Regulatory Impediments to Commercializing Biobased Products

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ABSTRACT

Current naming conventions under the Toxic Substances Control Act (TSCA) adversely impact the commercialization of biobased chemicals derived from novel sources. Such chemicals cannot utilize an existing naming option, known as the Soap and Detergents Association nomenclature that allow names based on simple alkyl ranges. Instead, these new biobased chemicals must include their source as part of their identity and this source must also appear in the identities of downstream intermediates and products. The Biobased and Renewable Products Advocacy Group (BRAG®) has been actively advocating for new approaches within the chemical naming conventions to address this disparity.

Keywords: TSCA, EPA, biobased, nomenclature, SDA text

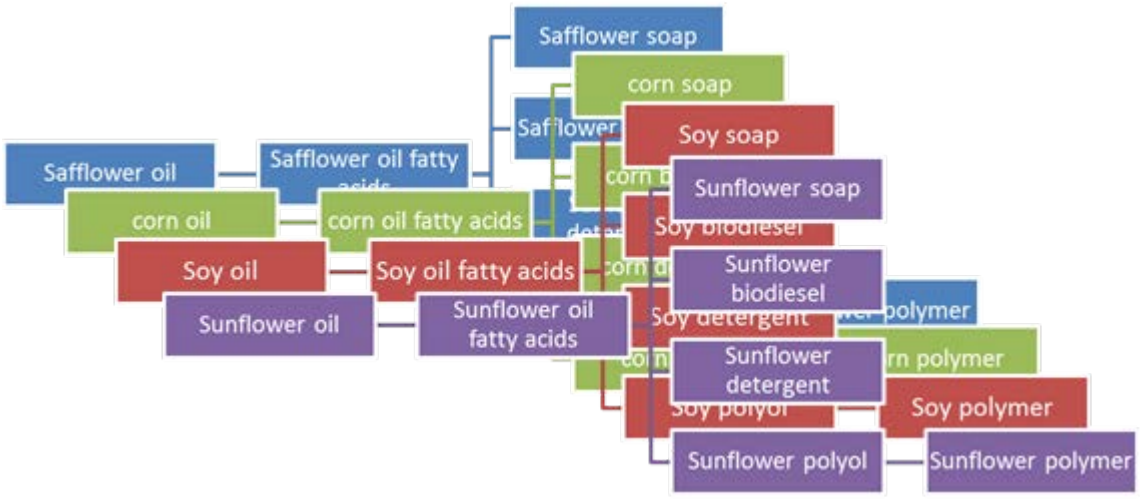
1. BACKGROUND

As renewable fuel and biobased chemical companies successfully make the leap from research and development to market, they face another set of underappreciated regulatory challenges in order to lawfully commercialize their products.

Under TSCA, all chemical substances, including biofuels and biobased chemicals, must be listed on the TSCA Inventory (or specifically exempted) prior to manufacture or import. U.S. Environmental Protection Agency (EPA) policy requires that listed chemicals be described as precisely as possible, and only substances meeting that precise identity can rely on that chemical name. This issue of precise naming for purposes of listing on the TSCA Inventory has and will continue to prove critical for successful commercialization of many biobased chemical products.

Many biobased substances are not substances with a single molecular structure, but instead are mixtures that are referred to as "unknown or variable composition, complex reaction products or biological" (UVCB) materials. In most cases, UVCB substances include their source as part of the chemical identity. The source also appears in the identities of downstream intermediates and products. As depicted in Figure 1, while the list of sources on the left starts simply, the source-based naming convention creates a downstream myriad of essentially duplicate chemicals with different names.

Figure 1: Depiction of how source species names propagate through a supply chain.



