The impact of Toxic Substances Control Act nomenclature on the commercialization of biobased chemicals

Regulatory Review is a regular column featuring updates on regulatory matters concerning oils- and fats-related industries.

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Imagine receiving a certified letter from the US Environmental Protection Agency (EPA) announcing that it plans to conduct an audit of your company's facility in two weeks. The audit will focus on your company's compliance obligations as a chemical manufacturer under the Toxic Substances Control Act (TSCA). Would you be prepared or are you unsure of what TSCA is and whether it applies to you?

Moving from bench to market

Many small companies or those new to chemical manufacturing are not aware of their obligations under TSCA. Most biobased chemical companies have likely operated under the research and development (R&D) exemption under TSCA Section 5(h) (and maintained all required paperwork). But as soon as the manufacturer is ready for a commercial launch, the R&D exemption no longer applies. To avoid hefty fines of up to $37,500 per day per violation, it is critical for companies to understand their obligations under TSCA Section 5 not only to avoid inadvertent violations, but also to avoid any undue delays in bringing their products to market.

A chemical manufacturer or importer of a substance for a TSCA use (that is, everything but a food, food additive, drug, cosmetic, medical device, pesticide, tobacco product, firearm, or nuclear source material) must comply with all aspects of TSCA. This article focuses on the rules related to chemical nomenclature, including how those rules could adversely impact a company's ability to market new biobased substances.

A company must ensure that any chemical substance it manufactures (or imports) is listed on the TSCA Chemical Substance Inventory (the Inventory) or be eligible for an exemption. If a substance is not listed on the Inventory (either as a public or confidential identity), the manufacturer must submit a premanufacture notice (PMN) to EPA 90 days prior to producing or importing that substance. TSCA applies to feedstocks, intermediates, microorganisms, enzymes, and other catalysts, in addition to final products.

The importance of identity

The first step in determining Inventory status is determining the appropriate Chemical Abstracts Index name for the substance. Note that the existence of a Chemical Abstracts Index name or Chemical Abstracts Service (CAS) Registry Number does not mean that a substance is listed on the Inventory. In fact, many CAS identities do not comport with the TSCA nomenclature rules.

For a single, defined substance (what EPA calls a Class 1 chemical), such as ethanol, the identity is straightforward

and a search of the Inventory can easily reveal if a substance is listed and if there are any restrictions to its manufacture, processing, or use. Like many petroleum substances, many biobased substances are not single, defined substances. They are considered unknown or variable composition, complex reaction products, or biological materials (UVCB), or Class 2 chemicals. UVCB substances are typically identified by source and/or process and may include a definition in addition to the substance name. Triglyceride oils provide an instructive example of how the source is included in the substance identity.

Corn oil is listed on the Inventory as:

Corn oil.

Definition: Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic. (*Zea mays*).

(CAS registry number 8001-30-7).

It is a distinct substance from other vegetable oils, such as:

Soybean oil.

Definition: Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic. (*Soja hispida*).

(CAS registry number is 8001-22-7).

The definitions of these two oils are the same, except for the source names: *Zea mays* and *Soja hispida*. Even though the two oils have very similar fatty acid profiles and content, and are often used interchangeably, the different source designations mean that these are two different substances under TSCA. A manufacturer of one could not rely on the identity of the other for TSCA purposes. The source-based name may also extend into a downstream product. For example, a fatty acid methyl ester (FAME) biodiesel made by the transesterification of corn oil with methanol would be:

Fatty acids, corn-oil, Me esters

(CAS registry number 515152-40-6),

while the soy FAME would be:

Soybean oil, Me ester

(CAS registry number 67784-80-9).

These two identities are distinct and a biodiesel producer would have to be sure that the corresponding FAMEs were listed on the Inventory before making biodiesel from either corn or soybean oil.

TSCA reform gaining momentum

Reform of the US Toxic Substances Control Act (TSCA), which has never been updated in the 39 years since it was passed in 1976, has limped along for years without meaningful action. Recent legislative activity, however, suggests reform may yet happen.

As *Inform* went to press, signs of renewed life included a unanimous vote on May 15 by the House Subcommittee on Environment and the Economy to send a revised draft bill (the TSCA Modernization Act of 2015) for full committee consideration. A similar bill was approved after modification by the Senate Environment and Public Works Committee in late April. Known as The Frank R. Lautenberg Chemical Safety for the 21st Century Act—named for the late US senator who championed TSCA reform for years—the bill has picked up a number of bipartisan sponsors, suggesting that a floor vote may be called soon. If the bill passes the Senate, it will move to a joint conference committee where the two versions (assuming the House passes its bill) will have to be reconciled. Then the conference report would go back to both chambers for new votes, after which it would have to be signed by the President. All of which is to say, reform is anything but a done deal.

Industry generally is in favor of both bills. Ernie Rosenberg, president of the American Cleaning Institute (ACI), noted in a statement, "Along with the progress on bipartisan legislation in the Senate, action in the House sets us further on the path to passing a more effective law to govern chemicals in commerce.

"A stronger federal chemical law should reflect progress in science and technology and advance further innovations. A well designed, updated law can further enable our industry's ongoing work to develop . . . more sustainable cleaning products."

Feedstock flexibility

Clearly this source-based nomenclature system for UVCB substances is complicated. In fact, EPA and industry recognized that this nomenclature system would be a barrier to manufacturers that use a variety of oil sources to produce derivatives, such as surfactants. EPA and the Soap and Detergent Association (SDA) (now the American Cleaning Institute) developed a source-agnostic nomenclature system based on alkyl ranges and substance type. The SDA nomenclature procedure covers 35 natural sources of fats and oils and their synthetic (i.e., petroleum) equivalents.

