

Promoting Renewable Chemicals

Biofuels have gotten all the press. But biobased chemicals have equal environmental and health potential, and also the most exposure under the Toxic Substances Control Act. Implications range from irritating to crippling, depending upon a manufacturer's responses



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To look at corporate annual reports and environmental blogs, the popularity of biobased products in commerce and industry may seem new — think ethanol fuels or plastics made from corn — but in reality chemicals manufactured from renewable feedstocks go way back. Henry Ford promoted panels produced from soy that could be used in his cars. Many chemicals in the 1920s were alcohol-based, derived from grain and wood. Many polymers were based on cotton. And wood was a popular source of home energy. The introduction of seemingly limitless supplies of oil later in the 20th century replaced many biobased products with petroleum as a primary feedstock. Today, geopolitical realities, diminishing supplies, and a greatly enhanced understanding of sustainability are causing a shift back to renewable feedstocks.

The 2002 Farm Bill defines the term *biobased products* as commercial or industrial products (other than food) that are composed in whole or in significant part of biological materials, renewable agricultural materials, or forestry materials. The definition was extended in 2008 to include biobased intermediate ingredients or feedstocks. For Toxic Substances Control Act purposes, biobased products can be placed into two broad groupings: *biofuels* and *biobased chemicals*. While biofuels may be a more prominent category, and certainly more controversial these days with federal requirements to use ethanol in gasoline, the domain of biobased

chemicals has frequently been overlooked. Both groups are regulated under TSCA, but biobased chemicals are expected to have larger, more diverse use patterns and therefore will likely have the greater potential for TSCA-related reporting and record keeping. Manufacturers of renewable chemicals will need to take note and respond appropriately.

Market analysts predict tremendous growth in the biobased chemical industry in the years ahead. The renewable chemicals market is estimated to reach \$83.4 billion by 2018. Biobased chemicals' share of the global chemical industry is expected to grow from 2 percent to 22 percent by 2025. The United States could, by some estimates, replace 20 percent of its petrochemical consumption used in manufacturing with biobased products during the next ten years. Two large commercial-scale biobased chemical deals reported recently include BASF's May 2013 announcement it would make 1,4-butanediol (an industrial solvent) using a fermentation-based product, and the initiation of commercial production in June of bio-succinic acid (used as a pigment and in plastics) by Myriant Corporation.

These are but two large-scale examples. Market segments particularly likely to benefit from this growth include lubricants, soaps and detergents, adhesives, paints, and pharmaceuticals. Drivers for this growth include a concerted national effort to reduce our dependence on oil, to cultivate capacity for a less volatile and more consistently reliable supply of raw materials, and of course the relentless



pressure to green business operations. Sustainability is a watchword for many brand owners, especially those that market to consumers, and renewable chemicals can facilitate the marking off of many boxes on the “environmentally preferred” checklist.

One big box that remains unchecked and curiously sometimes unnoticed altogether is an understanding of the application of TSCA to renewable chemicals. We discuss here TSCA’s requirements and restrictions, offer a few thoughts for stakeholders to assure the successful marketing of these chemical products, and explain why there is an urgent need for an even playing field within TSCA and its implementing regulations that will promote

and not discourage the development of new, greener chemical substances.

The Toxic Substances Control Act is the federal law that governs new and existing chemical substances throughout their production, distribution, use, and disposal. *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. That biobased substances are derived from “natural” or renewable feedstocks does not

preclude TSCA's application to them. Likewise, by-product chemicals derived from biobased chemical processes that are commercially reused or recycled may also be regulated under TSCA.

