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October 5, 2015

Via E-Mail

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Section 21 Petition for Equivalency Determinations for Class 2
Substances under TSCA

Dear Administrator McCarthy:

The Biobased and Renewable Products Advocacy Group (BRAG[®])¹ submits this petition under the authority of Section 21 of the Toxic Substances Control Act (TSCA)² to initiate a rulemaking under TSCA Section 8³ that would establish a process to amend the list of natural sources of oil and fat in the “Soap and Detergent Association” (SDA) nomenclature system by considering the chemical equivalency of additional natural sources.

Great strides have been made over the last decade in the development of renewable chemical products from novel biobased sources. As further detailed below, the key hindrance to commercialization of these biobased chemical products is the limited list of natural sources of fats and oils in the SDA nomenclature system. This petition requests that the U.S. Environmental Protection Agency (EPA) address the disproportionate regulatory burden imposed on those companies striving to address the critical needs for sustainability within the

¹ BRAG provides a platform for organizations engaged in biobased chemistries to promote their products, identify and address regulatory barriers for their unique products, and work collectively to address them. BRAG tackles regulatory hindrances related to commercialization of biobased products and works to improve public awareness of the benefits of these products.

² TSCA § 21, 15 U.S.C. § 2620.

³ TSCA § 8, 15 U.S.C. § 2607.

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chemical sector. BRAG believes this can be accomplished without compromising EPA’s mission to protect human health and the environment.

Background

Many chemical substances, including 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. TSCA requires that all chemical substances manufactured or processed in the United States, including UVCBs, be listed on the TSCA Inventory with a scientifically valid chemical name and description. 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 below, while the list of sources on the left starts simply, the source-based naming requirements create a downstream myriad of essentially duplicate chemicals with different names.

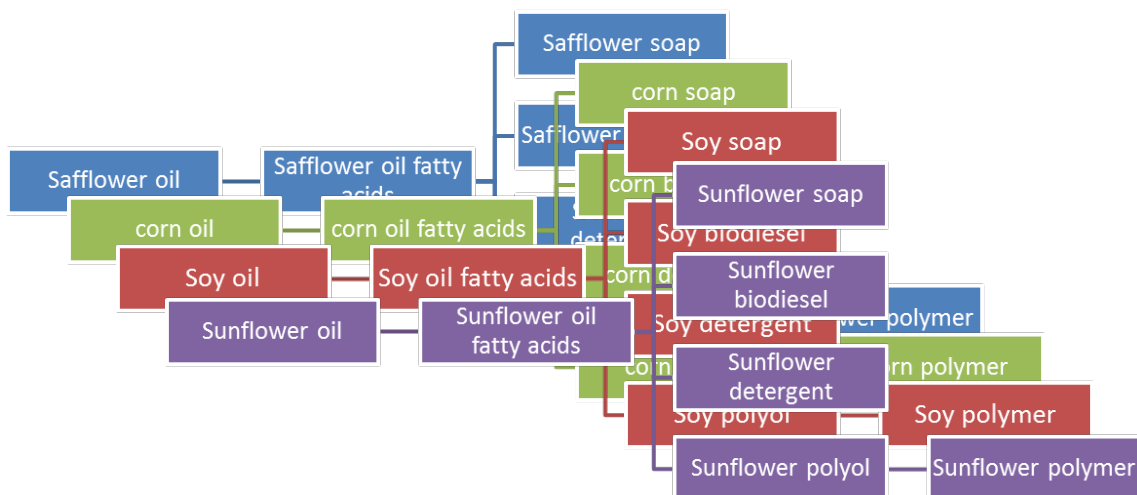


Figure 1. Depiction of how source species names propagate through a supply chain.

SDA nomenclature is an alternate nomenclature convention for UVCB substances that reduces this supply chain complexity and provides some source flexibility within specific



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groups. 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 fatty acid chain lengths present in those sources, without naming the source organisms. This allows a chemical producer to identify its product using that alkyl range, when it is made from any plant oil included in the SDA system that has a corresponding fatty acid profile. This reduces the burden on chemical manufacturers, as they change between these equivalent oil sources based on price and availability. It also reduces EPA's burden, as it eliminates the need to review dozens of new chemicals as manufacturers develop new, otherwise identical, downstream intermediates and products that can be made from any of these SDA-eligible sources.

