventory and be designated as such, but EPA will not expend resources prioritizing and assessing them for risk.

Forward-Looking Commercial Activity Notices

Forward-looking commercial activity notification would provide a mechanism for future manufacturers or processors of inactive chemicals to re-

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establish them as active with EPA to avoid TSCA violations. Under Lautenberg, it is a violation to manufacture or process an inactive substance for a non-exempt commercial purpose without first notifying EPA. EPA is proposing to require manufacturers and processors to file prospective notices on NOA Form B. Once submitted, the chemical will be deemed "active," and the filing entity can begin manufacturing or importing as soon as the form is filed. To maintain the accuracy of this reporting, however, forward-looking notifications cannot be filed more than 30 days in advance of the date of actual manufacturing or processing.

Notification Exemptions

To ease burdens on industry, EPA is exempting from notification obligations and automatically declaring as active all non-confidential chemicals reported to EPA under the 2012 and 2016 TSCA Chemical Data Reporting (CDR) rules. However, confidential chemicals from these CDR reports will need to re-report to maintain confidential status.

EPA also is exempting from notification certain naturally occurring substances, chemicals produced in small quantities for R&D, chemicals imported as part of articles, and certain chemical categories described in 40 C.F.R. §§ 720.30(g) or (h). In addition, chemical substances added to the Inventory on or after June 22, 2016 through the New Chemicals pre-manufacture notice (PMN) process would be automatically designated as active.

Interim Substances List

Prior to publication of the final Inventory Notification Rule, EPA must issue an "interim" active substances list consisting of all chemicals reported under the TSCA 2012 CDR rule in order to assist industry to determine their notification obligations. That list later will be expanded after the 2016 CDR data becomes available.

How to Maintain Confidential Status

Finally, under the proposed rule, the confidential portion of the TSCA Inventory would continue to be maintained. Persons who wish to report chemical substances listed on the confidential portion of the TSCA Inventory would be required to report the chemical substances using a TSCA Accession Number and generic name.

Relatedly, however, the new rule also would substantially revise portions of the TSCA confidential business information (CBI) rules. If a company manufactures or imports a chemical that is currently on the confidential Inventory, and it wishes to maintain its confidential status, that request would have to be asserted in NOA Form A. If a chemical is identified as "active," but no manufacturer or processor requests on their NOA Form A to maintain the existing CBI claim for chemical identity, EPA would move the chemical to the non-confidential portion. However, manufacturer substantiation that the claim is valid would not be required at the time NOA Form A is submitted. Instead, that issue will be addressed in a substantiation rule to be proposed within one year of publishing the first compiled list of active chemicals.[1]

In contrast, requests to maintain existing CBI claims for a specific chemical identity on the forward looking NOA Form B will need to be substantiated not later than 30 days after submitting the NOA Form B or at the same time that NOA Form B is filed. The same set of questions used for NOA Form A will be required for NOA Form B.[2] ■

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[1] Nonetheless, a manufacturer can voluntarily substantiate chemical identity confidentiality claims up front with the NOA Form A submission by answering eleven questions that EPA has included in the current proposed rule. These questions seek to establish whether or not a chemical's identity is legitimately protected, and that the information is unavailable to the public through means other than the TSCA Inventory (*e.g.*, Can the substance be reverse engineered? Is it patented? Is its identity anywhere else in the public domain (*e.g.*, journals, promotional materials). *See* 40 C.F.R. § 710.37(a)(1)(iii).

[2] Certain other elements of NOA Forms A & B (other than chemical identity) can also be claimed as confidential but substantiation is required when NOA Form A or B is filed. Responses to the substantiation questions set forth at §710.37(b)(1) must be included with the submission.

Vermont and Other States Consider Chemical Monitoring Bills

By Martha E. Marrapese

A bill introduced in the Vermont State Legislature, HB 268, would amend the Vermont State Toxics Use Reduction and Hazardous Waste Program to build upon the state's current reporting requirements for 66 chemicals in children's products and expand the program to a broad range of other consumer products. The enactment of TSCA reform at the federal level does not preempt reporting requirements such as the one proposed in Vermont. The introduction of this bill at this juncture, before EPA has even had time to get implementation rules for existing chemical reviews in place, signals that in Vermont, there is continued interest in pursuing consumer product regulation.

The Vermont bill seeks to establish an Interagency Committee on Chemical Management. This Committee would evaluate chemical inventories and identify potential risks from the inventories. The bill would also establish a private right of action for medical monitoring damages and authorizes a citizen suit of action for relief for violation of solid waste or hazardous waste permits, standards, regulations, etc.

