# New Technologies and an Old Law: Renewable Chemicals Invite Challenges under TSCA

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The resurgence of chemical production derived from renewable feedstocks reflects the new business imperatives of which chemical product manufacturers are all keenly aware: produce greener chemicals and reduce carbon footprints. Careful review of the Toxic Substances Control Act (TSCA), a law enacted almost forty years ago during the heyday of petroleum-derived chemical production, suggests that more can be done now to promote the commercialization of renewable chemicals to achieve these imperatives. This article describes renewable chemicals, provides a brief overview of TSCA, discusses key TSCA challenges as applied to them, and suggests actions to ensure TSCA's implementation now and potential future TSCA revisions to facilitate the commercialization of renewable chemicals.

Renewable chemicals, also referred to as biobased chemicals, are chemicals derived predominately from plants and, to a lesser extent, animals. While there is no formal definition, the Farm Security and Rural Investment Act of 2002 defines "biobased product" as a product composed "in whole or significant part, of biological products or renewable domestic agricultural materials." Biobased products are varied but are generally viewed as falling into two broad groupings: biobased chemicals and biofuels. Biofuels are attracting most of the headlines these days, particularly given the ongoing Renewable Fuels Standard debate. Biobased chemicals are, however, rapidly gaining momentum and are the focus of this article as TSCA has its most significant application to renewable chemicals.

Contrary to popular belief, renewable chemicals are not new. Prior to the 1920s, a large percentage of chemicals were alcohols derived from wood and grain. Many solvents and organic acids were products of fermentation until the middle of the twentieth century, when fossil energy displaced fermentation due to the inexpensive and apparent abundant supply of fossil feedstocks. The pendulum is swinging back in a big way. The gas boom is a key driver and has benefited both the renewable and petrochemical manufacturing sectors. Two other drivers—carbon footprint reduction and broad downstream chemical user interest in green chemicals—have accelerated and intensified interest in the renewable chemicals market, which is expected to reach $83.4 billion by 2018.

Renewable or not, plant-based chemicals are just that—chemicals—and are subject to TSCA. The federal law that governs chemical substances throughout their lifecycle, TSCA, is a complicated and highly nuanced law, and no attempt is made here to dig deeply into how the law in its totality applies to renewable chemicals. The U.S. government, especially the U.S. Environmental Protection Agency (EPA) that implements TSCA, strongly encourages the development of biobased products as a matter of policy. TSCA is a mature statute, and it grew up largely in the company of petroleum-derived chemicals. TSCA regulations, customs, and practices are just as applicable to renewable chemicals, however, but the fit can be awkward, creating tension between meeting policy goals and satisfying TSCA legal requirements for renewable chemicals. The focus here is on challenges unique to the renewable chemical industry under certain TSCA provisions, specifically in the areas of chemical nomenclature, risk mitigation, and risk-benefit determinations pursuant to TSCA Section 2, Section 8(b)(1), and Section 5 www.gpo.gov/fdsys/pkg/STATUTE-90/pdf/STATUTE-90-Pg2003.pdf.

Renewable chemicals used for commercial purposes under TSCA's jurisdiction (i.e., use other than as drugs, pesticides, food, or related applications that are subject to other federal laws) and not otherwise exempt are required either to be listed on the TSCA Chemical Substance Inventory or submitted to EPA for premarket review. Whether premarket review is needed is a determination that needs to be known well in advance of any plans for commercial activities. If TSCA Chemical Substance Inventory listing for the chemical(s) can be confirmed, the Premanufacture Notification (PMN)—the name of the official premarket notification—hurdle can be avoided entirely. If one or more of the chemicals is subject to TSCA new chemical notification, this point needs to be addressed early as part of a company's business development plan for the product. Statistically, most new chemicals submitted for EPA review are not ultimately further regulated under TSCA Section 5 after the PMN is submitted. Those new chemicals that are targeted for further regulation, however, may be in for a bumpy ride as the regulatory process inevitably results in unplanned delays, potentially lasting for months to years and, under the worst case, could result in the imposition of significant regulatory barriers that can diminish market access and limit potential growth.

