Biotechnology Innovation Organization

BIOBASED AND RENEWABLE PRODUCTS ADVOCACY GROUP

White Paper:

Proposal for a Toxic Substances Control Act (TSCA) Inventory Representation and Equivalency Determinations for Renewable and Sustainable Bio-based Chemicals

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I. Executive Summary

Renewable and sustainable manufacturing practices, processes, and products are re-shaping today's industrial manufacturing landscape. The Biotechnology Innovation Organization (BIO) and the Biobased and Renewable Products Advocacy Group (BRAG®) support the Environmental Protection Agency's (EPA) oversight of bio-based chemicals through the Toxic Substances Control Act (TSCA). We are optimistic that Section 8(b) of the Act, which provides new agency authority to make equivalency decisions for existing chemicals, can be used to fix the main challenges of TSCA for our industry. Our organizations seek to work cooperatively with EPA to put Section 8(b) into practice and centralize TSCA guidelines and policies for bio-based chemicals. As explained in our in-depth White Paper, an Inventory Representation and Equivalency Initiative would:

- Establish guidance for naming bio-based chemicals based on the equivalency language in TSCA while maintaining EPA oversight of equivalency determinations.

- Effectively decouple bio-based sources and processes from Class 2 chemical identities when that information harms commercialization and is not necessary to protect health and the environment. A "source and process-agnostic" approach that includes the ability to use alkyl or SDA descriptors will prevent a cascade of premanufacture notifications (PMN) when a bio-based chemical is derivatized.

- Include ways to reduce other duplicative burdens beyond redundant PMNs (e.g., the current need for separate tracking, storage, and handling, and duplicative reporting and recordkeeping for equivalent substances under TSCA).

- Identify physical-chemical parameters that may be used to determine equivalency for existing bio-based chemicals and existing processes for such determinations to be made (e.g., prenotice consultation, bona fide requests, PMN reviews, or existing chemical prioritization process), as well as explore establishing a stand-alone process to respond to a manufacturer's request for an equivalency determination.

II. Introduction

The Biotechnology Innovation Organization (BIO)[1] and the Biobased and Renewable Products Advocacy Group (BRAG®)[2] support the U.S. Environmental Protection Agency's (EPA) oversight of bio-based chemicals through the Toxic Substances Control Act (TSCA). Renewable and sustainable manufacturing practices, processes, and products are re-shaping today's industrial manufacturing landscape. These bio-based technologies rely on plants, microbes, waste streams, or by-products to innovate industrial chemicals that include enzymes and proteins, fuels and additives, polymers, essential oils, and triglyceride oils. Microbes and microalgae act, in effect, as the manufacturing plant: they metabolize biomass feedstock into chemicals that are then harvested from the fermentation broth or directly from the microorganism's cellular matrix. As these technologies develop, we are also seeing their use in the capture and conversion of waste gases into chemicals, thereby preventing their release into the atmosphere and "fixing" them into durable, added value products.

Bio-based manufacturing is well established in many product sectors, but the continued absence of a cohesive system that recognizes equivalence and avoids redundant premanufacture notification (PMN) submissions is a roadblock to market adoption of innovative or novel[3] products. We think a possible solution lies in the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016 Lautenberg Act) provisions that require EPA to maintain its Class 2 nomenclature systems and authorize EPA to use discretionary authority to make equivalency determinations. We urge EPA to apply this approach to bio-based chemicals. Specifically, BIO and BRAG request that EPA establish and implement new guidance in the form of an inventory representation (Inventory Representation) for the nomenclature of bio-based chemicals based on the equivalency language in TSCA as amended, while retaining oversight of which chemicals are not equivalent and thus require review.

III. Problem Formulation

Today's bio-based companies compete in established markets dominated by traditional products, both petroleum-based and bio-based, that were "grandfathered" onto the Inventory by original TSCA. Most existing chemical products listed on the TSCA Inventory, with which bio-based chemicals compete, have yet to be reviewed for safety. Bio-based manufacturers welcome EPA risk assessments for their products. The current regulatory system, however, is weighted

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1 BIO is the world's largest biotechnology trade association, representing small and large companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. The BIO Industrial and Environmental Section (BIO-IES) has a particular interest in TSCA and its implementation.

2 BRAG is a trade association that consists of companies and organizations engaged in bio-based chemistries. Our organization addresses regulatory challenges related to the commercialization of bio-based products and works to improve public awareness of the benefits of these products. BRAG provides an informed advocacy voice for policy change for bio-based chemicals where opportunities exist to address challenges unique to this industry sector.