The problem for newly developed biobased chemicals is that the existing nomenclature system limits source flexibility to the 35 natural sources of fats and oils (and their petroleum synthetic equivalents). As the name implies, the nomenclature system was developed by SDA (now known as the American Cleaning Institute (ACI)) when the TSCA Inventory was initially compiled. TSCA Section 8(b)(2) allows EPA to list substances in the TSCA Inventory by category instead of listing them individually. The 35 natural sources were included in the listed categories established using the SDA nomenclature because they were identified as being in commerce in 1978 when the system was developed. At that time, EPA set up the SDA alkyl ranges and determined in which alkyl range each of the 35 sources belonged. This was, effectively, a determination of chemical equivalency. Since its adoption of the SDA system in 1978, EPA has not attempted to amend the list of 35 sources or made equivalency determinations for other natural sources.

Most of the 35 sources eligible for SDA nomenclature are derived from food crops, such as corn or soy. Many in the biobased chemical sector have focused their current efforts on finding new sources of fats and oils. Some new sources are isolated from non-traditional plants, like camelina and jatropha. Some are derived from algae and some are derived from microbes. These novel sources yield oils that are functionally equivalent to, and may be chemically indistinguishable from, oils listed in the SDA nomenclature system. Because novel sources of chemically equivalent fats and oils are not among the 35 sources already listed, however, new oils cannot be named using the SDA alkyl ranges. Without access to the alkyl range names, novel biobased chemical producers and their customers must submit a premanufacture notification for fats and oils derived from each new source and for all of the downstream intermediates and products. This delays commercialization of novel sources of fats and oils and, more importantly, creates a disincentive for customers to switch from traditional oils to these novel sources because the customers would be forced to submit new chemical notifications for substances that would be existing chemicals if only they were made from SDA-eligible sources.



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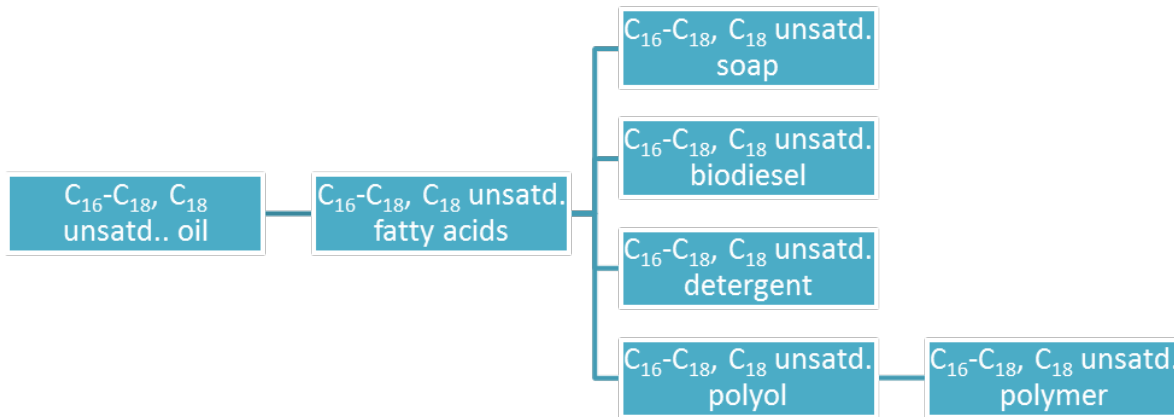


Figure 2. SDA nomenclature simplifies supply chain nomenclature. In this case, thirteen sources, including the four shown in Figure 1, or a petroleum equivalent, may use the C₁₆-C₁₈, C₁₈ unsatd. alkyl descriptor.

For 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 “C₁₆-C₁₈ and C₁₈ 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.

This limitation of source categories in the SDA system results in inequitable regulatory treatment for chemical substances that are functionally the same and chemically nearly identical.

TSCA Section 21 Authorizes EPA to Issue a Rule to Set Equivalency Determinations for Class 2 Substances

Under TSCA Section 21, any person may petition the EPA Administrator to “initiate a proceeding for the issuance, amendment, or repeal of a rule” under TSCA Sections 4,



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6, or 8, or an order issued under TSCA Sections 5(e) or 6(b)(2).⁴ A TSCA Section 21 petition must set forth facts that the petitioner believes “establish that it is necessary to issue, amend, or repeal a rule” subject to the petition.⁵