TSCA Sections 2(b)(1) and 2(b)(2), respectively, address the need for industry to develop test data adequate to describe the effects of chemicals and for EPA to have adequate regulatory authority to control chemicals believed to present "unreasonable risks" to health and the environment.

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Importantly for present purposes, TSCA Section 2(b)(3) clarifies that this authority should not "impede unduly or create unnecessary economic barriers to technological innovation." TSCA Section 2(c) reflects Congress' intent that in implementing TSCA, EPA "shall consider" the environmental, economic, and social impact of regulatory actions taken under TSCA. Read together, these provisions make clear that in seeking to address unreasonable risks under TSCA, EPA must consider and balance the risks, costs, and benefits presented.

TSCA Section 8(b)(1) directs EPA to compile and keep current a list, formally referred to as the TSCA Chemical Substance Inventory, of each chemical substance that is manufactured in or imported into the United States. The initial TSCA Chemical Substance Inventory was developed from 1978 to 1979, using input from the chemical industry that allowed "existing" chemical substances already in commerce to be grandfathered and automatically included on the TSCA Chemical Substance Inventory without any EPA review. New substances, meaning any substance not listed on the TSCA Chemical Substance Inventory, may be added to the TSCA Inventory (and thereafter be considered existing) by an administrative process that involves submission of a PMN.

**EPA is strongly supportive of new chemistries that can replace incumbent, non-renewable petroleum-based chemistries.**

Given the late 1970s timing for creation of the TSCA Chemical Substance Inventory, the organic chemicals listed on it are reflective of the commercial chemistry of that time, which consisted largely of petroleum-based chemicals. Many of these chemicals are complex mixtures with a singular chemical identifier that includes a process description. In other words, the names of these complex substances explicitly reference petroleum sourcing in their name. According to the EPA rules that dictate how chemicals should be named for TSCA Inventory purposes, if a similar chemical is manufactured using a different process that is not petroleum sourced, it is considered a different chemical. That means that if a substance is derived from a biobased feedstock, but is virtually indistinguishable from a petroleum feedstock substance, the manufacturer of the renewable substance would be unable to rely on the petroleum process chemical name for purposes of determining if the renewable chemical is listed on the TSCA Chemical Substance Inventory. While biobased chemicals were in commerce at the time the original TSCA Inventory was created, their number and variety were limited in comparison to petroleum-based substances with the result that many biobased chemicals may well be considered "new" chemicals subject to TSCA Section 5 premarket notification. The implications of this inconvenient fact are significant, as discussed below.

TSCA Section 5 governs the manufacture in and import into the United States of chemical substances considered new. The EPA review process by statute takes no less than ninety days, but can take considerably longer. Unsurprisingly, although the new chemical review process is sophisticated and routinely receives high praise from industry stakeholders, its application to renewable chemicals is not always clear, straightforward, or quick.

Under TSCA Section 5, EPA assesses the information provided in a PMN, augmented by application of EPA's own scientific analysis. This analysis consists of sophisticated predictive modeling methodologies based on Structural Activity Relationship (SAR) data from analogue chemical substances to determine if a new chemical presents potential unreasonable risks. Analogue data are used because TSCA does not require the development and submission with the PMN of any minimum amount of data. Most PMNs do not contain data pertinent to the new chemical, and EPA relies instead on SAR analogue data to assess the potential risks of a new chemical. Other types of information that must be included in the PMN pursuant to TSCA include a description of the new chemical substance, estimated annual production volume, intended uses, worker exposure information, information on releases to the environment, and any test data in the possession of the notifier on health and environmental effects, that as noted, typically are not available.

