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The logo for the Biobased and Renewable Products Advocacy Group (BRAG), featuring the word "BRAG" in a white, bold, sans-serif font inside a light green rectangular box. A small green leaf icon is positioned to the right of the letter "G".

BRAG

**BIOBASED AND
RENEWABLE PRODUCTS
ADVOCACY GROUP**

Equivalency and Naming for Bio-Based Chemical Substances Under
the Toxic Substances Control Act

June 13, 2018

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

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

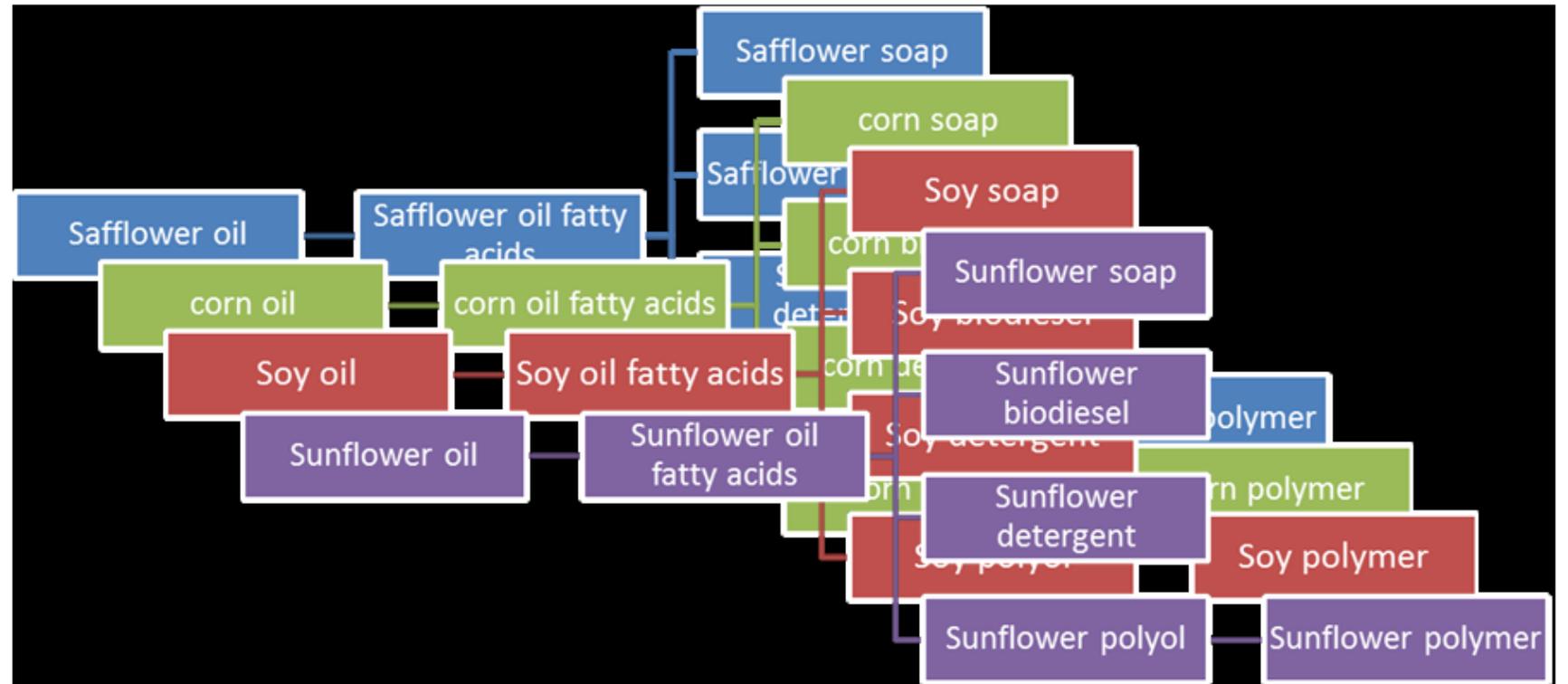
- In April, BIO and BRAG sent EPA a proposal to initiate implementation of section 8 of new TSCA concerning equivalency determinations and naming for bio-based chemicals.
- **BIO** is the world's largest biotechnology trade association, representing small and large companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. The BIO Industrial and Environmental Section (BIO-IES) has a particular interest in TSCA and its implementation.
- **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.

Why We're Here Today

- The source- and process-based TSCA naming system for certain class 2 chemicals acts as **a very significant barrier** to the adoption of bio-based chemicals without a concomitant benefit in terms of identifying or managing risk (that we can identify).
- A new Inventory Representation guidance document and more workable naming rules for bio-based substances is needed to centralize and reform the current guidance in use today.

Section 5 – Cascade of PMNs for Duplicative Chemistry

- Under the current system, EPA reviews the same derivative chemistry repeatedly, when sourced from with bio-based chemicals that are chemically and functionally equivalent to traditional molecules. The SDA nomenclature system was developed to reduce this redundancy.