3 For the purposes of this document, "novel" includes microbial, algal, plant, and other non-traditional bio-based sources.

against them based on the criteria EPA uses to determine whether a chemical is "new" and, therefore, subject to EPA review. Even existing bio-based substances are subject to PMN requirements if a manufacturer substitutes its current bio-based feedstock with a novel bio-based source. The net effect is to require customers to make multiple, redundant PMN submissions if: (a) they further chemically react (*i.e.,* "derivatize") a bio-based chemical that is designed to be equivalent to a petroleum based product; or (b) the upstream production strain is modified, even when the change does not require a new Microbial Commercial Activity Notice (MCAN) and does not change the molecular identity of the manufactured, bio-based chemical.

This situation presents challenging regulatory hurdles when compared to using existing counterparts or equivalents listed on the Inventory. For example, EPA advises our members to submit new PMNs even for minor changes in their manufacturing operations including, *inter alia,* genetic changes to the parent organism that are intended solely to improve yield and do not otherwise change the composition or risk profile of the product. This means customers who derivatize these products are also urged to file more and subsequent PMNs for their own products. We question the need for and value of EPA repeatedly reviewing the same chemistry, and changes to the microorganism that are intrageneric, because the hazard, and therefore the risk, is the same.

Redundant PMN submissions slow or prevent the adoption of sustainable chemistry, place severe regulatory burdens on customers, and deplete EPA's limited resources. The redundancy extends beyond the PMN review process, however, and impacts how companies manage and track their bio-based products. Under the current system, companies must keep different source- and process-based, but chemically and structurally equivalent, substances separate to avoid jeopardizing downstream derivatives. This results in the need for duplicative manufacturing and processing equipment, recordkeeping, and risk assessments for chemically equivalent substances. Such redundancy significantly increases a company's operating costs and hinders its ability to remain competitive and innovative.

Furthermore, the current system places U.S. bio-based manufacturers and processors at a competitive disadvantage compared to countries that rely on a feedstock neutral approach. For instance, the European Union (EU) approach to nomenclature is based on alkyl ranges, and thereby already decouples the bio-based source or process from the produced chemical. Currently, a bio-based oil that is imported from the EU into the U.S. must be renamed at the border, and vice versa, which adds an additional burden to the cost of doing business in the U.S. and an element of brand and regulatory confusion. The EU approach is followed by South Korea, China, and Japan. The approach outlined in this White Paper harmonizes TSCA with the feedstock neutral approach in place globally, which reduces the regulatory burden of conducting business in the U.S. and provides flexibility to U.S. bio-based companies. Adoption by EPA of the approach outlined here would make TSCA more internationally harmonized and help the U.S. remain competitive in the global bioeconomy. Furthermore, the proposed approach would benefit the environment by facilitating greater use of renewable waste stream or by-products (for example) in chemical manufacture, which can, in turn, reduce reliance on non-renewable chemical feedstocks.

IV. Bio-based Chemical Substance Descriptions under TSCA

An Inventory Representation for bio-based substances is needed to centralize the current guidance documents and other resources in use today. Interpretations of the TSCA Inventory status of bio-based substances are scattered in various publicly available sources, making the meaningful use and reliance upon these documents challenging. These documents include the proposed[4] and final biotechnology rulemakings,[5] the TSCA Inventory Representation for Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB) Substances (UVCB Inventory Representation),[6] and the TSCA Inventory Representation For Certain Chemical Substances Containing Varying Carbon Chain Lengths (Alkyl Ranges Using The Cx-Y Notation) (Alkyl Range Inventory Representation).[7] These documents were issued in final form over 20 years ago and do not necessarily address many of the innovative bio-based substances now in commerce. Even at that time, however, EPA stated that it recognized the need for guidance:

> Numerous relatively simple biological materials are listed as UVCB products on the TSCA Inventory, either by themselves or as components of further reaction products. The more complex biologicals, including enzymes, organisms and products of the biotechnology industry are also considered to be UVCB substances. *Although some of these more complex biological substances were reported and included on the Inventory, EPA has not yet developed guidance for their Inventory representation.*[8]

The effect of the current system is that EPA reviews the same derivative chemistry repeatedly, even when bio-based chemicals are chemically and functionally equivalent to traditional molecules. A method to establish equivalency between these chemistries is urgently needed to avoid depleting limited EPA resources on redundant PMN reviews; eliminate the need for duplicative industry processes; and align TSCA with other international chemical regulations. Appendix A to this White Paper provides an illustrative set of principles to guide the development of an Inventory Representation and make equivalency determinations. Section 8(b)(2) of amended TSCA empowers EPA to issue guidance and establish a level playing field. We believe that, with the input of expert stakeholders, EPA can issue a coherent nomenclature policy without the need for rulemaking.

