

The Regulation of Renewable Chemicals under the Toxic Substances Control Act (TSCA)

By Lynn L. Bergeson

Biobased Chemicals—a Fast-Growing Sector—are Subject to TSCA

The United States government is committed to reducing our dependence on foreign oil and to greening our economy. The production of chemicals and fuels from renewable feedstocks is an important component in achieving these goals. The share of biobased chemicals produced by the global chemical industry is expected to grow from two percent in 2010 to 22 percent by 2025.¹ In the short term, biobased chemicals production capacity is expected to double in market potential to \$19.7 billion by 2016.²

The application of the Toxic Substances Control Act (TSCA) to biobased chemicals is sometimes overlooked, given the enthusiasm supporting the commercialization of biobased products. This article explains TSCA's application to these products and outlines strategies to ensure the successful marketing of biobased chemical products.

Biobased Chemicals

Biobased chemicals are made from animal fats, vegetable oils, tall oil, tall oil fatty acids, and naval stores (e.g., turpentine and rosin), among other feedstocks. Today, biobased chemicals' use as a feedstock by the chemical industry replaces approximately 10 percent of the petroleum consumed in the United States. Thus, the development and commercial introduction of renewable biobased alternatives can help to reduce the environmental footprint attributable to petrochemicals.

Biobased substances include many products. For TSCA purposes, these products can be placed into two broad groupings: chemicals and biofuels. While biofuels may be the more well-known category of products

derivative of renewable feedstocks (most notably corn and soybeans) compared to biobased chemicals, the primary focus of this article is on biobased chemicals, as TSCA has its greatest potential application within this product grouping.

TSCA Overview

TSCA is the federal law that governs new and existing chemical substances throughout their production, distribution, use, and disposal.³ “Chemical substances” are defined broadly to include “any organic or inorganic substance of a particular molecular identity,” excluding pesticides, drugs, and food, which are regulated under other federal laws.⁴ That biobased substances are derived from renewable feedstocks does *not* preclude TSCA’s application to them. The focus here is on understanding the provisions critical to recognizing and appreciating how TSCA applies to biobased chemicals.

Key TSCA Provisions

Three TSCA sections are relevant to this discussion: TSCA Section 2, Section 8, and Section 5. TSCA Section 2(b) outlines TSCA policy, and TSCA Sections 2(b)(1) and 2(b)(2), respectively, discuss the need for test data to be developed on the effects of chemicals and for adequate regulatory authority to control chemicals presenting “unreasonable risks” to health and the environment. Section 2(b)(3) clarifies that this authority should be exercised as not to impede or create “unnecessary economic barriers to technological innovation.” TSCA Section 2(c) states that it is Congress’s intent that the United States Environmental Protection Agency (US EPA) “consider the environmental, economic, and social impact” of any actions taken. Read in combination, TSCA Sections 2(b) and (c) confirm that in taking action to control unreasonable risks, EPA is to consider and balance the risks, costs, and benefits presented.

TSCA Section 8(b)(1) directs the US EPA to compile and maintain the TSCA Chemical Substance Inventory of each chemical substance that is domestically manufactured or imported into the United States. The initial

Inventory was created in 1978-79. During this time period, chemicals were listed on the Inventory automatically and without the US EPA's review. New substances are added to the TSCA Inventory through a process that involves submission of a Premanufacture Notification (PMN). Approximately 1,000 to 2,000 new chemical substances undergo this process each year. The US EPA reviews the new chemical and imposes any needed regulatory requirements. Then, after a notice to the US EPA by the notifier has been filed confirming that manufacture of the chemical has commenced, the agency adds the chemical to the Inventory.

Given the timing of the TSCA Inventory's creation in the late 1970s, the organic chemicals listed within it reflect the commercial chemistry of that time, which was largely petroleum-based. Thus, a large number of petroleum-based feedstocks are listed on the original Inventory. While biobased chemicals were present on the original TSCA Inventory, their number and variety were limited in comparison to petroleum-based substances. As a result, many biobased chemicals will be considered "new chemicals" subject to TSCA Section 5 notification.