Following PMN review, EPA can take a variety of regulatory actions under TSCA Section 5(e) if certain determinations can be supported. The first involves a "risk-based" finding under TSCA Section 5(e)(1)(A)(ii)(I), where EPA determines that the new chemical "may present an unreasonable risk" to health or the environment. A determination of "unreasonable" risk involves consideration of cost-benefit and relative risk factors, including, for example, the cost or performance-based benefits of the new chemical, the economic impact of testing or regulation, and the relative risks of the new chemical in comparison to existing chemical alternatives.

The second involves an "exposure-based" finding under TSCA Section 5(e)(1)(A)(ii)(II), where EPA determines that the new chemical's production is "substantial" and that it has substantial or significant exposure or release. By applying its section 5(e) authority, EPA can prohibit or limit manufacture, processing, use, or disposal of the new chemical pending development of test data needed to support a reasoned evaluation of potential risks. EPA's election to pursue any one of these authorities could spell commercial disruption for the chemical producer and its downstream customers, and invite delays and other market challenges.

## *TSCA Challenges for Renewable Chemicals*

While renewable chemicals were included on the original TSCA Chemical Substance Inventory, the vast majority of grandfathered chemical substances consist of chemicals derived from petroleum feedstocks. This means that unless otherwise exempt, renewable chemicals not explicitly listed on the TSCA Inventory are likely to be subject to premarket review under TSCA Section 5. Renewable chemical producers face challenges, largely occasioned by TSCA's maturity and its alignment with petroleum-derived chemical substances. We discuss below several such challenges, each illustrative of regulatory anomalies that need to be addressed to ensure the promise of renewable chemicals is not undermined by unintended regulatory barriers imposed under TSCA.

## Nomenclature Challenges

One of the first challenges renewable chemical manufacturers face is determining whether a renewable chemical is in fact listed on the TSCA Chemical Substance Inventory. This challenge is the result of byzantine and complex Inventory "naming" conventions that tend to disfavor renewable chemical substances. Given the way that the TSCA Chemical Substance Inventory has evolved with its heavy emphasis on petroleum-based substances, a number of anomalous situations arise, the most obvious and potentially disruptive being the requirement for premarket review of many renewable chemicals. EPA is strongly supportive of new chemistries that can replace incumbent, nonrenewable, petroleum-based chemistries. That said, however, most renewable chemicals are and will continue to be the subject of regulatory scrutiny by EPA as "new" chemicals. This inevitably leads to a disproportionate amount of regulatory scrutiny at the point of commercial introduction when these new chemicals are attempting to break into the market and compete with established, nonrenewable, incumbent chemicals that escaped regulatory scrutiny under TSCA's grandfathering provisions. Nomenclature, therefore, becomes critical because whether a chemical is considered "new" is a function of whether it is listed on the TSCA Inventory. To illustrate these unique challenges, we consider several examples.

***Naturally Occurring.*** A nomenclature issue of special relevance to renewable chemicals involves naturally occurring substances. "Naturally occurring substances" are defined as a "combination that occurs in nature is a chemical substance and not a mixture." Under EPA's regulations, certain naturally occurring chemical substances are automatically listed on the TSCA Inventory, including chemical substances that are naturally occurring and that are unprocessed or processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; by heating solely to remove water; or that are extracted from air by any means. Examples of such substances include raw agricultural commodities such as corn and soy; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

EPA's treatment of naturally occurring substances reflects the agency's general view that a certain amount of minimal processing does not materially alter a substance such that the substance continues to retain its naturally occurring status notwithstanding minimal processing. The act of mechanically isolating a substance from nature, for example, does not alter its status as naturally occurring. If, however, a chemical substance is chemically extracted or produced from naturally occurring substances by chemical treatment, it is not considered naturally occurring for TSCA Inventory purposes and these substances are subject to PMN requirements if they are not already listed on the TSCA Inventory. The line between "minimal processing" and chemical extraction is fuzzy, and in most cases, EPA can be expected to determine a PMN is needed.