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4 Microbial Products of Biotechnology; Proposed Regulation Under the Toxic Substances Control Act, 59 Fed. Reg. 45526 (Sept. 1, 1994).

5 Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act, 62 Fed. Reg. 17910 (Apr. 11, 1997).

6 UVCB Inventory Representation (1995), available at https://www.epa.gov/sites/production/files/2015-05/documents/uvcb.pdf.

7 Alkyl Range Inventory Representation, available at https://www.epa.gov/sites/production/files/2015-05/documents/alkyl-rg.pdf.

8 UVCB Inventory Representation at 6-7 (emphasis added).

V. Key Inventory Interpretation Policies

The status of an industrial, bio-based chemical substance as new or existing is determined, in large part, by its "Class 1" or "Class 2" chemical composition. A Class 1 chemical substance is a single compound composed of molecules with particular atoms arranged in a definite, known structure. It is described on the Inventory by the parent structure, the identity, the number and position of the attached chemical groups, as well as counterions, stereochemical relationships, and the like. A Class 2 composition cannot be represented by a definite chemical structure diagram. The subgroup of Class 2 compounds relevant to this White Paper, specifically Class 2 UVCBs, may be described with reference to their partial or incomplete chemical structure; combination of known or unknown components; or method of manufacture, immediate precursor substances, and/or processing information (*e.g.*, distillation, fermentation). In addition, a reaction product combination can be named as a mixture of individual Class 1 substances, if all the individual molecules in the product are known and always present.[9] A substance is naturally occurring if only mechanical means (or similar) are used. In this case, it is implicitly included on the TSCA Inventory.

A. Bio-based Class 1 Chemicals

Bio-based chemicals with a well-defined molecular structure (Class 1 composition) share the same chemical description as the molecule produced by traditional means. EPA confirmed this in the examples provided in the Alkyl Range Inventory Representation. Methanol, ethanol, butanol, succinic acid, and other bio-based Class 1 chemistries are listed on the TSCA Inventory regardless of the feedstock or production method. If a Class 1 substance is produced by an intergeneric microorganism, there are no biological descriptors associated with the Inventory listing. Since the current nomenclature system does not present a regulatory barrier to the commercialization of Class 1 substances derived from novel sources, further guidance on such substances is not requested.

B. Bio-based Class 2 Substances including Polymers and Triglycerides

Bio-based UVCBs are a group of products for which equivalency determinations and alternatives to source and process descriptors are most needed due to the source-based descriptors assigned to many chemicals. For instance, a particular triglyceride oil can be derived from different strains of the same microbial genus and species, using glucose or sucrose as the carbon source. In this way, the microbe functions as a molecular factory. If the end product is designed to duplicate the composition of a substance identified as, for example, soybean oil on the TSCA Inventory, there is currently no mechanism to establish the regulatory equivalency of the two chemicals or to rely on the same listing for the bio-based oil. As a result, EPA would be of the view that the company must file a PMN for the microbial product. Similarly, a company manufacturing fatty acid methyl ester from soybean oil could not supplement the soybean feedstock with another source or process and still rely on the same TSCA listing, even if the fatty acid composition was maintained.

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[9] *Id.* at p.3.

Additionally, essential oil listings on the Inventory typically include the phrase "[e]xtractives and their physically modified derivatives" followed by the genus and species of the biological source. Use of another source, even if the same composition of oil is obtained, requires a separate Inventory listing.[10] Similarly, in the case of bio-based polymers, regardless of how closely they may mirror the synthetic equivalent, EPA advises that they do not share the same description on the Inventory. The synthetic and bio-based listings for polyhydroxyalkanoate (PHA) polymers illustrate this trend.

Based on the experience of our members, we understand the Class 2 UVCB nomenclature system EPA is using employs a rubric of "source, process, and structure," where:

- The **source** field includes reference to the chemical feedstocks (*e.g.*, corn, soybean carbohydrate, or fermentable sugars), including those that are added to the fermentation;

- The **process** field identifies the manufacturing process (*e.g.*, distillation, transesterification, or extraction) or, in the case of intergeneric microbes, production strain (*e.g.*, via fermentation with Saccharomyces cerevisiae, modified), with the details of the strain normally described in an associated MCAN submission[11]); and

- The **structure** field describes the molecular identity of the commercial product (*e.g.*, Glycerides, C10-C12 and C16, unsaturated).

