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The Assistant Administrator for Chemical Safety and Pollution Prevention signed the following *Federal Register* document on December 31, 2015:

Title: TSCA Inventory Equivalency Determinations for Certain Class 2 Substances; TSCA Section 21 Petition; Reasons for Agency Response

FRL: 9940-61

Docket No.: **EPA-HQ-OPPT-2015-0823**

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2015-0823; FRL- 9940-61]

TSCA Inventory Equivalency Determinations for Certain Class 2 Substances; TSCA

Section 21 Petition; Reasons for Agency Response

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This document announces the availability of EPA's response to a petition it received under the Toxic Substances Control Act (TSCA). The TSCA section 21 petition was received from the Biobased and Renewable Products Advocacy Group (BRAG) on October 7, 2015. The petitioner requested EPA to promulgate a rule pursuant to TSCA section 8 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." After careful consideration, EPA denied the TSCA section 21 petition for the reasons discussed in this document.

DATES: EPA's response to this TSCA section 21 petition was signed [*insert date of signature on response letter*].

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kent Anapolle, Chemistry, Economics, and Sustainable Strategies Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8578; email address: anapolle.kent@epa.gov.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are or may manufacture or import biobased chemicals similar to fats and oils described by the SDA nomenclature system. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How Can I Access Information About this Petition?

The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0823, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. TSCA Section 21

A. What is a TSCA Section 21 Petition?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a

rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90-day period.

B. What Criteria Apply to a Decision on a TSCA Section 21 Petition?

Section 21(b)(1) of TSCA requires that the petition “set forth the facts which it is claimed establish that it is necessary” to issue the rule or order requested, 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition, 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested to evaluate this TSCA section 21 petition.

III. Summary of the TSCA Section 21 Petition

A. What Action was Requested?

On October 7, 2015, EPA received a petition from the Biobased and Renewable Products Advocacy Group (BRAG) requesting the Agency to address the “disproportionate regulatory burden” imposed on companies in the bio-based chemical sector, noting that a “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.” Specifically, the petition asks EPA to commence a rulemaking process under TSCA section 8, the objective of which would be to “establish a procedure by which EPA can add new sources of fats and oils to the SDA-eligible list.”

The petition states that the SDA-eligible list is part of a broader “nomenclature system developed by SDA when the TSCA Inventory was initially compiled.” The term “SDA-eligible list” refers to a list found in the 1978 Candidate List of Chemical Substances on the TSCA Inventory, in “Addendum III: Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials” (Ref. 2). In Section I of that document, EPA described a chemical substance naming convention, attributed to the SDA that was available for “identifying and reporting certain multicomponent Class 2 chemical substances derived from natural fats and oils and synthetic long-chain alkyl substitutes.” The identification and reporting in question was the identification and reporting of chemical manufacture and processing to EPA, pursuant to a past reporting obligation under TSCA section 8(a), to inform EPA’s original compilation of the TSCA Inventory under TSCA section 8(b). The document listed 35 “natural fats and oils,” as potential alkyl group sources. It provided that the particular chemical substances named under the SDA convention would not be identified “in terms of source.” However, chemical substances with alkyl groups derived from unlisted natural sources were beyond the scope of the naming convention. Thus, each time that a particular chemical substance was identified, reported, and entered into EPA’s original compilation of the TSCA Inventory based on the SDA naming convention, the definition of that particular substance inherited a certain characterization from the SDA naming convention: Specifically, that the chemical substance in question was derived either from one or more of the 35 listed natural fats

and oils or from synthetic long-chain alkyl substitutes.

The procedure that the petition asks EPA to establish by a TSCA section 8 rule is a procedure for submitting further requests to EPA. Specifically, it would be a regulation governing how the public would submit requests to amend the SDA-eligible list and how EPA would respond to such requests. The procedure would detail how EPA would review a request to include an additional source material of a fat or oil substance, “following a premanufacture notice or other appropriate notification to EPA,” in order to determine if it is “sufficiently similar” to sources of fat or oil substances with the same alkyl range that are already built into the SDA naming convention. After review, if EPA found “such similarity” between the requested additional source material and already-listed source materials, the contemplated rule would direct the Agency to add the requested source material to the SDA-eligible list in the SDA naming convention.

The petition explains that the outcome sought (in the event EPA granted a request under the procedure that petitioners now ask EPA to establish by section 8 rule) would be to authorize manufacturers of various chemical substances derived from the additional source material to “rely on the appropriate SDA alkyl range identity for purposes of Inventory listing and TSCA nomenclature.” The petition elsewhere clarifies what it means by “rely on,” when it notes that without “access to the alkyl range names,” the manufacturers would need to submit premanufacture notifications to EPA. The petition makes clear that the intended effect of enlarging the definitions of existing chemical substance listings in this fashion would be to limit the circumstances in which manufacturers would be deemed to be manufacturing a new chemical substance, and thus be subject to the requirements of TSCA section 5(a)(1)(A).

