people of color, low-income populations, and/or indigenous peoples. See section IV.F of this preamble for related information regarding environmental justice analyses.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

[FR Doc. 2023–07627 Filed 4–26–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA–HQ–OPPT–2022–0923; FRL–10453–01–OCSPP]

Polyvinyl Alcohol (PVA); TSCA Section 21 Petition for Rulemaking; Reasons for Agency Response; Denial of Requested Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: On January 26, 2023, EPA received a petition from Blueland, Plastic Pollution Coalition, and partners, including Beyond Plastics, Plastic Oceans International, The Shaw Institute, Lonely Whale, 5 Gyres, Global Alliance for Incinerator Alternatives (GAIA), Oceanic Global Foundation, The Last Beach Cleanup, Rio Grande International Study Center, Inland Ocean Coalition, Occidental Arts and Ecology Center, Turtle Island Restoration Network, Friends of the Earth, Surfrider, and Made Safe. The petition requests under the Toxic Substances Control Act (TSCA) that EPA require manufacturers and processors of polyvinyl alcohol (PVA) affiliated with EPA's Safer Choice certification program to fund and conduct health and environmental safety testing using independent, third-party scientists. The petition also requests under the Administrative Procedure Act (APA) that EPA update the status of PVA on EPA's Safer Chemical Ingredients List (SCIL) from ''green circle'' to ''gray square'' until the testing is complete and reviewed by EPA. The Safer Choice program is a voluntary EPA program that certifies cleaning and other products made with ingredients that meet criteria for human health and the environment and manages these safer ingredients on the SCIL. After careful consideration, the EPA has denied the TSCA petition and APA petition requests for reasons discussed in this document.

DATES: EPA's response to the petition was signed on April 21, 2023.

ADDRESSES: EPA established a docket for this petition under docket identification (ID) number EPA–HQ–OPPT–2022–0923 which is available online at *https://www.regulations.gov*. Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Brian Barone, Data Gathering and Analysis Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0233; email address: *barone.brian@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCAHotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. However, this action may be of particular interest to those who manufacture (including import), distribute in commerce, process, use, or dispose of polyvinyl alcohol (PVA). Since other entities may also be interested, the Agency has not attempted to describe all of the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or to issue an order under TSCA sections 4, 5(e), or 5(f). A TSCA section 21 petition must set forth the facts which it has claimed establish that it is necessary to initiate 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 seeking to compel initiation of the requested proceeding within 60 days of a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

Under the Administrative Procedure Act (APA) section 553(e), any person may petition for a rule's issuance, amendment, or repeal. Petitions should identify the rule requested to be repealed or provide the text of a proposed rule or amendment and include reasons supporting the petition. The agency may either grant the petition, undertake public rulemaking proceedings, or deny the petition. If an agency grants a petition for rulemaking—thereby initiating an action to issue, amend, or repeal a rule per request of the petitioner—any relevant procedural requirements for rulemaking or other types of action would still apply. In the case of the full or partial denial of a petition, prompt notice is given to the interested parties. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

C. What criteria apply to the decision on the TSCA section 21 petition?

1. Legal standard regarding TSCA section 21 petitions.

TSCA section 21(b)(1) requires that the petition ''set forth the facts which it is claimed establish that it is necessary'' to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, EPA has relied on the standards in TSCA section 21 and the provisions under which actions have been requested to evaluate this TSCA section 21 petition.

2. Legal standard regarding TSCA section 4.

TSCA section 21(a) authorizes any person to petition the Agency to ''initiate a proceeding'' for the issuance of a rule or an order under TSCA section 4. 15 U.S.C. 2620(a). To grant a petition for the testing of a chemical substance, EPA must find that the petitioners ''set forth the facts which it is claimed establish that it is necessary'' for testing under TSCA section 4(a)(1)(A)(i), TSCA section 4(a)(1)(A)(ii), or TSCA section 4(a)(1)(B). If the information the petitioner provides fails to present such facts, the petition must be denied. Additionally, if testing is initiated under TSCA section 21, TSCA section 4(h) dictates requirements for limiting testing on vertebrate animals. The specific section 4 provisions are provided in the units that follow.

a. Legal standard regarding TSCA section 4(a)(1)(A)(i) and TSCA section 4(a)(1)(A)(ii).

Under TSCA section 4(a)(1)(A)(i), in order to initiate a rule or order, EPA must find that the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment; that information and experience are insufficient to reasonably determine or predict the effects of such activity or activities on health or the environment; and that testing of the chemical substance or mixture is necessary to develop the missing information. 15 U.S.C. 2603(a)(1)(A)(i).

Under TSCA section 4(a)(1)(A)(ii), in order to initiate a rule, EPA must find that the chemical substance or mixture is or will be produced in substantial quantities, and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to such substance or mixture; that information and experience are insufficient to reasonably determine or predict the effects of the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture on health or the environment; and that testing of the chemical substance or mixture is necessary to develop the missing information. 15 U.S.C. 2603(a)(1)(A)(ii).

b. Legal standard regarding TSCA section 4(a)(1)(B) and relationship to TSCA section 21(b)(4).

In the case of a mixture, per TSCA section 4(a)(1)(B), EPA must also find that the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal, or any combination of such activities, may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture. 15 U.S.C. 2603(a)(1)(B). 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). EPA believes TSCA section 21(b)(4) does not provide for judicial review of a petition to promulgate a test rule for mixtures. TSCA section 21(b)(4)(B)(i) specifies that the court's review pertains to application of the TSCA section 4 factors to chemical substances. Moreover, TSCA section 21(b)(4)(B)(i) does not contain the additional finding that TSCA section 4 requires for issuing a test rule for mixtures (that the effect may not be reasonably and more efficiently determined or predicted by testing the chemical components). Congress left the complex issues associated with the testing of mixtures to the Administrator's discretion.

c. Legal standard regarding TSCA section 4(h).

TSCA section 4(h) requires EPA to reduce and replace the use of vertebrate animals in the testing of chemical substances or mixtures, to the extent practicable, scientifically justified, and consistent with the policies of TSCA. 15 U.S.C. 2603(h).

3. Legal standard regarding TSCA section 26.

TSCA section 26(h) requires EPA, in carrying out TSCA sections 4, 5, and 6, to make a decision using ''scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science,'' while also taking into account six considerations, including the relevance of information and any uncertainties. TSCA section 26(i) requires that decisions under TSCA sections 4, 5, and 6 be ''based on the weight of scientific evidence.'' Finally, TSCA section 26(k) requires that EPA consider reasonably available information in carrying out TSCA sections 4, 5, and 6.