Manufacturers of biobased chemicals as well as their downstream customers must understand the regulatory implications of the TSCA status of their biobased chemicals. Manufacturers and importers of chemical substances considered "new" must notify the US EPA of the chemical substance through the submission of a PMN prior to commercialization of the product. Unless a PMN exemption applies, a company must submit a completed PMN form to the agency at least 90 days before commencing the manufacture of a new chemical substance. By statute, the US EPA review process takes no more than 90 days, but in actuality, it can take considerably longer. The uncertainty of the review's outcome is the source of considerable business anxiety.

Under TSCA Section 5, the US EPA assesses the PMN to determine if a new chemical presents potential "unreasonable risks." TSCA Section 5(d)(1) requires that certain information be provided in the notice. This information includes, among other things:

- Description of the chemical.
- Estimated annual production volume.

- Intended uses.
- Worker exposure information.
- Any test data in the possession of the notifier on health and environmental effects.

Information provided in an “Optional Pollution Prevention Information” section” (e.g., information on expected net benefits, such as reductions in risk or releases associated with the new chemical, energy or product efficiency, use of less toxic intermediates, and related factors) is also requested.

Regulatory Outcomes of PMN Review

If the US EPA’s review identifies risk concerns with a new chemical, TSCA Section 5(e) authorizes the agency to issue consent orders allowing the manufacturer to market the chemical only in conformance with certain enforceable conditions.⁵ The agency has discretion to limit the manufacture, processing, distribution, use, or disposal of the chemical to address the concerns its review has revealed. Once the chemical is commercialized, subject to the terms and conditions set forth in a consent order, the notifier is legally required to observe these terms and conditions as a condition of commercialization.

The moment the chemical has been placed on the TSCA Inventory, it is no longer considered “new,” however, and other manufacturers of the same chemical may manufacture it without submitting a PMN, provided that the same use patterns are observed. TSCA Section 5(a)(2) authorizes the US EPA to require notifications on “significant new uses” of existing chemicals. In promulgating a Significant New Use Rule (SNUR), the agency is required to consider “all relevant factors,” including, for example, the projected volume and the extent to which a new use increases the magnitude or changes the type of exposure.

To avoid the competitive imbalance that would otherwise ensue if follow-on manufacturers were free to manufacture and use the chemical without the commercial restrictions imposed on the original PMN submitter under the TSCA Section 5(e) consent order, the US EPA can issue a SNUR

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imposing the consent order's requirements on subsequent chemical manufacturers. These are known as "Section 5(e) SNURs."

For other substances, the US EPA may determine that although the manufacture, processing, and/or use of the chemical substance as described in a PMN does not present health and/or environmental risks requiring agency action, there are other potential uses not described by the PMN submitter that the US EPA determines represent "significant new uses" requiring a SNUR. The US EPA can use its SNUR authority to regulate such potential uses. These are referred to as "non-5(e) SNURs" to reflect the fact that no Section 5(e) consent order was issued to the original PMN submitter.

When Commercializing Biobased New Chemicals, Remember This

A question that needs to be asked well in advance of any plans for commercial activities is whether a biobased chemical is new or existing. If an Inventory listing for the chemical(s) can be established, the PMN hurdle as a new chemical can be avoided. However, if one or more of the chemicals is subject to TSCA's new chemical notification, this point needs to be recognized and addressed early on. When the US EPA targets a chemical for regulation, this will result in unplanned delays that can potentially last from months to years, creating a barrier to commercialization.

Given the origins of the Inventory with its prevalence of petroleum-based substances, a number of anomalous situations arise. While the US EPA is generally supportive of new chemistries that can replace older, petroleum-based chemistries, biobased chemicals will continue to be the subject of regulatory scrutiny as "new" chemicals. This can lead to a disproportionate amount of scrutiny at the point of commercial introduction when these new, presumptively greener chemicals are attempting to break into the market and compete with established, non-renewable chemicals, which as Inventory-listed substances, escape review under TSCA.