***Nomenclature Clarity.*** Naming conventions are products of past practices and courses of conduct that EPA and industry have evolved over decades. They are not cut and dried recipes applied rigidly assuring predictable results. As anyone in the TSCA field knows, nomenclature and naming conventions are a curious mix of science, regulatory policy, and art. For biobased chemicals, the confluence of these factors does not always end well. Nomenclature guidance for chemical substances containing varying carbon chain lengths typically applies to renewable chemicals because they are often derived from fats and oils that range in carbon length. Also significant is EPA's evolving policy, articulated in various EPA guidance documents but applied somewhat inconsistently, that TSCA Inventory entries should be identified as precisely as possible. A chemical substance may be listed on the TSCA Chemical Substance Inventory with a general description, but depending on the circumstances and the knowledge that a more specific chemical identity may apply, it may be the case that a company cannot fit its biobased chemical into an Inventory-listed nomenclature. The result is the biobased chemical is considered "new" and subject to premarket review.

Naming rules for renewable chemicals are complex. If the name includes a single plant source (e.g., soybean), only that plant source can be used, regardless of whether other plant sources are identified later. If the plant material is processed to increase or decrease relative amount of various carbon lengths (e.g., C5-C8 as opposed to a chemical with a listed carbon length of C5-C15), it could impact the name of the substance and whether it is considered listed on the Inventory. When a new biobased chemical intended for use as a chemical intermediate is introduced, downstream derivatives based on that chemical, depending on how they are named and identified, can also be considered new chemicals.

***Fatty Acid Concentration.*** As noted, renewable chemicals are typically derived from fats and oils. Some oils resulting in hybridization have modified fatty acid distributions. It is often unclear how to determine how much modification must occur before the oil is likely to be considered by EPA to be "new," thus triggering the need for a new Chemical Abstracts (CA) Index name and premarket review. Procuring a CA Index name takes time and signals the need for a notification to EPA for the new chemical. Consultation with the Chemical Abstracts Service, Inventory Expert Service, or EPA is advisable if there is doubt whether a modified oil requires a new name and the concomitant PMN. The problem from a regulatory perspective is there is no guarantee the advice given, albeit professional and sound, will be consistent with prior determinations, or even legally supportable. The absence of recognized naming conventions and clear guidance invite potentially wildly divergent nomenclature decisions, all of which translate into TSCA Chemical Substance Inventory naming chaos. Given the core significance of the TSCA Chemical Substance Inventory and its "go, no go" relevance for commercial production, much greater specificity and clarity is needed.

As new sources of biobased feedstocks and chemicals, such as transgenic plants and algae are developed, interesting and complex challenges with chemical nomenclature will inevitably develop—that will be certain to complicate the situation. Examples are soybean oil, which has been modified intentionally to contain calendric acid, and algae oil. If these oils are chemically processed, as most oils typically are, PMNs will be required under EPA's current policy. If these oils are further chemically reacted, care will be needed to determine the TSCA Inventory status of the products and whether additional PMNs may be needed.

## Replacing Incumbents: Regulatory Equity

In addition to nomenclature anomalies, renewable chemical manufacturers face challenges in addressing a finding of

potential "unreasonable risk" resulting from the PMN review process. TSCA Section 5(e) authorizes EPA to issue a consent order to the chemical manufacturer if a risk is identified allowing the PMN submitter to market the chemical only in conformance with certain enforceable conditions. In such a consent order, EPA has considerable discretion to limit the manufacture, processing, distribution, use, or disposal of the chemical to address the concerns EPA's review has revealed. EPA has other authorities under TSCA that allow the PMN submitter to use a chemical in a particular way, but disallow any other use (by the submitter or any other entity) of the substance absent premarket review by EPA of that new use.

For the reasons noted above, because many renewable chemicals can be expected to require notification under TSCA, a regulatory disparity arises immediately merely by virtue of the characterization of renewable chemicals as "new." That they are subject to premarket review places new renewable chemicals immediately at a competitive disadvantage opposite incumbent products that escaped review because of the grandfathering of existing chemicals when TSCA was enacted.