II. Summary of the Section 21 Petition

A. What action was requested under TSCA section 21?

On January 26, 2023, EPA received a TSCA section 21 petition (Ref. 1) from Blueland, Plastic Pollution Coalition, and partners Beyond Plastics, Plastic Oceans International, The Shaw Institute, Lonely Whale, 5 Gyres, GAIA (Global Alliance for Incinerator Alternatives), Oceanic Global Foundation, The Last Beach Cleanup, Rio Grande International Study Center, Inland Ocean Coalition, Occidental Arts and Ecology Center, Turtle Island Restoration Network, Friends of the Earth, Surfrider, and Made Safe (petitioners) to initiate a rulemaking proceeding or issue an order under the authorities afforded to EPA under TSCA section 4(a)(1), compelling health and environmental effects tests under the TSCA on PVA and ''ultimately regulate PVA used in dishwasher and laundry pods and sheets as a toxic substance, pending the results from testing'' (Ref. 1, Pg. 11). This petition specifically requests a test order be issued to those manufacturers and processors of PVA who ''are part of the EPA Safer Choice Program, have products with the EPA Safer Choice certification, and who are seeking an EPA Safer Choice certification for pods or sheets products'' (Ref. 1, pg. 11). The petitioners request that EPA require the test order recipients to fund and conduct this testing under the guidance and direction of independent, third-party scientists.

B. What support did the petitioners offer for the TSCA section 21 request?

By referencing TSCA section 4(a)(1) the petitioners assert that EPA can direct manufacturers and/or processors to test a chemical substance or mixture if all three of the following findings are made:

- The manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment or is produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to such substance or mixture;
- There is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted; and
- Testing of such substance or mixture with respect to such effects is necessary to develop such information.

The petitioners assert that ''Given the potential for PVA to persist in the environment as a harmful plastic pollutant, this petition requests that the EPA require health and environmental safety tests under the Toxic Substances Control Act'' (Ref. 1, pg. 11). Although not explicitly stated, EPA interprets this assertion as indicating that the petitioners believe PVA may present an ''unreasonable risk of injury to health or the environment.'' Similarly, the petitioners provide estimates of the use of PVA-wrapped laundry pods in the United States (Ref. 1, pg. 3), which EPA interprets as an assertion that PVA is ''produced in substantial quantities.'' The evidence the petitioners provide for each assertion is detailed in the units that follow.

1. May present an unreasonable risk of injury to health or the environment or produced in substantial quantities.

a. May present an unreasonable risk of injury to health or the environment.

In support of the belief that PVA may present an unreasonable risk of injury to

health or the environment, the petitioners provide some references which specifically discuss PVA, while others focus generally on microplastics (Ref. 1, pg. 5–6). Based on the references provided, the petitioners conclude that ~75% of PVA from dishwasher and laundry pods persist through conventional wastewater treatment, passing into waterways and ecosystems beyond (Ref. 1, pg. 4 and 6). Petitioners claim that PVA could bioaccumulate and potentially absorb dangerous contaminants and move those contaminants up the food chain (Ref. 1, pg. 3 and 6). Although it is not explicitly stated, from these claims the Agency infers that the petitioners believe that PVA may present an ''unreasonable risk of injury to health or the environment.''

b. May be produced in substantial quantities.

The petitioners do not directly provide a statement indicating that they believe PVA is produced in ''substantial quantities'' as discussed in TSCA section 4(a)(1). Typically, substantial quantities are defined by EPA as any production in excess of one million pounds per year (Ref. 2, pg. 6). The petition states that ''. . . over 20 billion PVA wrapped laundry and dishwasher pods are used every year in the United States alone'' (Ref. 1, pg. 3). The petition also cites a study by Rolsky and Kelkar, which estimates that ''17,200 ± 5000 metric ton units per year (mtu/yr) of PVA are used . . . [in laundry detergent pods] in the United States'' (Ref. 3, pg. 1; see also Ref. 1, pg. 6). Although it is not explicitly stated, the Agency infers through the discussion of volumes of PVA used and the discussed widespread consumer uses of soluble PVA that the petitioners believe that the soluble PVA films used in detergent pods are produced in ''substantial quantities'' and ''there is or may be significant or substantial human exposure to such substance.''

2. Insufficiency of information and experience.

The petitioners assert, ''Further research is needed to determine the potential hazards that polluted PVA can pose to ecosystems and human health'' (Ref. 1, pg. 14). To support their assertion, the petitioners did not provide evidence of a literature search or data gap analysis. However, a literature review was conducted as part of the study by Rolsky and Kelkar (Ref. 3, pg. 3) related to the fate of PVA in wastewater treatment plants. The objective of this study was to estimate the US nationwide emissions of PVA resulting from domestic use of laundry and dish detergent pods corroborated by a nationwide, online consumer survey and a literature review of its fate within conventional wastewater treatment plants (WWTPs) (Ref. 3, pg. 1). As evidence of insufficient information and experience related to the effects of PVA on health and the environment, the petitioners reference the testing methods commonly used to establish biodegradability, including Organization for Economic Cooperation and Development (OECD) 301 and OECD 310 tests for Ready Biodegradability (Ref. 1, pg. 9). The petitioners believe that these testing procedures are insufficient to evaluate biodegradation in wastewater treatment plants and assert that there are ''critical gaps between the OECD tests and real-world WWTP conditions'' (Ref. 1, pg. 10). The petitioners assert that the established OECD testing methodologies are inadequate for the evaluation of the biodegradation of PVA due to the testing conditions differing from those present in a wastewater treatment plant (Ref. 1, pg. 9–10). The petitioners also assert that the elapsed time required for PVA to degrade in these tests is not being evaluated appropriately (Ref. 1, pg. 10).

3. Need for testing.

The petitioners claim that PVA poses unknown dangers to the environment, and further research is needed to understand PVA's ability to absorb and bioaccumulate dangerous contaminants up the food chain (Ref. 1, pg. 6). Additionally, the petitioners claim that the established OECD tests for inherent biodegradation are insufficient to determine if PVA poses a risk to human health and the environment (Ref. 1, pg. 10–12).

C. What additional information did EPA receive regarding the TSCA section 21 request?

As a result of this petition, Proctor and Gamble has made available to EPA previously unreleased tests related to the biodegradability and toxicity of the forms of PVA used in detergent pods and sheets. EPA has posted this information in the petition docket, which is available to the public for review online at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#polyvinyl.*

III. Disposition of Section 21 Response

A. What was EPA's response?

After careful consideration, EPA has denied the section 21 portion of this petition. A copy of the Agency's response, which consists of the letter to the petitioners and this document, is posted on the EPA petition website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#reporting.* The response, the petition (Ref. 1), and other information is available in the docket for this TSCA section 21 petition (see **ADDRESSES**).

B. What was EPA's reason for this response?

In considering the petition within the statutory 90-day petition review period, EPA evaluated the information presented or referenced in the petition and considered that information in the context of the applicable authorities and requirements contained in TSCA sections 4, 21, and 26, as previously described in Unit I.C. of this document. Also, notwithstanding that the burden is on the petitioners to present ''the facts which it is claimed establish that it is necessary'' for EPA to initiate the rule or issue the order sought, EPA nonetheless evaluated relevant information that was reasonably available to the Agency during the 90-day petition review period.

EPA finds the petitioners have not provided the facts necessary for the Agency to determine that existing information and experience are insufficient and that testing of such substance or mixture with respect to such effects is necessary to develop such information. These deficiencies, among other findings, are detailed in this document.