Three TSCA sections are especially relevant to this discussion: Section 2, Section 8, and Section 5, which we'll take up in that order. Section 2(b) outlines TSCA policy, and Sections 2(b)(1) and (2), respectively, discuss the need for test data to be developed on the effects of chemicals and that adequate regulatory authority should exist to control chemicals presenting "unreasonable risks" to health and the environment. Section 2(b)(3) clarifies that this authority should be exercised so as not to create "unnecessary economic barriers to technological innovation." TSCA Section 2(c) states that it is Congress's intent that the Environmental Protection Agency "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 EPA to compile and maintain the TSCA Chemical Substance Inventory, listing each chemical substance that is manufactured domestically or imported into the United States. The initial inventory was created in 1978–79, when chemicals were originally listed automatically via a notification to EPA, but with no agency review of them. New substances are added to the inventory through a process under Section 5 that involves submission of a Pre-manufacture Notification, or PMN, which typically accounts for 1,000 to 2,000 new chemical substances being added to the inventory each year. Under the Section 5 process, EPA reviews the new chemical and imposes any needed regulatory requirements, and adds it to the inventory once a notice to EPA by the PMN notifier has been filed confirming that manufacturing (or importing) has commenced.

Given the timing of creation of the inventory, the organic chemicals listed are largely reflective of the commercial chemistry of the 1970s, which was principally petroleum based; a large number of petroleum-based feedstocks are listed on the original inventory. While a very few biobased chemicals were listed, their number and variety were quite limited. For today's biobased chemical industry, this imbalance is important because it means that many biobased chemicals that are undergoing com-

mercialization today will be considered "new chemicals" subject to Section 5 notification obligations.

While it may be easy to breeze over the regulatory and business implications of these notification obligations, companies must fully recognize the potential impacts they will have on marketing and business strategies. Manufacturers (including importers) of chemical substances considered "new" must notify EPA of a chemical substance through the submission of a PMN — unless an exemption applies, a company must submit a completed PMN form to EPA at least 90 days before commencing the manufacture of a new chemical substance. The EPA review process by statute takes no less than 90 days, but as we are witnessing today, the process can take considerably longer, and typically does for new renewable chemicals. The implications of this protracted process range from irritating to crippling, depending upon how well the regulatory process has been managed by the business.

Under TSCA Section 5, EPA assesses the PMN to determine if a new chemical presents potential "unreasonable risks" to human health or the environment. TSCA Section 5(d)(1) requires that certain information be provided in the notice, including a description of the chemical, estimated annual production volume, intended uses, worker exposure information, and any test data in the possession of the notifier on health and environmental effects, among other information. Information provided in the 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.

If EPA's review reveals risk concerns (real or perceived) 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. EPA has discretion under Section 5 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 a consent order, the notifier is legally required to observe the terms and conditions in the consent order, and must maintain appropriate records documenting its actions.

The moment the chemical has been listed on

the TSCA inventory (which occurs after the company that submitted the PMN informs EPA of the commencement of commercial manufacturing or importation), it is no longer considered new and other manufacturers of the same chemical may manufacture the chemical without submitting a PMN. 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, EPA can issue a Significant New Use Rule imposing the consent order's requirements on subsequent chemical manufacturers. These are known as *Section 5(e) SNURs*. For other substances, EPA may determine that although the manufacture, processing, or use of the chemical substance as described in a PMN does not present health or environmental risks requiring agency action, there are other potential uses not described by the PMN submitter such that EPA determines a SNUR is needed. EPA can use its SNUR authority to regulate potential uses and 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.

Whether a biobased chemical is new or existing is a question that needs to be known well in advance of any plans for commercial activities. If an inventory listing for a chemical can be established, the PMN hurdle as a new chemical can be avoided. If one or more of the chemicals is subject to TSCA new chemical notification, this point needs to be recognized and be addressed early. When EPA targets a chemical for regulation, this will result in unplanned delays, potentially lasting for months to years, resulting in a barrier to commercialization.

Given the origins of the TSCA inventory with its prevalence of petroleum-based substances, a number of anomalous situations arise. While EPA is supportive of new chemistries that can replace older, petroleum-based chemistries, biobased chemicals will continue to be the subject of regulatory scrutiny by EPA as new chemicals. This can lead to a disproportionate amount of regulatory 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 that, as inventory-listed substances, escape such regulatory scrutiny.