In prior decisions responding to Section 21 petitions, EPA has focused on different elements as to whether a petitioner has set forth sufficient facts demonstrating that it is “necessary” for EPA to act as requested. In denying a Section 21 petition seeking a Section 6 rule, for example, EPA stated that TSCA Section 21 implicitly incorporates the statutory standards that apply to the requested actions, and the petitioner had not set forth sufficient facts to demonstrate the Section 6 standard could be satisfied.⁶ In another petition asking EPA to, in part, issue a TSCA Section 8(d) rule to obtain information on “exposure of consumers to air fresheners,” EPA found the broad scope of the proposal and the resources to be expended a factor in determining that petitioners had not persuaded EPA that it is necessary or appropriate to issue the requested TSCA Section 8(d) rule.⁷

As set forth in this letter, BRAG has identified sufficient facts demonstrating that the existing source-based nomenclature system is unfairly restrictive and should allow for new sources to be added. The reasoning for adding the new sources is the same as when EPA decided to list categories using the initial 35 sources; there are no significant differences between chemicals in the various alkyl categories, nor are there differences between substances derived from the listed sources in each range. The rulemaking that BRAG seeks is focused, and will ensure that EPA’s regulations are equitable in their treatment of substantially similar substances.

⁴ TSCA § 21(a), 15 U.S.C. § 2620(a).

⁵ TSCA § 21(b)(1), 15 U.S.C. § 2620(b)(1).

⁶ 73 Fed. Reg. 32573 (June 9, 2008).

⁷ 72 Fed. Reg. 72886 (Dec. 21, 2007). *See also* 79 Fed. Reg. 13968, 13970 (Mar. 12, 2014) (“Based on the expected limitations in the availability and utility of the records to EPA’s analysis of lead-based paint hazards created by renovations in P&CBs, EPA does not believe that the expenditures of time and resources inherent in proposing and finalizing a TSCA section 8(d) rule are justified”).



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EPA Should Initiate a Rulemaking to Expand the Plant and Animal Sources Listed in the SDA Nomenclature

The SDA nomenclature system is currently limited to the fats, oils and synthetic equivalents of the specific plant and animal sources listed in the SDA procedures. Because alkyl descriptors are used instead of specific sources, manufacturers have some flexibility to switch from one source to another listed in the SDA nomenclature, as long as the alkyl range descriptors for the two sources are the same. The SDA system specifically states, however, that alkyl groups derived from natural sources not listed in the SDA procedures are not eligible to use the SDA nomenclature. The SDA procedures currently list 35 plant and animal sources, which were presumably representative of the sources used in the late 1970s. To date, EPA has not modified that initial list of 35 plant and animal sources.

BRAG believes that EPA is authorized under TSCA Section 8 to commence a rulemaking, the object of which would establish a procedure by which EPA can add new sources of fats and oils to the SDA-eligible list. This petition under TSCA Section 21 requests that EPA initiate such a rulemaking. In the requested rule, EPA would establish a process by which a new fat or oil source can be reviewed, following a premanufacture notice or other appropriate notification to EPA, to determine if its make-up is sufficiently similar to existing fat or oil sources with the same alkyl range. Upon finding such similarity, EPA would add that source to the list of sources eligible to use SDA nomenclature and assign the appropriate alkyl range descriptor code. Once the new source is deemed eligible for SDA nomenclature, the manufacture of the fat or oil and customers converting the fat or oil into chemical derivatives could rely on the appropriate SDA alkyl range identity for purposes of Inventory listing and TSCA nomenclature.

By allowing the list of SDA sources to expand, EPA would treat the original and novel sources equally, and remove the burden of industry reporting *and* of EPA reviewing many chemical substances that are effectively identical both in terms of performance and environmental and human health risk.

This petition sets forth sufficient facts demonstrating that it is “necessary” for EPA to act as requested. The standard EPA utilized when it decided that nomenclature flexibility was warranted for the original 35 natural sources of fats and oils is equally applicable to novel sources, once they are reviewed by EPA. There are no significant expenditures of time and resources inherent in proposing to establish such equivalency that could cause EPA to determine this rule is not justified. To the contrary, establishing such equivalency could relieve EPA from the burden of reviewing premanufacture notices for numerous nearly identical substances.



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BRAG members look forward to the opportunity to discuss with EPA any questions regarding this petition, and to EPA's response to the petition request. Please call me at 443-964-4653 or e-mail me at kroberts@bc-cm.com for further information or to schedule a meeting.

Sincerely,

A handwritten signature in black ink that reads "Kathleen M. Roberts". The signature is written in a cursive, flowing style.

Kathleen M. Roberts
BRAG Executive Director