1. May present unreasonable risk of injury to health or the environment or produced in substantial quantities.

EPA is not opining on the sufficiency of the information presented for purposes of determining whether PVA may present unreasonable risk because the Agency finds that petitioners have not provided the facts necessary for the Agency to determine that existing information and experience are insufficient and that testing with respect to such effects is necessary to develop such information, as described in more detail later in this document. However, EPA agrees that PVA is or will be produced in substantial quantities and that there is or may be significant or substantial human exposure due to its common use in agriculture, foodstuffs, cleaning, and personal-care products. 15 U.S.C. 2603(a)(1)(A)(ii)(I).

2. Insufficiency of information in the petition.

The petition does not set forth the facts necessary to demonstrate that there is ''insufficient information and experience'' on which the effects of PVA can reasonably be determined or predicted, as TSCA section 4(a)(1) requires.

Although the petitioners point to some evidence that there is insufficient

information on soluble versions of PVA commonly used in detergent pods and sheets, the information supplied by petitioners is only a sample of the information available on the health and environmental risks potentially associated with PVA. The petitioners primarily rely on a study that models the potential extent of biodegradation of soluble versions of PVA at wastewater treatment plants, and a limited number of additional studies related to PVA and microplastics. The petitioners also assert that, ''[m]any of the tests used to determine PVA's biodegradability rely on OECD standards for biodegradability. While OECD biodegradability standards can be an important tool to determine a material's end of life implications, in the case of PVA and current conditions within WWTPs, these tests are insufficient'' (Ref. 1, pg. 14). Petitioners rely on this assertion to claim that there is a data need for biodegradability of PVA in real world scenarios to inform EPA's understanding of health and environmental effects from PVA. However, as explained in further detail in the Unit V.B.1, the OECD biodegradation test conditions are more conservative than real world conditions in WWTPs and are appropriate tools for predicting biodegradation of PVA. The petitioners have not provided the facts to show that ''there is insufficient information and experience'' per TSCA section 4(a)(1)(A)(i)(II).

Furthermore, the petitioners failed to acknowledge the nature and extent of existing data and articulate why these data are insufficient. While the petitioners point to a single study that models the potential extent of biodegradation of soluble versions of PVA at wastewater treatment plants, and a limited number of additional studies related to PVA and microplastics, they do not refer to or provide an assessment of other reasonably available health and environmental effects studies completed on the soluble versions of PVA commonly used in detergent pods and sheets. EPA performed a cursory search of publicly available databases on the endpoints raised by the petition request (*i.e.,* biodegradation, toxicity, and bioaccumulation potential of PVA) and has found that there is, at a minimum, one study assessing the biodegradation of PVA using non-OECD test guidelines, as well as multiple studies—which were not identified or considered by the petitioner—on the toxicity and bioaccumulation potential of PVA available in the public domain. These studies include, but are not limited to, materials related to the approval of PVA as a food additive, approval for use in pharmaceutical products, and approval for use in medical appliances and devices, some of which are as follows:

- ''Review of the oral toxicity of polyvinyl alcohol (PVA)'' (Ref. 4) was published in the journal Food and Chemical Toxicology in March 2003. The study investigated the toxicity of PVA in association with its use as an indirect food additive and coating agent for pharmaceutical and dietary supplement products. The study concluded that orally administered PVA has low oral toxicity, is poorly absorbed from the gastrointestinal tract, does not bioaccumulate when administered orally, and is not mutagenic or clastogenic.
- ''Assessment of Toxicity and Biodegradability of Poly(vinyl alcohol) Based Materials in Marine Water'' (Ref. 5) was published in the journal Polymers in September 2021. This study characterizes the biodegradation and ecotoxicity of PVA polymers in marine environments. The results support the limited biodegradability of PVA materials under conditions representative of a natural marine environment but also concluded that none of the tested polymers pose a relevant risk to the model marine organism used in the studies.
- ''Final Report on the Safety Assessment of Polyvinyl Alcohol'' (Ref. 6) was published in The International Journal of Toxicity in 2003. In this study, PVA was evaluated by the Cosmetic Ingredient Review Expert Panel. The study included an assessment of general biology, toxicology, mutagenicity, carcinogenicity, and a clinical assessment of the safety of PVA. The CIR Expert Panel concluded that Polyvinyl Alcohol is safe for use in cosmetic formulations.
- The European Food Safety Authority (EFSA) released its ''Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) related to the use of polyvinyl alcohol as a coating agent for food supplements'' in 2006. (Ref. 7). In this report, EFSA provides an evaluation of PVA as a food additive. The report included an assessment of an analysis of toxicological data, the reaction and fate of PVA in food, and exposure levels to PVA through ingestion in order to assess its safety for use in food supplements. The panel concluded that the consumption of the PVA through the use as a coating agent for food supplement tablets and/or capsules at its intended use level is not a safety concern.

Specific to the petitioner's claim that there is a data gap regarding the biodegradation endpoint because OECD guidelines fail to inform real world scenarios at WWTPs, the petitioners do not provide an inventory of other biodegradation data on PVA that could potentially address the purported data need. In addition to not identifying existing studies, the petitioners have not provided facts to show why such studies or other existing resources are insufficient to inform the characterization of biodegradation of PVA in the real world at WWTPs. Because EPA, upon a cursory review, has been able to easily identify existing, reasonably available information on PVA's biodegradation and toxicity potential not mentioned in the petition, the petitioners have failed in carrying their burden of setting forth facts which are necessary to demonstrate that there is insufficient information, thereby necessitating the requested action. The petitioners do not provide evidence that a literature search of publicly available information has been completed, have not included an analysis and characterization of the results of such a literature search, and have not provided an inventory of knowledge they claim is missing from the public domain, specifically the ''health and environmental safety tests'' they claim are needed because ''there is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted'' per TSCA section 4(a)(1)(A)(i)(II).

EPA finds the petitioners have not incorporated available existing information related to their request, or adequately indicated that gaps were located for data needed in order for EPA to make a decision using the best available science. Such an evaluation is necessary for EPA to carry out TSCA section 4, as provided under TSCA section 26(h).

3. Testing of such substance or mixture with respect to such effects is necessary to develop such information.

No evidence of toxicity or bioaccumulation potential for the soluble form of PVA used in detergent pods and sheets has been presented in the petition to the extent necessary to warrant EPA initiating a TSCA section 4 action. The petitioners provide no further information identifying specific gaps in the data already available to the public, or why additional testing in lieu of other data generation methods, such

as modeling or using existing analog data as read across, is necessary under TSCA section 4(a)(1)(A). The petitioners' request for ''full environmental and human health tests on both untreated and treated PVA'' also lacks specificity. For example, the petitioner did not specify the relevant PVA Chemical Abstracts Service Registry Number (CASRN) or polymer structure required for testing. EPA notes that the PVA used in consumer products and industry varies based on polymer size, degree of hydrolysis, solubility, and other physical and chemical characteristics (Ref. 4, pg. 144). These PVA structures are represented by several different CASRNs. Therefore, any requested testing should provide detail on which specific chemical substance, or category of chemical substances, testing should be conducted. In addition, the petitioners could have presented information about the types of tests that could be conducted, including some analysis of the methods that could be used to identify the data or information submitted or used, hazard thresholds recommended, and exposure estimates. The need for more specificity regarding testing requirements and a failure to identify the PVA forms that may require additional testing and studies disallows sufficient evaluation of associated data necessary to determine the need for new testing.