Existing EPA policy allows chemical companies to rely on the "Soap and Detergent Association" (SDA) nomenclature system, which is a nomenclature convention for UVCB substances that reduces supply chain complexity and provides some source flexibility. The SDA nomenclature system classifies 35 natural sources of fatty acids, and their synthetic equivalents, into a variety of alkyl group ranges that are based on the constituent chain lengths present in those sources (See Figure 2). For example, a chemical producer may identify its product using a SDA alkyl range, when the product is made from any plant oils that meet the criteria for that SDA range. This reduces the burden on chemical manufacturers, allowing them to change oil sources based on price and availability, without changing the identity of their product.

The problem for newly developed biobased chemicals is that the existing system limits source flexibility to 35 sources of fats and oils (and their petroleum synthetic equivalents), as shown in Figure 3.

Since its adoption of the SDA system in 1978, EPA has not attempted to amend the list of sources, most of which, as shown above, are derived from food crops, such as corn or soy. New sources of oils, such as those isolated from non-traditional plants, like camelina and jatropha, derived from algae, or produced by microbes, are functionally equivalent to, and may be chemically indistinguishable from, sources listed in the SDA nomenclature system. However, these novel sources of fats and oils are not among the SDA sources, so neither the oils nor their derivatives can be named using the SDA system. Instead, these substances can only use the source-based naming system, as depicted in Figure 4.

Figure 2: . SDA nomenclature simplifies supply chain nomenclature. In this case, thirteen sources, including the four shown in Figure 1, or a petroleum equivalent, may use the C_{16}-C_{18}, C_{18} unsatd. alkyl descriptor.

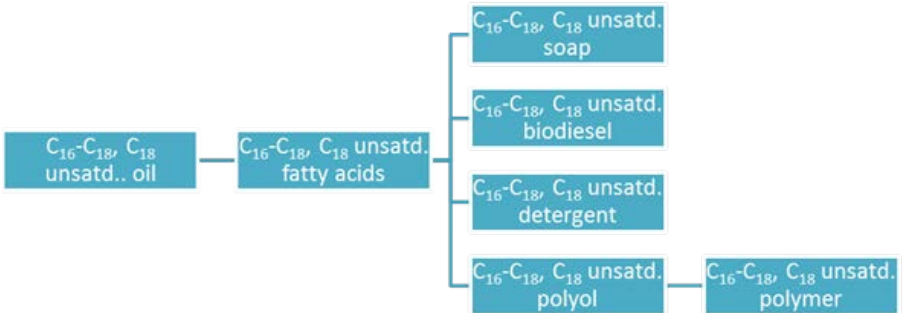
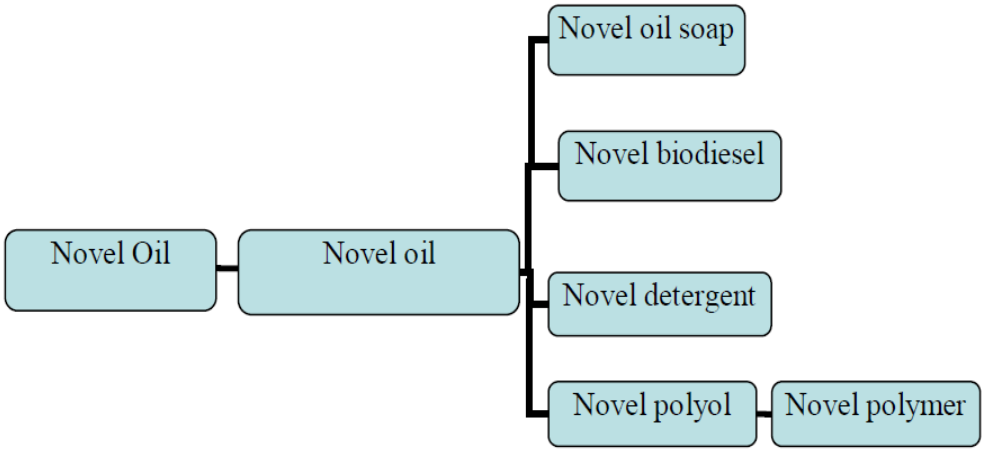