It is our understanding that EPA uses the above-referenced fields to describe the "method of manufacture" for bio-based, UVCB Class 2 substances. A resulting name representative of this system would be "Glycerides, C10-C12 and C16, unsaturated, from a fermentation process with recombinant Saccharomyces cerevisiae using fermentable sugars." A change in source, process, or structure results in a recommendation by EPA to make a new PMN filing. We understand that while this information can be important to the review process, such changes do not necessarily mean the chemical itself has been altered. For instance, a different bio-based process can produce a chemical with the same oil composition, function, and performance. Industry views these substances as equivalent and interchangeable, but the current system requires a unique TSCA Inventory listing before the substance can be produced using a new feedstock.

Under the current system, we understand that even a change in the production strain that does not warrant a new MCAN (*e.g.*, one that is classically improved), can be the basis for a new PMN filing for the chemical. This is because, under the current system, the production strain is in the process field part of the description of the chemical substance it produces, so **any** change to the microbial strain results in a "new" chemical substance, regardless of the composition of the microbial product. If EPA is aware of changes in production strains that would not result in the need for a new PMN for the chemical substance being produced, and these examples can be

[10] UVCB Inventory Representation at 7.

[11] We note that chemical products produced from non-microbial organisms only include the species in the substance identity.

publicly identified, EPA should publish those conditions. Redundant PMNs are also required when the microbial strain is modified to express additional copies of the same production gene. The manufacturer's intent in these cases is not to make "Microorganism X" oil, but the EPA approach to source-based nomenclature achieves exactly this effect. The organisms are engineered to be molecular factories – factories that may be designed to produce highly targeted products. Thus, the microbe is a manufacturing "facility" rather than a unique process. EPA's Alkyl Range Inventory Representation anticipates examples such as this. The Alkyl Range Inventory Representation states:

> The substances described by this [alkyl range] notation may be derived from a source not described in SDA nomenclature, be purified to enhance one or more of the alkyl chains from a natural source or be derived from two or more interchangeable sources.[12]

This guidance permits describing a substance by an alkyl range without specifying a source or process, whether natural or synthetic. Despite the clear statement in the guidance, EPA consistently insists on including the production strain along with an alkyl range in the identity of substances when reviewing bio-based substances submitted to EPA as part of Inventory Correspondence, Bona Fide Intent to Manufacture Notices, or PMNs.

The primary problem with source-based descriptions is that each derivative substance must carry the name of the source. Once a derivative substance is listed on the TSCA Inventory with a specific source- and process-based descriptor, the manufacturer of that derivative cannot change to a feedstock that is chemically equivalent but produced by a different source or process without ensuring that the derivative made from that source or process is also listed on the TSCA Inventory.[13] Customers face the prospect of multiple PMN submissions for isolated intermediates and reaction products made from a bio-based feedstock that is considered "new" under EPA's current policy. Furthermore, the creation of new source- or process-based chemical descriptors for isolated intermediates necessitates manufacturing, processing, and handling that forces redundant manufacturing equipment, such as storage tanks, to keep each substance separate for TSCA compliance even though their particular molecular identity is the same.[14] Additionally, separate recordkeeping and reporting must be conducted for the chemically equivalent substances. For example: In the case of corn oil sourced from corn, there will likely be acceptable TSCA listings for most traditional derivatives. When the same oil profile is produced from another natural source or a genetically engineered (GE) microbe, the customer will need to file PMNs for each derivative and ensure that the corn oil and "new" oil are handled and reported separately. *See* Figure 1.

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[12] Alkyl Range Inventory Representation at 1-2.

[13] This assumes that the second source is listed on the Inventory.

[14] TSCA defines a "chemical substance" as any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. 15 U.S.C. § 2602(2)(A).