EPA finds the petitioners have not explained why the testing requested, as compared to other testing or other data generation methods, would provide the quality of data being sought in order for EPA to make a decision using the best available science. Such an evaluation is necessary for EPA to carry out TSCA section 4, as provided under TSCA section 26(h).

4. Request for oversight by a third party.

Regarding the petitioners' request that testing be conducted only under the guidance and direction of independent third-party scientists, EPA finds that such an oversight arrangement is not in keeping with the authority provided under TSCA section 21. *See Ctr. for Envtl. Health, et al.* v. *EPA,* No. 7:22–CV–00073–M, slip op. at 25–26 (E.D.N.C. March 30, 2023). Additionally, the petition has not demonstrated a need for additional measures ensuring the reliability of studies required under TSCA section 4 beyond that already provided in the Good Laboratory Practice Standards in 40 CFR part 792, and the petitioners provide no legal, administrative, or organizational procedures for the implementation of such oversight. Therefore, the Agency has no obligation to grant or deny this request. All test orders must be planned and completed in a manner consistent with the best available science per TSCA section 26(h). To that end, EPA conducts reviews of all testing plans, reports, and test data to ensure the validity of results. When reviewing data in response to a TSCA section 4 test order, EPA is required to consider the extent to which information, procedures, measures, protocols, and methodologies or models employed are ''reasonable for and consistent with the intended use of the information.'' EPA also must consider, per TSCA section 26(i), the extent of independent verification and peer review and ''shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.''

C. What were EPA's conclusions under TSCA section 21?

EPA is denying the request to initiate a rule or issue an order under TSCA section 4 because the TSCA section 21 petition does not set forth the facts necessary for the Agency to determine that existing information and experience are insufficient and testing of such substances or mixture with respect to such effects is necessary to develop such information. Therefore, the petitioners have yet to demonstrate that the rule or order they requested is necessary.

Additionally, because the authorities provided to EPA under TSCA section 4 specifically relate to test rules, enforceable consent agreements, or orders issued directly to manufacturers and/or processors of a chemical substance, any requests made under section 4 that extend beyond those statutory authorities cannot be granted. Therefore, the petitioners' request for the EPA to require third-party oversight of PVA testing, paid for by manufacturers and/or processors is outside of the authorities provided in TSCA section 4.

IV. Administrative Procedure Act Petition

A. What action was requested under Administrative Procedures Act?

The petitioners also asked EPA to change the geometric color code indicating the status of PVA on the Safer Chemical Ingredients List (SCIL) from a green circle to a gray square until the health and environmental safety testing requested in the TSCA section 21 portion of the petition is complete (Ref. 1, pg. 13–14). EPA is responding to this portion of the petition under the APA.

B. What support and rationale do the petitioners offer for the APA request?

The petitioners define PVA as ''a synthetic, petroleum-derived polymer'' with many applications and commonly ''used as a plastic film in all dishwasher and laundry pods and sheets'' (Ref. 1, pg. 3). The petitioners state that PVA ''can contribute to plastic pollution in oceans, waterways and soil . . . and may negatively impact ecosystems and the food and water supply'' (Ref. 1, pg. 3), citing Rolsky and Kelkar (Ref. 3). The petitioners also suggest that PVA meets EPA's definition of a persistent, bioaccumulative, and toxic (PBT) substance (Ref. 1, pg. 13–14).

In support of their claims, the petitioners provide information on the persistence and bioaccumulation potential of PVA. The petitioners also address marketing claims by companies regarding the use of PVA in products. The petitioners' arguments on these topics are summarized in the units that follow.

1. Persistence of PVA.

The petitioners cite research that models PVA as it travels through a wastewater treatment plant. This modeling estimates that 77 percent of PVA remains intact after passing through conventional wastewater treatment (Ref. 3; see also Ref. 1, pg. 7–8). Based on these results, the authors suggest that the incomplete degradation of PVA results in the release of PVA into the aquatic environment through WWTPs effluent and the terrestrial environment through the application of biosolids (Ref. 3).

2. Bioaccumulation of PVA.

The petitioners posit that PVA has the potential to bioaccumulate (Ref. 1, pg. 13–14). The petitioners argue that PVA has the ability to carry toxic chemicals and carcinogens up the food chain and may be present in human breast milk (Ref. 1, pg. 6). EPA notes that the source materials in the references cited by the petitioners are specific to microplastics and not relevant to the types of PVA used in Safer Choice-certified products (Ref. 3; Ref. 8; Ref. 9).

3. Marketing claims of PVA.

The petitioners also describe marketing claims made in relation to use of PVA in products. The petitioners state that many brands market products containing PVA as '' '100% biodegradable' and or '100% plastic-free' . . . [which] can mislead consumers to think these products are better for the environment than they are'' (Ref. 1, pg. 14). The petitioners further request ''that the EPA Safer Choice program review claims about PVA through the lens of truth in

advertising to ensure that consumers have accurate information about PVA and its potential environmental impacts'' (Ref. 1, pg. 14).

C. What is EPA's Safer Choice program?

Safer Choice is a voluntary EPA program that certifies cleaning and other products made with ingredients that are safer for human health and the environment. Importantly, the Safer Choice program identifies safer ingredients by functional use within a product formulation and does not describe any chemicals, ingredients, or products as ''safe.'' EPA reviews every chemical within a product, regardless of use level, against the Safer Choice Standard and its applicable functional class criteria. Under the Safer Choice Standard, the Safer Choice criteria define data requirements and toxicity thresholds for a chemical to be considered low concern or best in class for a given functional use. Chemicals that meet EPA's Safer Choice criteria are eligible for listing on SCIL. The Safer Choice Standard also contains requirements (*e.g.,* use limits) for the chemical's use in a product or formulation.

EPA lists chemicals on the SCIL by CASRN. The CASRN-level listing of ingredients on SCIL is one tool that can help manufacturers as they formulate products with safer chemicals that may be eligible for Safer Choice certification. Manufacturers may not use chemicals from SCIL in Safer Choice-certified products unless those SCIL chemicals also meet the requirements of the Safer Choice Standard.

In some cases, a single CASRN may cover a broad range of chemical structures. For example, for a given polymer listing, a CASRN might cover a range of structures and chain lengths. Similarly, for a given surfactant listing, a single CASRN might cover varying degrees of ethoxylation and propoxylation. When considering a product for Safer Choice certification, EPA requires complete disclosure of the name(s), CASRN(s), and concentration(s) of all chemicals in a formulation. If a proposed formulation includes a SCIL chemical with a CASRN that covers a broad range of chemical structures, EPA also requires disclosure of the structure(s) under the CASRN associated with that chemical. EPA evaluates data associated with these specific structures and allows use of only chemicals with structures that meet both the Safer Choice Standard and criteria to be used in Safer Choice-certified products.