Emphasizing the pollution prevention benefits of a biobased new chemical is critical. The PMN form includes a section entitled "Optional Pollution Prevention Information." This section should be used to discuss the benefits of the new chemical. In developing the points of this discussion, it may be helpful to view this task as essentially, "making the case," for the

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new, biobased chemical introduction. Points that notifiers will want to consider making should establish:

- Renewable sourcing.
- Pollution prevention or risk reduction benefits (these could include reduced pollution, role of, or contribution to, recycling [e.g., uses agricultural waste], use of safer processes or products, avoidance of toxic intermediates, reduced or less toxic waste generation, energy efficiency, relatively safer or less polluting than competing existing chemicals, and related considerations).
- Cost or performance benefits (these could include improved product performance, lower costs, more energy efficient production, processing, or use, and related factors).

How to Manage PMNs for Biobased Chemicals to Help Ensure Success

Ensure TSCA Compliance Is a Core Element of the Business

Plan: Know the TSCA requirements, understand the regulatory responsibilities, and be prepared to meet both the requirements and the responsibilities as part of a business development plan for the biobased chemical.

Understand the Relevance of Chemical Nomenclature and

Naming Conventions: Recognize and understand the importance of how a chemical is named and identified and how that can affect new chemical responsibilities. It is important to understand the relevance of chemical nomenclature and naming conventions to the manufacturing process.

Know the TSCA Review Process: A basic understanding of the US EPA's review process and regulatory approach is essential. While the agency works off of the information included in the PMN, it also considers information on other, "related" cases, applies structural activity relationship analysis when hazard test data are not available, and uses assumptions about likely exposures and releases if information is not provided in the PMN.

Consider Testing in Advance of PMN Notification: If the US EPA is likely to impose testing requirements on a biobased new chemical, consider the benefits of either doing the testing in advance of the notification or, if future commercialization plans involve additional, structurally similar new chemicals, whether it might make sense to develop a testing strategy that would encompass and account for the range of new chemicals likely to be introduced. If other firms are known to be active in this area of new chemical development, significant cost saving and advocacy opportunities may be realized by organizing consortia to share the costs and responsibility of testing.

Work with the US EPA: Regardless of the approach taken, it is always wise to consult with the agency before embarking on chemical-specific testing or developing and implementing a testing strategy. Such consultation promotes an understanding of the US EPA's views on, and receptivity to, the proposed approach.

Be an Advocate: Advocate the benefits of a biobased new chemical. This should involve careful preparation of the points that can be made in the "Optional Pollution Prevention Information" section of the PMN notice. Beyond that, there may be value in recognizing and advocating the "big-picture" policy benefits of biobased chemicals to ensure that the US EPA's new chemical reviewers are aware of, and will appropriately consider and appreciate, those aspects.

While US EPA staff occupying the upper levels of management are likely aware of United States government policy drivers (such as the recently announced National Bioeconomy Blueprint⁶), this awareness may or may not have reached the scientists and other career agency staff members who are actually reviewing PMN notifications. As with testing, while individual companies can and should emphasize relevant policy drivers in their interactions with the US EPA's new chemical reviewers, there may also be considerable value in—and a role for—consortia to press these points with the US EPA.

¹ *U.S. Biobased Products Market Potential and Projections Through 2025*, M.A. Williamson (editor), 2010,
p. 1.

² Lux Research, Inc., *Global Bio-based Chemical Capacity Springs to Scale* (Dec. 2011), available at
https://portal.luxresearchinc.com/research/report_excerpt/9418.

³ 15 U.S.C. §§ 2601-2692.

⁴ TSCA § 3(2), 15 U.S.C. § 2602(2).

⁵ *See* TSCA § 5(e)(1)(A), 15 U.S.C. § 2604(e)(1)(A).

⁶ White House Office of Science and Technology Policy, *National Bioeconomy Blueprint* (Apr. 2012),
available at <http://www.whitehouse.gov/blog/2012/04/26/national-bioeconomy-blueprint-released>.

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