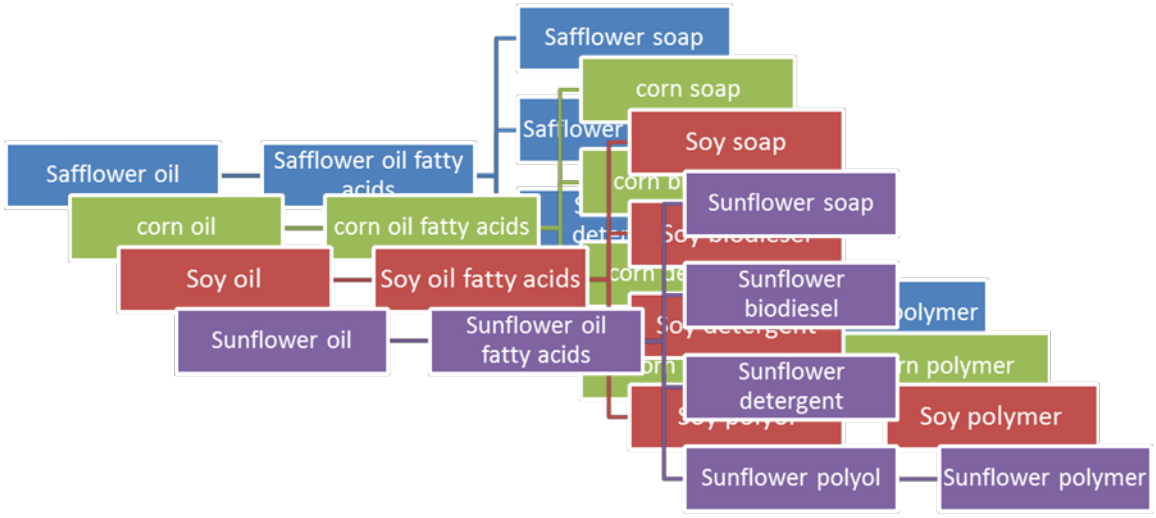

Figure 1. Depiction of how source names propagate through a supply chain.

As shown above, every "new" oil derived from a new bio-based feedstock sets in motion a cascade of PMN submissions and requires duplicative processing, handling, and reporting requirements for every customer that wants to create a derivative using that oil. This acts as a very significant barrier to the adoption of bio-based chemicals without any concomitant benefit in terms of identifying or managing risk.

C. Soap and Detergent Association (SDA) Nomenclature

Duplicative regulatory reviews are what prompted EPA to develop the SDA policy. EPA recognized the challenges TSCA imposes on manufacturers and partnered with SDA (now the American Cleaning Institute) when the TSCA Inventory was first compiled to relieve some of the challenges associated with substance identity. The use of an SDA alkyl range descriptor allows a derivative to be manufactured in a source-agnostic manner and permits customers to select among the permitted sources that produce that alkyl range. Again, these are mixtures of different alkyl ranges in which the precise amount of individual alkyl chain lengths may vary. The SDA policy applies to "substances derived from natural fats and oils and synthetic long-chain alkyl substitutes," and is a nomenclature system used to determine whether a substance is a "new chemical" such that a PMN is required prior to use. It is the SDA policy's departure from other TSCA naming conventions (requiring source-based nomenclature) that makes it unique. It eliminates duplicative listings of chemically indistinguishable and equivalent substances.

The SDA policy lists certain alkyl ranges derived from an illustrative list of feedstocks. The 35 feedstocks included on the SDA list were probably identified and selected based on their ubiquity in commerce and history of safe use. Industry's understanding is that when it was first implemented, the intention was to create a source-agnostic approach to naming specific fats and oils produced from such feedstocks, by providing the option of using alkyl ranges as the identifier as opposed to the feedstock source. Thus, as originally implemented, the SDA list was a closed list of alkyl ranges with an illustrative (open) list of sources, as long as the same alkyl ranges were being sourced from them. In what is now TSCA Section 8(b)(3), Congress recognized this original intent by providing that:

> (A) In general — In carrying out paragraph (1), the Administrator shall --
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> * * *
>
> (ii) [M]aintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in Section 1 of addendum III of the document entitled "Candidate List of Chemical Substances", and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a).

This language appears intended to correct subsequent EPA statements that characterize the system as limited both to certain alkyl ranges and a small number of possible sources. Those statements had the effect of revising the interpretation of the SDA policy as having an additional sourced-based requirement that went beyond the original intention to limit the policy to specific alkyl ranges. EPA's later view implies that manufacturers of the listed alkyl ranges need to file PMNs if the source is not included in the 1978 SDA list. While we do not argue that the SDA policy could have been drafted to provide greater clarity, the SDA policy, taken in whole, clearly contemplates source- and process-neutral nomenclature for all UVCBs containing the specified alkyl groups. In our view, requiring manufacturers to file a PMN when producing an alkyl derivative that matches an SDA-permitted alkyl range based solely on the use of a new feedstock conflicts with the SDA policy as originally envisioned.