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For example, either corn oil fatty acids or soybean oil fatty acids could be identified as:

> **Fatty acids, C16-18 and C18-unsatd.**
>
> **Definition:** This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated alkyl carboxylic acid and SDA Reporting Number: 11-005-00. Consult SDA Substance Identification Procedure.
>
> (CAS registry number 67701-08-0).

These SDA names allow feedstock flexibility all along the supply chain: from triglyceride producers, to intermediate fatty acids, to final products, such as fatty acid ethoxylates. For example,

> **Fatty acids, C16-18 and C18-unsatd., ethoxylated.**
>
> **Definition:** This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated alkyl carboxylic acid ethoxylate and SDA Reporting Number: 11-017-00. Consult SDA Substance Identification Procedure
>
> (CAS registry number 68989-58-2)

could be produced from fatty acids derived from any of the 13 vegetable oils listed in the SDA Substance Identification Procedures [2] that are identified as predominantly "C16-18 and C18-unsaturated."

Feedstock Inflexibility

This long-standing nomenclature system has provided manufacturers substantial feedstock flexibility while relieving EPA of the burden of reviewing hundreds, if not thousands, of substances that have nearly identical properties, but differ only in the original plant source—but only if the plant source is one of the original SDA species.

The SDA nomenclature specifically states: "Alkyl groups derived from other natural sources are not covered by this procedure." This statement is especially problematic for companies that have developed triglycerides from other natural sources. For example, oils from jatropha or algae may match existing alkyl ranges, but because they are not on the list of fat and oil sources in the SDA Substance Identification Procedures, they are not eligible to be named using SDA nomenclature. This presents a burden on the oil producers, as they must file a PMN, and, perhaps more critically, it also presents a burden on customers looking to replace one of the SDA-eligible oils or other triglyceride sources, since they also must submit a PMN for their downstream product.

For example:

- A producer of an algal oil that is not listed on the Inventory would file a PMN for the triglyceride.
- That company's customer plans to saponify the algal oil to make algal oil fatty acids and would be required to file a PMN for the algal fatty acids.
- Buyers of the fatty acids must file PMNs for each of the products they plan to manufacture, such as the sodium salt (to make an algae-based soap), methyl ester (algal biodiesel), ethoxylate (an algae-based detergent), and a polymer with neopentyl glycol and adipic acid (an algal-based polyester polyol).

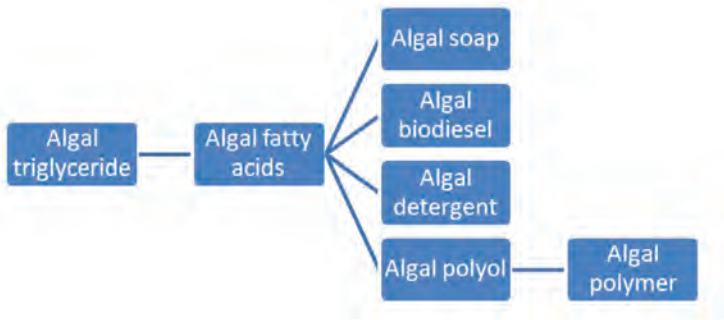

FIG. 1. Hypothetical algal oil supply chain. Each box represents a separate chemical substance that must be listed on the Inventory or be subject to a PMN.

Filing a PMN may not be a substantial barrier to a large, sophisticated chemical company, but for a company that does not frequently deal with PMNs, being required to submit notification to EPA might be enough to prevent them from switching from a traditional vegetable source to a novel source.

In the scenario depicted in Fig. 1, as the new algal oil propagates through the supply chain, there might be 10 or 20 PMNs from downstream customers of that algal oil and its derivatives. This is challenging from a commercial standpoint. To avoid delays to market or hindrances to commercialization for new renewable chemicals, the biobased chemical industry must coordinate on a strategy to revise the current system.

Call to action

The SDA nomenclature system was specifically developed to reduce the reporting burden on industry in cases where additional information is unlikely to improve EPA's ability to protect human health and the environment. Assuming that 1. EPA's review of the algal oil finds no unreasonable risk to human health or the environment for the oil itself, and 2. its fatty acid profile fits one of the SDA categories, EPA should have the discretion to allow the downstream products from the algal source to use the SDA nomenclature, and avoid submissions of PMNs for downstream products. In order to do this, the rules must be changed. Opening the SDA nomenclature system to other organisms would either require statutory changes in TSCA or for EPA

to undertake rulemaking. Fortunately, TSCA reform is on Congress's agenda in 2015, giving the biobased chemical industry a rare opportunity to update the nomenclature rules to level the playing field between legacy sources and new products. Even so, final legislation and implementing regulations are far off. Industry should convince EPA of the need to undertake rulemaking now in order to allow new oil sources to use SDA nomenclature once the new oils have been reviewed to allow the new oils to be smoothly integrated into the existing fatty acid supply chains. It is the proverbial win-win scenario—EPA has fewer PMNs to review without compromising its mission to protect human health and the environment; the innovative biobased products can move more seamlessly into the supply chain; and the increase in biobased/renewable chemicals benefits the global population as a whole.

Further reading

1. US Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA) PL 94–469, Candidate List of Chemical Substances Addendum III, Chemical Substances of Unknown or Variable Composition, Complex Reaction Products, and Biological Materials, 740R78103 (Mar. 1978) at 6.
2. *Id.* At 29.

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