Consider, for example, the case of KiOR, Inc. (KiOR). EPA in 2012 proposed to issue Significant New Use Rules for six substances, all renewable chemicals. These substances are all manufactured by KiOR, and are complex mixtures of hydrocarbons made from lignocellulose, a natural constituent in wood and plant products. These products are all very similar in composition to refinery streams or to blends of refinery streams derived from petroleum. The intended use of these substances is as a substitute for similar existing products derived from petroleum. For the six subject PMNs, EPA stated that the PMN substances "are complex mixtures and have been assessed based on the toxic components within their mixture." EPA also stated that "the most important and primary component present is benzene." These products had, however, no more benzene than the incumbent petroleum products that they would substitute. According to comments submitted by a stakeholder, the lignocellulosic naphtha made by KiOR has less than two percent benzene, and motor vehicle gasoline may have up to 4.9 percent. If this biobased naphtha product is used to formulate or blend motor vehicle fuels, potential exposure to and risk from benzene is likely to be similar to or less than exposure and risk using the petroleum-based mixtures that the biobased products replace. Because the six subject PMNs are mixtures that are similar in composition, and that are intended to replace existing petroleum-derived mixtures, commenters argued that it made no sense for EPA to disregard data developed for these existing mixtures and urged EPA instead to focus solely on data for individual constituent chemicals, especially at the expense of the commercialization of the renewable chemicals at issue.

Rather than creating unnecessary barriers to the introduction of biobased products to replace petroleum, stakeholders argued in the KiOR case that EPA should encourage their substitution. Use of biobased products derived from plants rather than nonrenewable petroleum feedstocks reduces carbon emissions because carbon dioxide is taken up by growing plants and because some plant wastes that would otherwise emit carbon without benefits will be put to productive use. Additionally, substitution of biobased products for petroleum reduces the need for oil imports and avoids potential environmental impacts that may be associated with new oil production. As of this writing, the rule has not yet been issued in final.

## *Valuing "Renewable."*

TSCA explicitly recognizes that chemicals present both risks and benefits. Under TSCA Section 2(b)(3), EPA is expected to exercise its authority to control unreasonable risks in a way that does not "impede unduly or create unnecessary barriers to technological innovation."

This delicate balancing act illustrates the importance of emphasizing, in new chemical notifications, the benefits of a renewable new chemical. Importantly, however, there is little guidance on how, or even whether, the benefits of renewable chemicals are valued by EPA in the PMN review process. While the PMN form includes a section entitled "Optional Pollution Prevention Information," that it is optional is telling as it would seem almost a gratuitous afterthought rather than a central component in the risk-benefit calculus. This famously underutilized section in the PMN form can and should be used to identify in detail the benefits of a new renewable chemical.

Even when this field is completed, however, it is unclear how EPA interprets the information it receives. Relevant to the benefits calculus are points establishing 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); among many other considerations. There is no guidance, however, outlining what EPA might find useful for these purposes, or expressing EPA's strong support for renewable chemicals as a matter of national policy.

In other program contexts, EPA has developed over the years an impressive array of pollution prevention methodologies and lifecycle assessment tools. These existing resources can and should be repurposed for inclusion, modified as necessary, in a renewable chemicals "benefits framework" guidance document that clearly identifies the factors EPA requires to assess benefits and clearly explains how EPA interprets, values, and prioritizes these factors. The development of a benefits framework along these lines would be best accomplished through a transparent and interactive dialogue among EPA, industry, and related stakeholders so those most familiar with evolving chemical technologies are able to collaborate openly, efficiently, and quickly.

## *Conclusion*

The emergence of biobased chemicals is an exciting and promising area in the field of chemical production. To ensure EPA's commitment to support the commercialization of biobased chemicals is fully realized, EPA and interested others should engage in a robust dialogue on ways to address the issues noted above, and otherwise support the commercialization of biobased chemicals. As TSCA reform is likely to be in our future, legislative provisions should also be considered.