EPA also allows flexibility in nomenclature for oils from traditional sources, including petroleum, yet requires PMNs and more precise nomenclature for chemically equivalent oils produced from novel, bio-based sources. For example, there are 99 substances that may be named using the SDA range "C16-18 and C18 unsatd." These substances include such derivatives as biodiesel (Fatty acids, C16-18 and C18-unsatd., Me esters), soap (Fatty acids, C16-18 and C18-unsatd., sodium salts), and adhesive resins (Fatty acids, C16-18 and C18-unsatd., polymers with bisphenol A and epichlorohydrin). Each of these 99 substances can be manufactured from any of the sources listed in the SDA guidance, including corn oil, soy oil, sunflower oil, and petroleum, and can be identified using either a source- or alkyl-based descriptor. Under EPA's current policy, however, a manufacturer of one of these substances would be required to submit a PMN before producing the biodiesel, salt, or adhesive resin from an innovative source. Furthermore, the manufacturer would not be permitted to identify the

"new" substance using an SDA descriptor, even if the biodiesel, salt, or adhesive resin otherwise meets the alkyl range limits established in the SDA policy. Providing the same flexibility to innovative sources enhances diversification of feedstocks, optimizes renewable feedstocks, and increases customer choice. Expanding feedstock flexibility to novel bio-based sources would also bring TSCA in line with international regulatory policies and allow the U.S. to remain competitive in the global bioeconomy.

VI. Congressional Support for Chemical Equivalency

We are deeply concerned that EPA is interpreting the 2016 Lautenberg Act as requiring industry to continue to use source- and process-based nomenclature to name new bio-based chemicals. Based on our reading, Section 8 of amended TSCA allows EPA to adopt a different approach through a process that can determine equivalency with existing chemicals, to effectively decouple the bio-based source and process from the chemical name. A "source- and process-agnostic" approach will help prevent a cascade of PMNs when the bio-based chemical is derivatized. TSCA Section 8(b)(3) provides:

> (B) Multiple nomenclature listings. -- If a manufacturer or processor demonstrates to the Administrator that a chemical substance appears multiple times on the list published under paragraph (1) under different [Chemical Abstracts Service (CAS)] numbers, the Administrator may recognize the multiple listings as a single chemical substance.

As originally envisioned, Senate Report 114-67 on the 2016 Lautenberg Act (To accompanying S. 697) summarizes Congress' intention on equivalency as follows:

> Under TSCA, numerous nomenclature conventions exist that may prevent the efficient distribution of chemicals into commerce. It is the intent of the Committee that the provisions of Section 10 related to nomenclature will resolve these issues by requiring the Administrator to develop new guidance that will establish equivalency between these conventions, while preserving certain nomenclature approaches that have significant value. It will also permit any chemical substance appearing multiple times, each with a different Chemical Abstract Service (CAS) number, to be treated by the Agency as a single chemical substance. This will help prevent duplicative safety assessments and determinations by ensuring that substantially equivalent chemicals are considered at the same time, as appropriate. The Committee believes this approach will also help enhance EPA's ability to evaluate substances from new sources against existing substances for equivalence, enabling similar substances to rely on the Inventory listing of an existing substance. The Committee also intends that EPA's guidance should address those instances where multiple, different substances share the same CAS number. These substances may have different hazard profiles, but these

> distinguishing characteristics are not transparent to the public and stakeholders.
>
> Current TSCA provides EPA the authority to list a category of substances on the inventory, rather than list individually each chemical substance within a category. S. 697 maintains this authority to ensure that minor modification or variations in the formulation or structure of a chemical substance that have insignificant health or environmental consequences would not be automatically subject to the notification requirements of Section 5. The Committee believes that EPA's current policy of not requiring notification for variations in naturally-occurring substances or mixtures should generally be continued.[15]

The intended purpose of the final language adopted by the 2016 Lautenberg Act is well-described in an exchange preserved in the *Congressional Record* between the main sponsors of the legislation in the Senate on June 7, 2016:

> Mr. VITTER. Senator INHOFE, this leads me to another question on a provision that is rather technical and has been misunderstood by many and that is nomenclature. After the TSCA Inventory was established in 1979, questions arose about the appropriate chemical "nomenclature" to be used to list these chemical substances. EPA addressed many of these questions in a series of guidance documents. The compromise includes a provision on nomenclature. What is this provision intended to do?
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> Mr. INHOFE. Thank you, Senator VITTER. These provisions are very important to many major domestic producers including manufacturers of products like glass, steel, cement, along with domestic energy producers across the country. The chemical nomenclature provision in Section 8 of the compromise addresses several issues critical to the efficient functioning of the new chemical regulatory framework. For the purposes of the TSCA Inventory, a single, defined molecule is simple to name. For example, ethanol is a Class 1 chemical on the TSCA Inventory. Its identity does not depend on how it is made. Since one ethanol is chemically the same as another ethanol, a new producer of ethanol can use the existing ethanol chemical listed on the TSCA Inventory. For other substances known as Class 2 chemicals, nomenclature is more complex. For those substances, the name of the substance typically includes either -- or both -- The source material and the process used to make it. The compromise requires EPA to maintain the Class 2 nomenclature system, as well as

[15] S. Rep. No. 114-67, at 20 (2015).