1. PVA applicability in the Safer Choice program.

The structure and function of PVA can vary depending on how the chemical is synthesized. PVA is generated by hydrolyzing polyvinyl acetate—converting acetates to alcohols—resulting in either partially hydrolyzed or fully hydrolyzed PVA. The extent of hydrolysis, polymer size, and monomer arrangement impart physical-chemical properties that impact the polymer's functionality, water solubility, degradation potential, and other characteristics.

Optimum solubility in cold water is typically observed in PVA with a degree of hydrolysis between 87 to 89 mole percent and molecular weights between 25,000 and 100,000 Daltons. In contrast, fully hydrolyzed, high-molecular-weight PVA is highly crystalline and insoluble in cold water (Ref. 10). Manufacturers choose the grade of PVA for a given product based on function and other properties. To facilitate this choice, manufacturers usually characterize PVA using properties linked to structure, such as degree of hydrolysis and viscosity.

The petitioners do not specify PVA by CASRN, structure, grade, or specification in the petition. The petitioners do state, however, that their request is targeted at ''PVA used in laundry and dishwasher detergent pods and sheets as these are product categories relevant to the EPA Safer Choice program'' (Ref. 1, pg. 1). Based on this description of the type of PVA of interest to the petitioners, EPA understands that the request to mark PVA with a grey square on the SCIL is specific to two relevant CASRNs listed on SCIL that cover chemicals used in Safer Choice-certified products. EPA relies on this understanding throughout the remainder of the response. On SCIL, the PVA polymeric structures of interest to the petitioners are represented under CASRN 25213–24–5 (preferred Chemical Abstract Index Name: Acetic acid ethenyl ester, polymer with ethenol) and CASRN 9002–89–5 (preferred Chemical Abstract Index Name: Ethenol, homopolymer). The PVA structures allowed in Safer Choice-certified products, and which support the CASRN listings on SCIL range from 87 to 89 mole percent hydrolyzed with an average molecular weight ranging from 70,000 to 215,000 Daltons. The Safer Choice program allows use of only the PVA structures represented under CASRN 25213–24–5 and CASRN 9002–89–5 that are also associated with data demonstrating the chemical(s) meet(s) the Safer Choice Standard and criteria.

2. Safer Choice Program criteria for polymers.

The Safer Choice Master- and Functional-Class Criteria, available at *https://www.epa.gov/saferchoice/safer-choice-standard,* documents allowable toxicity thresholds for ingredients that are acceptable for use in Safer Choice-certified products. Within ''functional classes,'' many ingredients share similar toxicological and environmental fate characteristics. Recognizing this similarity, the Safer Choice program was able to focus its criteria—and its ingredient review—on the environmental and health characteristics of concern within a functional class. This approach allows EPA to distinguish the safest chemicals in each functional class and allows manufacturers to use ingredients with lower hazard profiles while formulating high-performing products.

The criteria for polymers are listed in EPA's Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals, available at *https://www.epa.gov/saferchoice/safer-choice-criteria-colorants-polymers-preservatives-and-related-chemicals,* and includes toxicological thresholds and data requirements polymers must meet to be eligible for use in Safer Choice-certified products. The following requirements in the criteria for environmental toxicity and fate endpoints are relevant to the petitioners' request:

- *Limitation on Persistent, Bioaccumulative and Toxic chemicals:* Acceptable chemicals must not be persistent (half-life >60 days), bioaccumulative (BCF/BAF ≥1,000), and aquatically toxic (LC/EC50 ≤10 mg/L or NOEC/LOEC ≤1 mg/L);
- *Limitation on very Persistent and very Bioaccumulative chemicals:* Acceptable chemicals must not be very persistent (half-life >180 days or recalcitrant) and very bioaccumulative (>5,000); and
- *Limitation on very Persistent and very Toxic chemicals:* Acceptable chemicals must not be very persistent (half-life >180 days or recalcitrant) and very aquatically toxic (LC/EC50 <1.0 mg/L or NOEC/LOEC <0.1 mg/L).

The Safer Choice criteria also requires polymers to be screened against authoritative lists (specified in EPA's Safer Choice Master Criteria, available at *https://www.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients*) for acute mammalian toxicity, repeated dose toxicity, carcinogenicity, genetic toxicity, reproductive and developmental toxicity, neurotoxicity, respiratory sensitization, and skin sensitization. Acceptable polymers must have low concern characteristics. See EPA's Safer

Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals available at *https://www.epa.gov/saferchoice/safer-choice-criteria-colorants-polymers-preservatives-and-related-chemicals.*

When necessary, EPA reviews information on chemicals or suitable analogs against the criteria using a weight-of-evidence (WOE) approach. For this WOE approach, EPA prefers experimental data but also considers estimated measures of fate and toxicity from predictive tools that are based on a chemical's physical/chemical properties and structural and/or biological similarity to known chemicals of concern. EPA's Safer Choice Master Criteria, available at *https://www.epa.gov/saferchoice/safer-choice-criteria-colorants-polymers-preservatives-and-related-chemicals,* outlines preferred toxicological test methods for the data used in Safer Choice chemical reviews. The preferred test methods include OECD Guideline studies, which are accepted internationally by professionals in environmental advocacy groups, industry, academia, and government as standard methods for characterizing chemicals. These Guidelines are updated as needed to ensure they reflect the latest science and techniques, in consultation with experts from regulatory agencies, academia, industry, and environmental and animal welfare organizations, and available at *https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_72d77764-en.* The preferred test methods also include EPA OPPT Test Guidelines that were developed in consideration of the guidelines published by the OECD, available at *https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances.* Standardized methods and guidelines are essential for proper comparison of chemical hazard profiles and to identify those that are considered safer.

V. Disposition of the APA Portion of the Petition

A. What was EPA's response?

EPA has considered the evidence presented by petitioners and is denying the request to remove PVA from SCIL for two reasons: (1) The petition does not demonstrate that PVA fails to meet the Safer Choice criteria, and (2) The data cited and explained in this unit indicate that the PVA structures allowed for use in Safer Choice-certified products under the EPA Safer Choice Standard meet the criteria of the program. The petition cites five blogs and eight peer-reviewed journal articles. Most of these focus on the environmental impacts of microplastics rather than the soluble PVA used in Safer Choice-certified products. EPA identified additional peer-reviewed literature not discussed in the petition that is relevant to the PVA structures used in Safer Choice-certified products.

B. What was EPA's reason for this response?

The petitioners cite a portion of the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals and write that ''if a polymer does break down into PBTs, it should be excluded from the EPA Safer Chemical list [sic]'' (Ref. 1, pg. 13). ''PBT'' in this text stands for persistent, bioaccumulative, and toxic chemical substances (86 FR 894, January 6, 2021 (FRL–10018–88)). EPA will address the persistence, bioaccumulation, and toxicity endpoints individually and explain that the PVA used in Safer Choice-certified products is not a ''PBT'' in the units that follow.

1. Persistence of PVA.

The petitioners state that ''dissolved PVA enters WWTPs but ~75 percent exits WWTPs intact'' (Ref. 1, pg. 7). The referenced Rolsky paper more specifically references the potential for PVA to persist within the environment with an estimated 77 percent of PVA (61.2 percent via biosolid sludge and 15.7 percent via wastewater effluent) remaining intact after wastewater treatment (Ref. 3, pg. 10). The petitioners also state that ''in conventional WWTPs within the United States, specific PVA-adapted bacteria and microbes are needed to aid in the near to complete degradation of PVA, though they are not likely present'' (Ref. 3, pg. 7; see also Ref. 1, pg. 7).