Figure 3. SDA List of Natural Sources

Vegetable		Animal	Marine
Avocado	Peanut	Grease	Herring
Babassu	Rapeseed	Lard	Menhaden
Castor	Rice Bran	Neatsfoot	Salmon
Coconut	Safflower	Poultry	Sardine
Corn	Safflower (high oleic)	Tallow	Sperm Body (whale)
Cottonseed	Sesame		Sperm Head (whale)
Crambe	Sorghum		Whale
Linseed	Soybean		
Olive	Sunflower		
Oiticica	Tung		
Palm	Wheat Germ		
Palm-kernel			

Figure 4. Impact of Ineligibility for SDA Nomenclature



2. COMMERCIAL IMPACTS

Without access to the alkyl range names allowed under the SDA nomenclature approach, novel biobased chemical producers and their customers must submit a premanufacture notice (PMN) for each new triglyceride, as well as each downstream intermediate and product **before before commercialization can occur.**

While the delay in commercialization is certainly problematic, the real market disincentive is the fact that downstream customers may need to submit their own new chemical notifications if they opt to switch from traditional oils to these novel sources. Convincing a customer to use a newly developed chemical substance is one thing; getting them to take on the regulatory responsibility of a new chemical notification is another.

As an example, a new oil that was chemically equivalent to corn oil, with the same properties and characteristics, but was derived from algae, could not rely on the existing SDA name "C_{16}-C_{18} and C_{18} unsaturated fatty acids," because the algae is not included on the existing SDA nomenclature list. A company producing the fatty acid ethoxylates from this new oil would have to submit a notification to EPA for each substance derived from the novel oil source even though these derivatives are otherwise chemically equivalent to derivatives made from corn or soy oil. Each new source would add another layer to the diagram in Figure 1, above, rather than being able to use the simplifying system depicted in Figure 2.

3. BRAG ADVOCACY EFFORTS

BRAG has been actively advocating for new approaches within the chemical naming conventions to address this disparity. In October 2015, BRAG submitted a citizen's petition under TSCA Section 21. That petition called on EPA to initiate a rulemaking under TSCA Section 8 that would establish a process to amend the list of natural sources of oil and fat in the SDA nomenclature system by considering the chemical equivalency of additional natural sources.

On January 12, 2016, EPA announced it denied the BRAG Section 21 petition via the *Federal Register* because, according to EPA, the Agency lacks the authority to initiate rulemaking under TSCA Section 8. EPA also claimed that BRAG did not justify the need for regulatory relief, given that the petition lacked a specific example of products experiencing this issue. While BRAG respectfully disagrees with EPA's reasoning, it was pleased to see in the *Federal Register* notice that EPA confirmed BRAG's position that the SDA nomenclature is limited to the existing list of natural sources:

The petition correctly recognizes the current limitations of certain TSCA Inventory listings (i.e., those listings that incorporate particular assumptions about the natural sources of fats or oils from which the listed substance is derived, because they were named according to the SDA naming convention). Manufacturers of a new chemical substance that clearly falls outside the definitional scope of an existing chemical substance are not allowed to determine that the new chemical substance is nonetheless sufficiently "similar" to the existing chemical substance, and simply deem the new chemical substance to be an existing substance on the basis of that similarity. Nor would EPA grant such a request….

In the notice, EPA also indicates that there are opportunities to achieve the BRAG objective of expanding the scope of the SDA categories:

[T]he petition presumes, without justification, that until a certain preliminary EPA rulemaking has been completed, those same manufacturers lack a meaningful opportunity to request that EPA enlarge the definitional scope of one or more existing chemical substances named according to the SDA naming convention.

Finally, in a separate communication to BRAG, EPA Assistant Administrator James J. Jones identified other options and opportunities that BRAG and other stakeholders could pursue that might achieve the same desired outcome.

BRAG and its members continue to lead this important effort to find a pathway to add sources to the SDA list or an alternative options that achieve the same goal, and to address other regulatory inequities as identified by BRAG members.