B. What Support Does the Petitioner Offer?

While the petition includes no specific request to add a particular natural fat or oil to the “SDA-eligible” list, the bulk of the petition is concerned with giving, by way of background, the petitioners’ general reasons to believe that such requests would have merit if submitted to EPA. The petition asserts, in general terms, that chemical substances derived from other natural sources “may be chemically indistinguishable from,” are “nearly identical” to, or are “substantially similar,” to chemical substances synthesized from one of the 35 listed natural sources. The petition also asserts that while such substances address “critical needs for sustainability,” there is a “key hindrance” to their commercialization. Specifically, the “key hindrance” is that certain of these chemical substances (or derivatives thereof) would be subject to EPA’s pre-manufacture review under section 5 of TSCA, while assertedly similar chemical substances derived from one of the 35 listed natural sources would be existing chemical substances and therefore would not need to undergo such review. The petition claims that continuing to treat chemical substances derived from “these novel sources,” as new chemical substances “creates a disincentive for customers to switch from traditional oils.”

The specific action requested in the petition is that EPA “initiate a rulemaking under TSCA section 8 that would establish a process to amend the list of natural sources of oil and fat [the SDA-eligible list] . . . by considering the chemical equivalency of additional natural sources.” The petition supplies two reasons for the specific action requested. First, that EPA “should allow for new sources to be added,” to the list and second, that issuing such a regulatory proposal would not require a “significant expenditure of time and resources.”

IV. Disposition of TSCA Section 21 Petition

A. What is EPA’s Response?

After careful consideration, EPA denied the petitioner’s request to initiate a TSCA

section 8 rulemaking. EPA denied the request because the petition neither justified the petitioners' claim (that the initiation of a TSCA section 8 rulemaking proceeding is necessary) nor explained how petitioners believe EPA's actual rulemaking authorities under section 8 could be used to accomplish the objectives that petitioners are seeking. To the extent the petition was actually seeking an Agency order under TSCA section 8(b) (e.g., effectuating the alteration of certain entries on the TSCA Inventory), EPA notes that a request for an order under TSCA section 8(b) is not cognizable in a petition that is submitted pursuant to TSCA section 21 (15 U.S.C. 2620(b)(1)). A copy of the Agency's response, which consists of a letter to the petitioner, is available in the docket for this TSCA section 21 petition.

B. What is EPA's Reason for this Response?

1. *Background on TSCA Section 8 Rules.* TSCA section 8 provides express rulemaking authority in three distinct subsections: First, TSCA section 8(a) (15 U.S.C. 2607(a)) authorizes EPA to promulgate rules under which current or prospective manufacturers (including importers) and processors of chemical substances must maintain records and submit such information as the EPA Administrator may reasonably require. TSCA section 8(a) also authorizes EPA to promulgate rules under which current or prospective manufacturers and processors of mixtures must maintain records and submit information to the extent the EPA Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of TSCA. Second, TSCA section 8(c) (15 U.S.C. 2607(c)) authorizes EPA to promulgate rules that "determine" certain obligations to "maintain records of significant adverse reactions to health or the environment." Third, TSCA section 8(d) (15 U.S.C. 2607(d)) authorizes rules for the submission to the Administrator of lists and copies of certain health and safety studies. If the Agency denies a petition submitted under TSCA section 21, judicial review in the

case of a petition to initiate a proceeding for the issuance of a rule under TSCA section 8 requires the petitioner to show by a “preponderance of the evidence that . . . there is a reasonable basis to conclude that the issuance of such a rule . . . is necessary to protect health or the environment against an unreasonable risk of injury” (15 U.S.C. 2620(b)(4)(B)).

2. *Background on the TSCA Inventory.* EPA’s authority to manage the TSCA Inventory is pursuant to TSCA section 8(b) (15 U.S.C. 2607(b)), which directs the Agency to “compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States.” Although EPA was directed to promulgate a data collection rule under TSCA section 8(a), “not later than 180 days after January 1, 1977,” to gather data “[f]or purposes of the compilation of the list . . . under subsection (b),” rules under TSCA section 8(a) do not themselves effectuate changes to the contents of the TSCA Inventory. The initial compilation process under TSCA section 8(b) was completed long ago, with the Agency noting in 1980 that henceforth “premanufacture notification requirements of section 5 will apply to all chemical substances manufactured and imported in bulk or as part of a mixture which has not been reported for the Inventory.” 45 FR 50544 (July 29, 1980). Today, it remains EPA’s practice to add entries to the TSCA Inventory on the basis of notices of commencement that are submitted “in accordance with [TSCA] section 5.” See 15 U.S.C. 2607(b) and 40 CFR 720.102. From time to time, EPA has also made corrections to the TSCA Inventory. EPA has consistently done so without rulemaking. See 66 FR 34193, 34197 (June 27, 2001) (making clear that the action in question was a “correction to TSCA Inventory nomenclature,” and “not a rule.”) and 75 FR 8266, 8272 (February 24, 2010) (again, “not a rule”)