> certain nomenclature conventions in widespread use since the early days of TSCA. The compromise also directs EPA to continue to recognize the individual members of categories of chemical substances as being on the TSCA inventory. The individual members of these categories are defined in inventory descriptions developed by EPA. ***In addition, the compromise permits manufacturers or processors to request that EPA recognize a chemical substance currently identified on the TSCA Inventory under multiple nomenclatures as "equivalents." Importantly, the equivalency provision relates only to chemical substances that are already on the TSCA Inventory. Although the equivalency provision specifically references substances that have Chemical Abstract Service (CAS) numbers, EPA could usefully apply an equivalency approach to substances on the Inventory that do not have CAS numbers as well, such as for naturally-occurring substances.***[16]

The legislative history of these provisions in House Report 114-176 on the TSCA Modernization Act of 2015 (To accompany H.R. 2576) reinforces the need for equivalency decisions:

> The legislation made a single conforming change to TSCA Section 8. When H.R. 2576 was ordered, the Committee was aware of five specific issues about which regulated stakeholders recommended legislative language in H.R. 2576 to improve the implementation of some portions of TSCA Section 8. These issues are: (1) resetting the TSCA Section 8(b) Inventory, (2) updating the standards for determining what constitutes a small manufacturer or processor for purposes of Section 8(a) reporting, (3) limiting Section 8(a) reporting requirements for byproducts if EPA already has that information and if the reporting discourages recycling, ***(4) requiring that EPA under Sections 8(b) consider chemical substances with multiple nomenclature conventions as a single inventory listing for both existing and new chemical substances***, and (5) getting quicker and clearer responses from EPA on petitions for partial exemption from TSCA Section 8(a) reporting due to a designation as a ''low current interest'' under 40 C.F.R. 711.6(b)(2)(iv). The exclusion of these items from H.R. 2576 should not be interpreted as a lack of interest by the Committee in the issues. Rather, the omission from H.R. 2576 is predicated ***on the understanding of the Committee that these are matters that EPA already has administrative authority under TSCA to address, and new or amended legal authority may not be required to accomplish these improvements under Section 8.***

[16] Senate Colloquy on S. 697, the TSCA Modernization Act of 2015, 162 Cong. Rec. S3511, S3520-21 (emphasis added).

> ***If the Administrator fails to promptly and adequately address these concerns, the Committee will work with other Members of Congress and with the Administration to consider legislative remedies.***[17]

VII. Requested Inventory Representation and Equivalency Framework

BIO and BRAG request that EPA allow manufacturers to use the PMN process and/or the bona fide process to request equivalency determinations and to nominate sources and processes (*i.e.*, microorganisms) to add to the SDA list. The PMN approach authorizes EPA to review both the safety of the alkyl range and the equivalency of the source, while the current bona fide process is typically limited to equivalency determinations. If EPA agrees with the equivalency request and/or adds the source or production strain to the SDA list, entities will not be required to file PMNs for derivatives that are listed on the TSCA Inventory with a source-agnostic description. We also request that manufacturers be permitted to request equivalency determinations for existing chemicals that are derived from different feedstocks. If EPA agrees with the equivalency request, the chemicals could be identified by an agnostic descriptor, which would eliminate the need for manufacturers to maintain duplicative equipment, processes, and recordkeeping. To be clear, we are asking that the biological equivalency of the source (*i.e.*, the plant or production organism) not be included in "equivalency determinations" for the resulting chemical substances. This underscores our point that feedstocks that lack biological similarity can produce equivalent chemical substances with analogous functionality and risk profiles.

Equivalency determinations address the problem of duplicative PMNs and add a mechanism voluntarily to update the SDA feedstock list within the existing TSCA framework. The equivalency provision of TSCA is intended to be applied to existing substances listed on the TSCA Inventory. EPA, therefore, could decide that two existing bio-based UVCB chemicals are equivalent to a third identity that is source- and process-agnostic. Similarly, once a PMN substance clears review and either in advance of or as a result of submission of a notice of commencement (NOC), EPA could make a finding that the new substance is considered by EPA to be equivalent to an existing chemical. The action needed to achieve this result is to establish and verify equivalency factors on which industry and EPA can rely to make these determinations consistently and coherently. These factors could range from establishing molecular equivalency through a spectral data analysis to the comparison of physical-chemical properties that contribute to the chemical's primary properties.