The bill would require testing of new groundwater sources and potable water supplies for specified chemical parameters. It would expand the current reporting requirement for children's products to require manufacturers of all consumer products—not just children's products—to notify the Department of Health of the presence of any of the 66 chemicals currently listed by the state as chemicals of high concern to children as well as any new high concern chemical designations by the state.

Beginning July 1, 2017, the list of chemicals would be reviewed biennially to provide opportunity for additional chemicals of high concern to be included in the reporting requirements. The definition of a "consumer product" is proposed to mean "any product that is regularly used or purchased to be used for personal, family, or household purposes" with a number of exceptions, including but not limited to:

- products primarily used or purchased for industrial or business use that does not enter the consumer product market or is not otherwise sold at retail;
- foods and beverages; tobacco products; EPA-regulated pesticides; and FDA-regulated drugs;
- consumer electronic products;
- inaccessible components of a consumer product; and
- batteries.

Additionally, the bill would prohibit the manufacture, sale, or distribution in the State of dental floss or food contact substances that contain perfluorooctanesulfonic acid.

According to figures collected by NGO Safer States, Vermont's measure is one of almost 100 chemical regulations that are under consideration in 23 states. For example, last Spring, Washington State banned five flame retardants used in children's products and residential furniture. Although several states that have previously enacted flame retardant restrictions in certain products, Washington is the first to include tetrabromobisphenol A (TBBPA). Additionally, the Washington Department of Ecology is required to review six additional flame retardants to be considered as high concern to children. Industry opposition to the measure had hoped the state would have allowed the federal review of flame retardant clusters to play out before taking regulatory action at the state level.

To add to the list, Minnesota has recently introduced SB 716. The bill would amend Minnesota statutes that regulate chemicals of high concern in children's products. The bill would require both proposed and adopted changes to the list of priority chemicals to be published

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on the Department of Health's website and the State Register. The bill also lays out reporting requirements for manufacturers and distributors of children's products that contain designated priority chemicals unless identified as exempt.

As our readers are aware, and as summarized in this Newsletter, the Toxic Substances Control Act (TSCA) is currently undergoing major reform. A central issue in ongoing discussions is the extent to which federal regulation of these substances will preempt state activities. Several state attorneys general and NGOs have advocated the preservation of states' regulatory authority, while industry groups have pushed for stronger federal preemption. However, it is likely that state legislative efforts to ban specific chemicals that the EPA has acted on will be preempted under a reformed law. ■

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U.N. Releases Report: *The Future of Food and Agriculture: Trends and Challenges*

By Keith A. Matthews

On February 22, 2017, the United Nations Food and Agriculture Organization (FAO) released a report on 21st century agriculture and food security. Titled "The Future of Food and Agriculture: Trends and Challenges" (http://www.fao.org/publications/fofa/en/), the report raises serious concerns about the likelihood that future global populations will have uniform food security. The report finds that the primary challenges jeopardizing food security are intensifying pressures on natural resources, increasing global socioeconomic inequality, and the undeniable impacts of climate change.

The report notes that significant worldwide progress has been made during the past century "in improving human welfare." This includes progress in reducing global hunger, as worldwide agricultural production has more than tripled between 1960 and 2015. These gains in worldwide food production are the result of the technologies associated with the "Green Revolution," and greater use of land, water and natural resources in agricultural production. However, the report notes, these gains "have often come at a heavy cost to the natural environment," as forests disappear, groundwater sources are depleted, and biodiversity declines.

Moreover, according to FAO, the future portends the likely possibility of a global population of 10 billion people by the year 2050, resulting in a rise in global demand for agricultural production of up to 50% over present levels. Coupled with changing diets that will demand more protein, fruits and vegetables, and climate change-induced increasing variations in precipitation and severe weather events, along with more droughts and floods, the strains on food production will be substantial.

The core question addressed by *The Future of Food and Agriculture* is whether, collectively, the world's agriculture and food systems will be able to sustainably meet the nutritional needs of the global population. In short, the report concludes that global food systems are capable of producing enough food to meet the demands of growing human populations, but that doing so sustainably will require "major transformations" in the way that food is grown and distributed.