Emphasizing the benefits of a biobased new chemical is important. The PMN form includes an option-

al pollution prevention section. This section should be used to highlight the benefits of a biobased new chemical. In developing the points to include, it may be helpful to think of the task as one of essentially making the case to the EPA reviewers for a new biobased chemical's introduction. Include points establishing renewable sourcing. The manufacturer should also highlight pollution prevention or risk reduction benefits — these could include reduced pollution, role of or contribution to recycling, 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. Finally, list cost or performance benefits — these could include lower cost, improved product performance, more energy efficient production, processing, or use, and related factors.

In light of the disarray on Capitol Hill and the deeply partisan nature of the legislative process, TSCA reform would appear to be far from certain this year, or even years from now. The current Senate bill, S. 1009, the Chemical Safety Improvement Act, is neutral on the issues discussed above. A helpful amendment to the bill would be a legislative directive to support continued development of renewable raw material feedstocks and processes and careful consideration to avoid unnecessary burdens to get these materials to market.

At a more programmatic level, EPA's scientists, risk assessors, and decisionmakers should be receptive to addressing what some would claim is an imbalance in the current implementation of TSCA with respect to how new chemical substances are reviewed and regulated while existing conventional chemicals have largely been grandfathered and thus spared agency review. Additionally, when reviewing a PMN application, it would be helpful if EPA were more transparent as to how it weighs the benefits offered in completed pollution prevention statements against any potential risk that might be identified through the PMN review process. Because the pollution prevention statement is optional, it is unclear whether and how EPA values the information in the review process.

EPA might also consider working with the renewables industry to develop new protocols and risk assessment approaches better suited to the new suite of chemistries that renewable feedstocks present. Many of the tools EPA uses are quite old and reflect arti-

facts that may not in all cases fully reflect the promise, diversity, and innovation inherent in new renewable chemistries. A joint effort to identify the most challenging issues for innovators in this space would go a long way toward addressing some of the more prominent science policy shortcomings that hamper innovation and impede commercialization opportunities.

Other tips for a successful launch of a new bio-based chemical include the following:

Ensure that TSCA compliance is a core element of the business plan. Know the TSCA requirements, understand the regulatory responsibilities, and be prepared to meet both as part of a business development plan for the bio-based chemical. Ensure your marketing plans contemplate timing for required regulatory review, including potential for delays. The first step in TSCA compliance is to know the inventory status of your company's chemical products, but TSCA compliance does not stop when a chemical is added to the inventory. A company should have a comprehensive plan for addressing the regulatory obligations for existing chemicals, including but not limited to reporting under the TSCA Chemical Data Reporting Rule, export notifications, and reporting of adverse effect and risk information.

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. A chemical substance derived from bio-based materials may be structurally similar to a substance derived from a petroleum stream, but could have a different name because of differences in the manufacturing process.

Know the TSCA review process. A basic understanding of EPA's review process and regulatory approach is essential. While EPA 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 will use assumptions about likely exposures and releases if information is not provided in the PMN. Research whether chemicals similar to yours have been evaluated by EPA and if so, what the outcome was.

Consider testing in advance of PMN notification. If EPA is likely to impose testing requirements on a bio-based 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, there might be significant cost saving and advocacy opportunities for organizing consortia to share the costs and responsibility of testing.

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

Advocate, advocate, advocate. As a final thought, advocate the benefits of a bio-based new chemical. This should involve careful preparation of the points that can be made on the optional pollution prevention section of the PMN notice. Beyond that, there may be value in recognizing and advocating the bigger picture policy benefits of bio-based chemicals to ensure that the agency's new chemical reviewers are aware of and appropriately consider and value those aspects. While EPA at the higher management levels is likely aware of U.S. government policy drivers (such as the White House's recently announced National Bioeconomy Blueprint), this awareness may or may not have reached the scientists and other career EPA staff levels actually reviewing PMNs. As with testing, while individual companies can and should emphasize relevant policy drivers in their interactions with EPA's new chemical reviewers, there may also be considerable value in and a role for consortia to press these points with EPA.