The Rolsky and Kelkar study does not use measured data and instead estimates or models the WWTPs emission of PVA into the environment. Through the following examples, EPA explains why the study has limited relevance to the specific PVA polymer structures allowed for use in Safer Choice-certified products (Ref. 3).

A first example is that the model assumes low degradation efficiencies in WWTPs, with 20 percent biodegradation in aerobic sludge and 10 percent in anaerobic sludge. These values were taken from studies on PVA in textile wastewaters and highly crystalline starch and PVA blends used in food packaging materials (Ref. 11; Ref. 12). Blends such as these behave very differently from the soluble PVA structures used in detergent applications and are not used in Safer Choice-certified products.

A second example is the assumptions Rolsky and Kelkar (Ref. 3) make about microbial communities in WWTPs. The authors include summaries of studies with higher biodegradation values in supplementary Table S1, but disregard these values based on an assumption that PVA degrading bacterial species would only be found in textile wastewaters and would not be found in conventional WWTPs (Ref. 3, pg. 7). This is not a valid assumption. Recent standard ready biodegradation tests that use unacclimated inoculum show degradation of PVA, demonstrating that competent organisms are present in conventional WWTPs where the inocula are collected (Ref. 13; Ref. 14).

A third example relates to Rolsky and Kelkar's assumption about sorption of PVA to solids. The authors' model assumes a removal efficiency of 30 percent in the primary clarifier and 75 percent in the secondary clarifier based on sorption to biosolids (Ref. 3 and 15). EPA expects less sorption to solids for the specific PVA structures used in Safer Choice-certified products based on the physical-chemical properties of these water-soluble PVA structures (Ref. 16; Ref. 17).

In summary, Rolsky and Kelkar did not address a range of factors that are critical to the fate of PVA used in detergent films and PVA allowed in Safer Choice-certified products. These factors are associated with the structure of the chemical and include degree of polymerization, degree of hydrolysis, tacticity of the main chain (regular or irregular stereochemical configuration), ethylene content, and 1,2-glycol content (Refs. 3, 16; and 18).

The petitioners state that guideline ready biodegradation tests (*i.e.,* OECD 301 series and OECD 310) ''evaluate the biodegradability of PVA, typically in laboratories, under the most optimal circumstances [and] in real world scenarios within conventional WWTPs, neither the conditions in the lab nor the amount of time needed for PVA to fully biodegrade are likely to be met'' (Ref. 1, pg. 9). Guideline OECD tests for ready biodegradation and their EU and EPA equivalent tests are not intended to mimic WWTPs. Ready biodegradation tests are designed to be conservative screening tests, with conditions that reflect a compromise between ''real world'' scenarios and what is practical and economical to ensure consistency. Although the OECD 301 series tests were not significantly updated since 1992, they have undergone review by OECD, both in 1995 and 2006 (Ref. 19; Ref. 20).

Because ready biodegradation tests are not simulations of WWTPs, the test

duration and biodegradation time are not directly analogous to WWTP conditions. The test conditions in ready biodegradation tests are less optimized to promote biodegradation and therefore more conservative than real world conditions in WWTPs. Ready biodegradation test inoculum, which per the testing protocol are unacclimated, have microorganism cell densities that are up to 10,000 times less concentrated than in WWTPs, resulting in a higher food-to-microorganism ratio (Ref. 19; Ref. 21). Ready biodegradation tests are run for 14–28 days to encourage microbial population to acclimate and grow to a sufficient level before consumption of test substances (Ref. 20).

The Safer Choice Master Criteria states that the preferred testing methods for screening chemicals for persistence in the Safer Choice program are OECD Guideline tests for ready biodegradability. Compounds that pass ready biodegradation tests (*i.e.,* meet the designated pass levels, such as 70 percent removal of DOC, within the 28-day period of the test) are understood to be completely removed within WWTPs (Ref. 19, pg. 70; Ref. 22 and 23). The Agency acknowledges that degradation potential may vary by PVA structure and across different environments (*e.g.,* terrestrial vs. aquatic; WWTPs vs. textile and paper mill effluents) based on the presence of specific microorganisms. However, the claim that PVA ''does not fully biodegrade due to the conditions in most wastewater treatment plants'' (Ref. 1, pg. 4) (*i.e.,* lack of microorganisms adapted to PVA) is unlikely to be correct because PVA biodegradation in activated sludge inoculum is well supported and discussed later in this unit. The inoculum allowed in the OECD Guideline tests for ready biodegradation may be derived from activated sludge, unchlorinated sewage effluents, surface waters and soils, or a mixture of these sources, available at *https://www.oecd-ilibrary.org/environment/test-no-301-ready-biodegradability_9789264070349-en.* The OECD Guidelines allow for pre-conditioning of the inoculum to the experimental conditions (*e.g.,* aerating activated sludge in mineral medium or secondary effluent for 5–7 days at the test temperature), but do not allow for inoculum to be pre-adapted to the test substance (*i.e.,* PVA) (Ref. 20).

The Agency identified peer-reviewed literature using OECD Guideline studies (Ref. 14) showing PVA chemical structures used in laundry detergent packets are readily biodegradable. The study measured the persistence of four different PVA structures, with molecular weights ranging from 10,000–130,000 Daltons and degrees of hydroxylation of 79 mole percent and 88 mole percent, using OECD 301B Guidelines to determine ready biodegradability of the structures (Ref. 14). The inoculum used in the study was activated, non-adapted sludge collected from a WWTP receiving greater than 90 percent domestic sewage in Fairfield, OH. The results indicated that the four PVA structures showed greater than 75 percent CO_2 evolution after 28 days and greater than 87 percent CO_2 evolution after 60 days, demonstrating that these four materials met the OECD 301B Guideline pass levels and are considered readily biodegradable (Ref. 14). Additionally, the study tested the same four PVA structures, using the same type of inoculum described previously, following OECD 302B Guidelines to determine inherent biodegradability of the structures. The results indicated greater than 88 percent CO_2 evolution after 28 days, showing all four structures are also considered inherently biodegradable (Ref. 14). Furthermore, additional studies of detergent formulations and films containing PVA suggest ultimate biodegradation following OECD Guidelines and have half-lives less than 60 days (Ref. 13; Ref. 24).

According to the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals, for a chemical to be classified as persistent or as very persistent, the half-life must be greater than 60 days or greater than 180 days, respectively. EPA notes that chemicals that pass ready biodegradation tests are projected to have half-lives of a few hours in sewage treatment plant sludges and half-lives of a few days in water (Ref. 25). EPA has reviewed the available modeled and experimental data, and EPA believes that the weight of the scientific evidence supports EPA's determination that the PVA structures used in Safer Choice certified products have a half-life of less than 60 days (*i.e.,* does not meet the criterion to be classified as persistent or very persistent). Thus, the data supports the continued listing of PVA CASRN 25213–24–5 and CASRN 9002–89–5 on SCIL.