Of course, one of the major transformations that will be required will be greater acceptance of agricultural technology, including agricultural biotechnology – which can be a major driver of

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improvements in productivity and resource-use efficiency. The report recognizes this: "The world will need to shift to more sustainable food systems which make more efficient use of land, water, and other inputs and sharply reduce their use of fossil fuels, leading to a drastic cut of agricultural green-house gas emissions, greater conservation of biodiversity, and a reduction of waste. This will necessitate more investment in agriculture and agrifood systems, as well as greater spending on research and development, the report says, to promote innovation, support sustainable production increases, and find better ways to cope with issues like water scarcity and climate change."

While the report is reasonably optimistic that the challenges to achieving global food security can be met, agrifood observers should note that it is not a given that the necessary investments in research and development and corresponding changes in regulatory policy will occur. Regulatory authorities in the European Union and the United States, which are generally considered progressive jurisdictions, have yet to institute fully risk-based regulatory approaches to agricultural biotechnology. Rather, in both the EU and the United States, agricultural biotechnology has been subjected to policy-based regulatory hurdles that have delayed the development of promising technologies and imposed significant unnecessary costs on vital agronomic advances. It is crucially important that these policy-based impediments to regulatory approvals be replaced by decisionmaking that is based on the actual risks of the technologies, and that takes full account of the benefits of this technology, if the challenges of the coming century are to be met. ■

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as confidential. Areas in which we recommend submitting comments by the 14th include:

- Requesting guidance on reporting considerations unique to importers of mixtures. These companies will need to work out the mechanics of reporting compliant ingredients whose identities are claimed as confidential by their upstream suppliers.
- Asking for guidance on when companies need to report byproducts as active substances.
- Supporting EPA's proposed exemptions for chemicals imported as part of an article, naturally occurring chemicals, impurities, and noncommercial byproducts.
- Confidential business information protection is complex in connection with health and safety information. It would be useful to have more guidance when making these submissions.

- The second proposed rule sets forth procedures and criteria that EPA proposes to use in prioritizing chemicals as high or low priority for subsequent risk evaluation. The public comment deadline is March 20, 2017. EPA designation of a chemical as high or low priority for risk evaluation will be extremely important. Chemicals designated as high priority will essentially be "shortlisted" for risk evaluation, whereas designation as low priority essentially constitutes a finding that risk evaluation is not necessary. We think the following considerations are important to consider and comment on:
  - Will EPA prioritize uses, or determine that a chemical meets the safety standard for a given use(s) during the prioritization stage?
  - In ultimately selecting a chemical substance on which to initiate prioritization, should EPA use criteria beyond those provided by Congress?
  - Should similar uses or similar chemistry be used to prioritize categories of chemical substances?
  - Should EPA place a lower priority on substances that have undergone new chemical reviews compared to chemicals grandfathered onto the Inventory that have never been reviewed?

  Areas in which the Agency is seeking comments include:

  - Should EPA define best available science, weight-of-the-evidence and sufficiency of information? Is it problematic not to define these terms?
  - How should EPA structure and seek public input during pre-prioritization?
  - Can and should EPA consider substitutes in the prioritization process?
- The third proposed rule is the "Procedures for Chemical Risk Evaluation Under the Amended TSCA." The public comment deadline also is March 20, 2017. The risk evaluation rule will establish the procedures that EPA will use for establishing the scope of a risk evaluation, conducting hazard and exposure assessments, and characterizing risks. EPA, for example, is proposing that any issues and concerns not raised during a public comment period cannot be raised later. What happens if information is newly discovered or becomes available later during the three and half year period these risk evaluations are underway?

  Some of the areas in which EPA is asking for comments include:

  - The need for regulatory text requiring the use of specific elements of a systematic review approach for hazard identification.
  - How can the proposed rule provide additional transparency, public accountability and opportunities for public participation?

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- Should the agency define or provide guidance on the circumstances that give rise to a finding of unreasonable risk to improve certainty and predictability in the process?
- To what extent should existing EPA risk assessment guidance be updated or codified?
- How should EPA gather information to support manufacturer requests?
- Do all risk evaluations warrant peer review?
- How should interagency cooperation be managed?

Once promulgated, these rules will govern how the regulated community must interact with EPA in the context of chemical reviews for many years to come. The opportunity for public comment is a critical time to foster inquiry and engagement, in order to establish a reasonable and common understanding of what to expect, what is expected from industry, and establish government accountability. These rules will benefit by being informed by the realities and needs facing manufacturers, importers, processors and end users of TSCA-regulated substances. The way that EPA conducts these procedures will be extremely important to the ultimate determination and communication of the risks associated with a particular chemical. ■

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