As of this writing, the pressure to reduce the 2014 statutory renewable volume obligations for all types of biofuels under the Renewable Fuel Standard is reaching new heights. Stakeholders seeking to repeal or weaken the RFS have doubled down and are pursuing judicial, legislative, and regulatory efforts. If they succeed, it is unclear what impact this will have on the renewable market, but emphasis may well shift to renewable chemical production. Even if the RFS remains intact, the relentless drive to produce chemicals from renewable feedstocks, and to lighten the environmental footprint of chemical production and use generally, will continue. The need for sensible regulation under TSCA will only intensify. Advocates in this commercial space are urged to collaborate with stakeholders, including EPA, and make it happen as quickly as possible. •

Goals of Industry and EPA Are Not Opposed

Sustainability is a dominant theme driving product development across the chemical industry. Areas of focus include energy reduction in manufacturing and product use and the utilization of biobased, renewable sources for the manufacture of chemicals. It is challenging to develop products that provide performance breakthroughs in these areas while maintaining a cost-performance profile that will lead to broad market reach.

Until recently, scientists' toolboxes have been limited to traditional petrochemical and oleochemical feedstocks. The past decade has seen significant advances in the use of biorenewable sources and bioprocessing to arrive at commercial technology in a more cost-effective manner. Over time it will be possible to develop feasible commercial routes to specific, targeted chemical structures in a fashion that has not been possible. Increasing crude oil prices, in combination with current and anticipated advances in bioprocessing, hold promise for the production of low-cost, novel chemistries capable of satisfying market needs for sustainability.

Solving the challenges of chemical product development related to market needs will involve the development of novel chemistry, bio-renewable based or otherwise. A key step in the commercialization process will be regulatory considerations under the Toxic Substances Control Act. The sustainability advantages in many application areas are significant. However, a key question to be addressed is exactly what is and what will be required to obtain TSCA pre-market approval for novel chemicals?

For any of a number of reasons, there exists a "new chemicals bias" under TSCA that makes it

more challenging to commercialize new chemicals compared to those currently listed on the inventory. Therefore, an important question to those engaged in the planning and execution of research and development in the chemical industry is, What will overcome this bias?

One of the major goals of our consumer products research is to facilitate the operation of laundry systems at lower temperatures, while achieving the same level of cleaning as in warmer water. Cold-water cleaning is challenging, as many stains exhibit different properties at lower temperatures, making traditional cleaning ingredients and formulation approaches less effective.

Let's assume that bio-renewable-based novel chemistry requiring TSCA pre-market approval will be part of the solution, and that the overall environmental and toxicological profile of the new chemistry is at parity with similar commercial technologies. As the new chemistry will face increased scrutiny, what benefits can help its commercialization? Will the fact that it's been developed from bio-renewable resources play a major role, or is a more valued factor the energy savings, and accompanying reduction in carbon dioxide emissions associated with converting a significant part of the home laundry market to cleaning at lower temperatures? Are there other benefits that ought to have been included as technology goals?

Whatever the answer, it needs to be understood by industry to a much higher degree than is currently the case, so that the relevant considerations may be rolled into the innovation process as early as possible. Most companies employ a "phase gate" process to manage

research and development projects, which is designed to optimize the deployment of resources across functional areas and develop important information in a coordinated manner. By the time the project progresses to the point of submitting a notice for TSCA pre-market approval, a large amount of resources has already been expended. If inaccurate assumptions were made regarding obtaining approval, significant effort will have gone to waste.

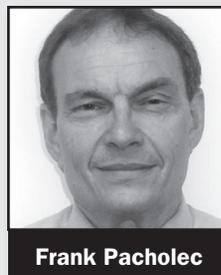
Having a clear and more certain understanding of the TSCA process

will enable regulatory considerations to be more effectively built into the R&D process, enabling sound strategic decisions regarding research programs and classes of chemistry, while most importantly enabling the production

of innovative, sustainable products that are safe and consistent with broader public policy goals.

The goals of EPA and industry should not be viewed as fundamentally opposed. The respective entities come to the regulatory process from different perspectives and areas of emphasis, and there is significant benefit to be gained through a collaborative and cooperative working environment. A higher level of mutual understanding and transparency than exists today from both industry and EPA would serve the entire process well, facilitating the most efficient deployment of resources on both ends, while enabling the delivery of safe, innovative, breakthrough technologies to the marketplace.

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