A comprehensive Inventory Representation could include several elements. Alternatives to source-based descriptions are warranted because, as the SDA approach demonstrates, various sources can be used to produce chemicals that are structurally, technically, and functionally equivalent. Requiring such substances to be listed separately on the TSCA Inventory results in a duplicative process that depletes EPA resources and places U.S. companies at a competitive disadvantage. Moreover, novel organisms, such as microbes, play a distinctly different role in these processes. The microbes are not a source; they simply provide a mechanism, means, or

[17] H.R. Rep. No. 114-176, at 33-34 (2015).

platform to manufacture the chemical that is produced. As a result, we seek an Inventory Representation strategy that:

- Recognizes that the identity of a substance is not affected by modifications to the production organism that do not materially affect the composition of the chemical substance derived from that organism. For instance, the production organism may be modified to produce a higher yield of the derived substance without changing the composition. This type of modification would not change the chemical identify of a class 2 substance. Changes to a production organism or production process that intentionally and substantively change the composition of a substance would have to be reflected in the substance identity, and such determinations should be consistent with the criteria used to identify these changes for competing petroleum- or traditional seed oil- based products.

- Affirms the SDA policy as source- and process-agnostic so that industry may continue to have confidence in these listings regardless of source and innovative bio-based Class 2 products have access to this system.

- Allows Class 2 bio-based substances access to the same set of rules available to traditional alkyl range chemistry, specifically regarding flexibility with respect to intended or unintended variation in the chemical composition that do not impact the risk profile of the substance.

EPA could take these actions as part of an existing review process when it determines that a Class 2 bio-based chemical meets the TSCA safety standard or as a standalone action in response to a manufacturer equivalency request, which may be managed through the bona fide submission or similar process. We understand that chemical descriptions are a means for EPA to assess risk. In this respect, the current system offers little or no increased protection to health or the environment once a bio-based chemical is reviewed the first time.

Bio-based companies need a level downstream playing field on which to compete in the marketplace. BIO and BRAG welcome the opportunity to work with EPA on the development of EPA guidance to make equivalency determinations and issue a TSCA Inventory Representation that captures the diversity of today's chemical products.

For further information please contact:

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Attachment (1)

Appendix A: BIO and BRAG "Principles for an Inventory Representation for Bio-based Chemical Substances"

1. In the interest of transparency, guidance must be made publicly available to support TSCA Inventory determinations for bio-based chemical nomenclature after adequate notice to, and comment by, stakeholders.

2. Manufacturers and importers have primary responsibility for determining the status of their bio-based chemical substances on the TSCA Inventory.

3. Nomenclature guidance should not lead to duplicative reporting and multiple names for equivalent chemical substances.

4. Nomenclature for bio-based chemicals must be feedstock neutral and must focus on the chemical product rather than the process. In other words, EPA must decouple the definition of the chemical from the primary product source and production strain for those chemicals which can be sufficiently identified by their chemical structure. Process- or source-based nomenclature is only necessary when such identification is not feasible.

5. Nomenclature should avoid placing U.S. bio-based product companies at a disadvantage domestically in comparison with other regulatory frameworks where a new chemical registration for bio-based chemicals that are equivalent to those already registered is not required.

6. The use of SDA nomenclature for natural source oils and their substitutes, as described in Addendum III to the 1978 TSCA Candidate List of Substances Guidance Document, must be available to name bio-based chemical substances under TSCA Section 8(b)(3)(A)(ii). This source-agnostic system for equivalent alkyl range products originally selected the covered alkyl ranges in recognition that equivalent chemistry is derived from multiple sources. The SDA system reduces duplicate reporting, removes regulatory barriers to innovation, and saves user fees and fixed equipment costs as well as EPA resources. EPA should develop a system to evaluate new sources that may be added to the SDA system.

7. Bio-based chemical substances must be given the same flexibility already provided to equivalent chemical products, and not require a new chemical notice when they exhibit intended or unintended variation in the amount of the individual components within a specified alkyl range.

8. The genus/species of microorganisms and the details of their construction must be fully recognized as confidential business information (CBI) under Section 14 of TSCA, so that business competitors are not afforded an unfair opportunity to benefit from resource intensive discoveries and intellectual property registrations. Descriptions of how strains are constructed are manufacturing details that are not subject to 2016 Lautenberg Act CBI substantiation requirements.