Cascading PMNs for Class 2 UCVBs Stem from How EPA Names Them Right Now

- **Source** - the chemical feedstocks (*e.g.*, corn, soybean carbohydrate, or fermentable sugars) added to the fermentation;
- **Process** - 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 submission¹¹); and
- **Structure** - describes the molecular identity of the commercial product (*e.g.*, Glycerides, C10-C12 and C16, unsaturated).
- 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.**”
 - The listing is tied to only one particular recombinant strain described in a separate MCAN filing, so the name appears broader than it actually is.
 - **Any change in source, process, or structure results in a recommendation by EPA to make a new PMN filing when the chemical itself is not altered.**

Section 5 – Problem Formulation for New Chemicals

- Manufacturers of class 2 bio-based products have to make **redundant PMN submissions** that slow or prevent the adoption of sustainable chemistry.
- It forces our customers to make PMN submissions if they chemically react (i.e., “derivatize”) a class 2 bio-based chemical that is designed to be equivalent to a petroleum based product. This **places a substantial regulatory burden on customers**.
- We question the need for and value of EPA repeatedly reviewing the same chemistry, and changes to production microorganisms when **the exposure and hazard, and therefore the risk, is the same**.

Section 5 Process Element Request

- We ask EPA to develop naming guidance for bio-based substances and production sources because current resources are scant, scattered, and dated. They include -
 - The proposed and final biotechnology rulemakings
 - The 1995 TSCA Inventory Representation for Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB) Substances (UVCB Inventory Representation)
 - Even here, EPA recognizes that for more complex products of the biotechnology industry, including UVCB substances, *guidance for their Inventory representation has yet to be developed.*

Section 5 – Technical Element Request

- Class 1 chemistry: The current nomenclature system does not present a regulatory barrier to the commercialization of Class 1 substances derived from novel sources, no change in guidance needed.
- Class 2 chemistry:
 - We want to be able to apply the SDA policy. We would like EPA to provide a voluntary mechanism to nominate sources and processes (*i.e.*, microorganisms) to add to the SDA list.
 - 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.” It is the SDA policy’s departure from other TSCA naming conventions (requiring source-based nomenclature) that eliminates duplicative listings of chemically indistinguishable and equivalent substances.
 - We want to be able to apply the TSCA Inventory Representation For Certain Chemical Substances Containing Varying Carbon Chain Lengths (Alkyl Ranges Using The Cx-Y Notation) (Alkyl Range Inventory Representation).
 - This 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.

Section 5 – Technical Element Request

- **Our organisms are not a “source”**—that is manufactures are not trying to make a particular microbial oil. Rather the **organisms simply provide a mechanism, means, or platform to manufacture a chemical substance.**
 - The identity of a substance should not change due to modifications to the production organism that do not materially affect the composition of the chemical substance derived.
 - For example, 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.

Section 8 – Problem Formulation on Equivalency

- **TSCA program redundancy extends beyond the PMN review process.** Companies must keep different source- and process-based, but chemically and structurally equivalent, substances separate to avoid jeopardizing downstream derivatives. This includes:
 - Separate tracking, storage, and handling
 - Duplicative reporting and recordkeeping for equivalent substances
- **Section 8(b)(3) 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:
 - Permits EPA to treat chemical substance appearing multiple times, each with a different Chemical Abstract Service (CAS) number, as a single chemical substance.
 - Once a bio-based chemical is on the Inventory and deemed equivalent, customers should not have to file redundant PMN submissions when they derivatize our products.
 - This also would lessen the need for separate handling, tracking and reporting.

Section 8 Process Element Request

- BIO and BRAG request that EPA **allow manufacturers to use the PMN or *bona fide* process to request equivalency determinations.**
- The PMN approach authorizes EPA to review both the safety of the product and the equivalency of the source, while the current *bona fide* process would presumably be limited to equivalency determinations.
- 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.
- EPA could decide that two existing bio-based UVCB chemicals are equivalent to a third identity that is source- and process-agnostic.
- **If EPA agrees with the equivalency request and/or adds the source or production strain to the SDA list, down-stream entities will not be required to file PMNs for derivatives that are listed on the TSCA Inventory with a source-agnostic description or for which EPA has determined the feedstocks are equivalent.**

Section 8 Technical Element Request

- We also request that manufacturers be permitted to **request equivalency determinations for existing chemicals that are derived from different feedstocks.**
- We specifically request that the biological equivalency of the source (*i.e.*, the plant or production organism) is not part of the “equivalency determination” for the resulting chemical substances to underscore our point that feedstocks produced by different organisms can produce equivalent chemical substances with analogous functionality and risk profiles.

White Paper Summary of Key Concepts

- Use a more predictable, “**source and process-agnostic**” approach for naming that includes the ability to use alkyl or SDA descriptors, to prevent a cascade of PMNs when a bio-based chemical is derivatized.
- **Establish guidance** for naming bio-based chemicals based on the equivalency language in TSCA while maintaining EPA oversight of equivalency determinations to eliminate duplicative reporting and recordkeeping, and the need to separately track, store, and handle equivalent substances.
- Work together to identify physical-chemical parameters that may be used to determine equivalency for existing bio-based chemicals.
- **Use existing processes for equivalency determinations** (e.g., prenotice consultation, bona fide requests, PMN reviews, or existing chemical prioritization process).

Thank you for
your time and
consideration
EPA.

- The changes we recommend would result in a **faster process that would ultimately require fewer EPA resources** to meet TSCA's statutory obligations, especially during challenging budgetary times.
- These changes would lead to **less confusion by the bio-renewable industry**, which would ultimately contribute to greater regulatory compliance.
- These changes would lead more companies **to use sustainable, bio-based chemicals**.
- We would like to cooperate with EPA to develop guidance on naming and to begin making equivalency determinations for bio-based chemicals.

For Further Information

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