2. Bioaccumulation of PVA.

Bioaccumulation describes a process by which an organism accumulates chemical substances across various routes of exposure. Bioaccumulation is typically evaluated using the Bioaccumulation Factor (BAF). The Bioconcentration Factor (BCF) can be used as part of a weight-of-evidence approach when BAF information is not available. EPA's Safer Choice program classifies chemicals with BCF or BAF value greater than 1000 as bioaccumulative, as listed on the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals at *https://www.epa.gov/saferchoice/safer-choice-criteria-colorants-polymers-preservatives-and-related-chemicals.* Water solubility is factored into BAF and BCF calculations. Chemicals with high water solubility have an affinity to remain in water versus bioconcentrating and bioaccumulating in biota (Ref. 26).

The petitioners contend that PVA can bioaccumulate, but do not provide any evidence on specific PVA structures relevant to the Safer Choice program (Ref. 1, pg. 6 and 9). In a Guideline bioaccumulation study conducted by Japan's National Institute of Technology and Evaluation (NITE), researchers exposed Rice fish (Oryzias latipes) to two concentrations of a PVA structure (MW approximately 77,000 Daltons, reported to be water soluble, and in the range of PVA types used in detergent film applications) dissolved in the test water for 6 weeks (Ref. 27). NITE performed the study using guidelines that measured the concentration of the PVA substance in test water and in the fish to calculate the steady state BCF. The results demonstrate a BCF value less than 10 for both concentrations, which provides strong evidence that water soluble PVA structures have low concern for bioaccumulation and invalidates the petitioners' contention.

The petitioners submitted two biomonitoring studies identifying microplastics in human breast milk and placenta (Ref. 8; and 28). Both studies included compositional analyses that classify the types of microplastics found in these tissues, and noted the presence of primarily polyethylene, polypropylene, polyvinyl chloride, and plastic additives such as pigments. Ragusa *et al.* (Ref. 8) also found that PVA accounted for 2 percent of the total microplastic composition and that ''no films or fibres were identified'' in breast milk. While these results demonstrate the presence of insoluble microplastics in human tissue, they do not indicate bioaccumulation of water soluble PVA structures. As noted in the previous section, the PVA structures used in Safer Choice-certified detergent products are highly water-soluble, have low potential to bioaccumulate in biota, and do not meet the European Chemicals Agency's (ECHA) definition of a microplastic. The ECHA describes microplastics as insoluble and nonbiodegradable solid particles measuring less than 5 mm (Ref. 29).

3. Potential for PVA to mobilize and transport other pollutants.

The petitioners also state that PVA may act as a vector to adsorb heavy metals and other pollutants (Ref. 1, pg. 9). Studies referenced in Rolsky and Kelkar report increased sorption of other pollutants in degraded solid microplastics (Refs. 3, 30; and 31). The authors state degraded microplastics may have a greater affinity for sorption to other pollutants, resulting in increased mobility of contaminants. Degraded microplastics may sorb other pollutants through various mechanisms such as through the formation of surface defects on the degraded microplastic particles that can trap other pollutants, or through an increase in the number of polar functional groups on the particle surfaces, which can enhance interactions with other polar pollutants (Ref. 30; Ref. 31). The petitioners' references are specific to microplastics and not relevant to soluble PVA structures in the Safer Choice program.

The petitioners argue that PVA also has the potential to ''mobilize heavy metals from sediments to water resources'' (Ref. 1, pg. 14). Rolsky and Kelkar's statement is based on evidence of PVA-based composite hydrogels removing heavy metals from wastewater (Ref. 3 and 32). Additives used in PVA-based blends, such as PVA-based composite hydrogels, can influence the sorption and bioaccumulation potential of PVA structures by altering the overall physical-chemical properties of the ingredient. EPA's Safer Choice program classifies a PVA-based composite hydrogel as an ingredient (made up of multiple chemicals). EPA organizes SCIL by CASRNs and does not include ingredients. For product certification, the Safer Choice program reviews every chemical within an ingredient (*e.g.,* impurities, residuals, stabilizers, etc.), regardless of use level, against the Safer Choice Standard, available at *https://www.epa.gov/saferchoice/safer-choice-standard,* and applicable functional class criteria. All components of an ingredient must meet the Safer Choice Standard and criteria to be used in Safer Choice-certified products. PVA-based composite hydrogels have never been reviewed for certification by the Safer Choice program and are different from and not relevant to the PVA structures and applications (*e.g.,* detergent packets) in question for this petition.

The petitioners' concerns over bioaccumulation and transport of other pollutants up the food chain appear to be based on microplastic pollution research with the assumption that PVA will degrade into microplastics. The PVA structures used in detergent films in Safer Choice-certified products do not degrade into microplastics; rather they degrade via successive oxidation and cleavage steps, producing shorter hydroxy, carboxy, and carbonyl-substituted products that are also water soluble (Ref. 13).

4. Toxicity of PVA.

The petitioners state that PVA ''can contribute to plastic pollution'' and that ''plastic pollution can inflict substantial harm to aquatic and marine environments'' (Ref. 1, pg. 3 and 5).

In addition to persistence and bioaccumulation, the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals require toxicity data on aquatic organisms and human health to be considered for the Safer Choice program. The petitioners argue that the requirements in the criteria—*i.e.,* that a polymer must not break down into PBT substances—are not met for PVA and therefore should be excluded from the SCIL (Ref. 1, pg. 14). While the petitioners do not provide environmental and human health toxicity data relevant to the endpoints listed in the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals in the petition, to substantiate these statements, the Agency believes there is sufficient toxicity information available on PVA structures used in Safer Choice-certified products to meet the program's criteria for low concern.

a. Aquatic toxicity of PVA.

The Agency identified toxicity studies measuring the effects on aquatic organisms of the subset of PVA structures that are used in detergent packets. Meier *et al.* (Ref. 24) performed aquatic toxicity testing using a raw material based on PVA that is a component of a liquid laundry detergent formulation. Additional information on the structures was not provided in the publication and the Agency is unable to confirm the PVA-based material is a film. The results indicated the potential for high concern for algal toxicity (EC50 = 1–10 mg/L based on an OECD 201 guideline study) and high concern for invertebrate toxicity (IC50 = 1–10 mg/L based on an OECD 202 guideline study) (Ref. 24).

The Agency has also reviewed aquatic toxicity data from companies to support the weight-of-evidence approach for the Safer Choice program's evaluation of the PVA structures. Proctor and Gamble (P&G) submitted supporting data on PVA structures used in their detergent films (molecular weight of 130,000 Daltons with 88 mole percent degree of hydrolysis) to EPA after this petition was filed. While the P&G PVA films are not Safer Choice-certified, the structures of the PVA in these films are relevant to the films used in Safer Choice-certified products. The data included an acute fish embryo toxicity study following OECD 236 Guidelines, an acute algal inhibition assay following OECD 201 Guidelines, and an acute invertebrate study following OECD 202 Guidelines on a PVA structure used in P&G detergent packets. The 96-hour algal inhibition study demonstrated no effects on growth or biomass at concentrations greater than 100 mg/L in Raphidocelis subcapitata. The 48-hour invertebrate study demonstrated no effects on mortality, resulting in an EC50 >100 mg/L. These results suggest low potential for algal and invertebrate aquatic toxicity, which differs from the results reported by Meier *et al.* (2013) (Ref. 24). The 96-hour Danio rerio fish embryo toxicity study submitted by P&G demonstrated an LC50 >100 mg/L.