3. *Necessity of Establishing a Regulatory Procedure for Requesting and Effectuating Changes to SDA Naming Conventions.*

The petition asserts that a new regulatory procedure is necessary, to govern public requests for changes to the SDA naming convention and EPA response to those requests. The reason given for why such a procedure is necessary is that the SDA naming convention “should allow for new sources to be added.” Yet the petition supplies no evidence of any current impediment to any party in making requests along these lines, or to EPA in considering such requests, which would be addressed if EPA were to promulgate a regulatory procedure governing the manner and method of making and responding to such requests. Part of the difficulty in following the petition’s reasoning stems from the petition’s conflation of two distinct issues: (1) Whether a chemical substance derived from an unlisted natural fat or oil can currently be treated as identical to another substance that *is* derived consistent with the SDA naming convention; and (2) whether alteration of the SDA naming convention, to encompass new sources of fats and oils, is currently “allowed.”

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, which would be inconsistent with TSCA section 3(9): A new chemical substance is “any chemical substance which is not included in the chemical substance list compiled and published under [TSCA section 8(b)].”

But the 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. The petition's failure to explain that a particular impediment exists (either to manufacturers in making these sorts of requests or to EPA in adjudicating them) is sufficient grounds to deny the request to commence a rulemaking proceeding intended to remove the unspecified impediment.

Thus, the petition does not demonstrate that the requested rule is necessary in any respect, much less that it is necessary to protect health or the environment against an unreasonable risk of injury.

4. Capacity of a Rule Under TSCA 8(a), 8(c), or 8(d) To Alter the Identification of New and Existing Chemical Substances under the SDA Naming Convention.

Even if the petition had established that a rulemaking proceeding is necessary, the petition would still be deficient. While the petition states in very general terms that it is seeking a change to the legal status quo (*i.e.*, establish some regulatory process "to allow" certain chemical substances derived from new sources of natural fats and oils to be nonetheless deemed existing chemicals), the petition still fails to explain how a rule under TSCA section 8 could be crafted to accomplish that objective. Rules under 8(c) and 8(d) only cover reporting and retention of certain health and safety related documents; they are inapposite to the stated objective. Nor does the petition suggest any plan to make specific use of EPA's rulemaking authorities under sections 8(c) or 8(d). Rules under section 8(a) are somewhat broader in potential scope, but once again, the rulemaking authority at issue here is inapposite; it is to require current or prospective manufacturers or processors of a chemical substance to supply existing information relating to that chemical substance. While, historically, information

collected using a TSCA section 8(a) rule provided the factual basis for EPA's assembly of the TSCA Inventory, TSCA section 8(a) does not itself govern or authorize EPA's management of the TSCA Inventory. That is instead authorized under TSCA section 8(b). Yet TSCA section 8(b) does not contain an express grant of rulemaking authority, and EPA has never used rulemaking to establish or make additions or changes to the Inventory. For its part, the petition merely makes a blanket assertion that "EPA is authorized under TSCA section 8 to commence a rulemaking." Especially since the text of TSCA section 8(b) does not itself refer to rulemaking authority, and the petitioners are seeking a change in legal requirements to "allow for new sources to be added," the absence of any particular explanation in the petition describing how petitioners believe EPA could issue an appropriate rule (under any subsection of TSCA section 8) is a critical deficiency of the petition. Finally, to the extent that petitioners are actually seeking an order under TSCA section 8(b), EPA notes that such petitions are not cognizable under TSCA section 8, 15 U.S.C. 2620(b)(1).

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Biobased and Renewable Products Advocacy Group. Petition to Promulgate Rule Pursuant to Section 8 of the Toxic Substances Control Act, 15 U.S.C. 2620, Concerning Equivalency Determinations for Class 2 Substances. October 5, 2015.

2. United States Environmental Protection Agency. Toxic Substances Control Act Pl 94-469, Candidate List of Chemical Substances, Addendum III: Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials. Washington, DC, March 1978.

List of Subjects in 40 CFR Chapter I

Environmental protection, Natural sources of oil and fat, SDA nomenclature system,
TSCA Inventory.

Dated: 12/31/15



Assistant Administrator, Office of Chemical Safety and Pollution Prevention.