Another supplier submitted an acute toxicity test to the Safer Choice program. This acute toxicity test on freshwater fish followed OECD 203 guidelines and demonstrated low aquatic toxicity for a PVA film used in Safer Choice-certified products. Guideline studies are available for PVA structures used in detergent film used in both Safer Choice certified products and other products across multiple suppliers. These studies suggest variable aquatic toxicity for algae and invertebrate, and low toxicity for fish. Note that the Meier study showing toxicity for PVA does not include details on the specific PVA structure tested. We have included consideration of these results to be conservative in our weight of the scientific evidence approach.

b. Human health toxicity of PVA.

PVA does not carry an EU Hazard or Risk Phrase for any of the human health endpoints identified in Safer Choice criteria and is not included on authoritative lists as a known or suspected carcinogen, mutagen, or reproductive toxicant. Additionally, for applications in pesticide formulations used for food animals, including polyvinyl acetate-polyvinyl alcohol copolymers with MW >50,000 daltons used in water soluble film, EPA established a pesticides tolerance exemption on the basis that PVA was poorly absorbed, showed a lack of carcinogenic effects, and was cleared as a food additive (59 FR 76, April 20, 1994 (FRL–4769–6)). While data is limited, human health hazards for PVA structures used in Safer Choice certified are not expected based on read across to other PVA structures.

5. EPA's Safer Choice evaluation of persistence, bioaccumulation, and toxicity endpoints for polymers.

To meet the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals, a chemical must not be ''persistent, bioaccumulative and toxic'', ''very persistent and very toxic'', or ''very persistent and very bioaccumulative'', available at *https://www.epa.gov/saferchoice/safer-choice-criteria-colorants-polymers-preservatives-and-related-chemicals.* In Unit IV.B., the Agency provides evidence that the PVA structures listed on SCIL do not meet the criteria to be considered ''persistent'', ''very persistent'', ''bioaccumulative'', or ''very bioaccumulative.'' Two of the three conditions (persistence and bioaccumulation) that must be met for a chemical to be characterized as a ''PBT'' are not met by the subset of PVA structures used in Safer Choice-certified products. Therefore, these structures do not meet the criteria to be classified as an ''PBT'' chemical. If only the most conservative aquatic toxicity data were considered (Meier *et al.* (2013) (Ref. 24), the PVA structures would be classified as ''toxic'' (characterized by an LC/EC50 values less than 10 mg/L) to algae and invertebrates, but still meet Safer Choice criteria due to the mitigation of aquatic toxicity through rapid biodegradation. These aquatic toxicity values do not meet the criteria for ''very toxic'' (characterized by an LC/EC50 value less than 1 mg/L). As a result, the PVA structures that form the basis for listing on the SCIL and are used in Safer Choice-certified products also do not meet the criteria of ''very persistent and very toxic.'' The weight of evidence for environmental toxicity and fate demonstrates that PVA meets the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals.

6. Marketing claims of PVA.

The petition finally requests ''the EPA Safer Choice program review claims about PVA through the lens of truth in advertising to ensure that consumers have accurate information about PVA and its potential environmental impacts'' (Ref. 1, pg. 14). As part of the Safer Choice product submission, companies must provide complete ingredient disclosures and product labels for review. Safer Choice evaluates environmental marketing claims on the proposed product label and website, encouraging partners to comply with Federal Trade Commission (FTC) Guidelines. Any language or claims made on or associated with Safer Choice-certified products are subject to FTC regulations and must be supportable. Under the Green Guides, the FTC recognizes that marketers make unqualified degradability claims, which are prohibited unless they have ''competent and reliable scientific evidence that the entire product or package will completely break down and return to nature within a reasonably short period of time after customary disposal,'' typically one year (Ref. 33). When certifying products, EPA does not substantiate label claims unless they are supported by the Safer Choice Standard. Examples of claims generally not substantiated by the standard include ''environmentally safe,'' ''100 percent biodegradable,'' or ''100 percent plastic-free.'' EPA requests that partners remove such claims from the product and marketing materials before EPA grants a Safer Choice certification.

Additionally, the petitioner states, ''PVA is currently on the Safer Choice Program's Safer Chemicals Ingredients List with a green circle, suggesting to consumers that the PVA plastic film encasing laundry and dishwasher pods is safe for people and the environment, and does not have any adverse impacts on the planet'' (Ref. 1, pg. 4). The Safer Choice program uses the Safer Choice Standard and relevant criteria to identify ingredients that are safer for their functional use within a product formulation and does not use the term ''safe'' to describe any chemicals, ingredients, or products.

C. What are the conclusions under the APA portion of the petition?

EPA evaluated the information presented in the APA portion of this petition and identified additional information relevant to the PVA structures allowed for use in Safer Choice-certified products and that form the basis for listing on SCIL. The clear weight of the evidence presented in this **Federal Register** notice demonstrates that the PVA structures allowed in Safer Choice-certified products meet the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals. Specifically, the PVA structures in Safer Choice-certified products that are the subject of this petition are not ''PBT'' substances, ''very persistent and very bioaccumulative'' substances, or ''very persistent and very toxic'' substances, and are expected to be of low concern for human health. The Agency therefore denies the request in the APA portion of this petition to change the status of PVA on the SCIL. The petition did not provide adequate information to demonstrate that the PVA structures used in Safer Choice-certified products and that form the basis for listing on SCIL do not meet the Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals, in light of the evidence supporting such use and listing identified by EPA.

While EPA is denying the APA portion of this petition, EPA does appreciate the petitioners' concerns, especially related to plastic pollution and microplastics. Past efforts for transparency relevant to the concerns stated by the petitioners are reflected in the Safer Chemical Ingredients List. SCIL includes a caveat for polymers as follows: ''Note for Polymers: The hazard profile of a polymer varies with its structure. Manufacturers using CAS numbers in this functional class may need to provide additional information for Safer Choice review'', available at *https://www.epa.gov/saferchoice/safer-ingredients#searchList.*

VI. 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. Yoo, S.J., and Cohen, D. 2023. Petition to Request Health and Environmental Testing and Regulation on Polyvinyl Alcohol Under the Toxic Substances Control Act and an Update to the Chemical Safety Status of Polyvinyl Alcohol on the EPA's Safer Chemical Ingredients Lists.
2. EPA. 1993. TSCA Section 4(a)(1)(B) Final Statement of Policy Notice (58 FR 28736, May 14, 1993 (FRL–4059–9).
3. Rolsky, C., and Kelkar, V. 2021. Degradation of Polyvinyl Alcohol in US Wastewater Treatment Plants and Subsequent Nationwide Emission Estimate. Int. J. Environ. Res. Public Health, 18: 6027. *https://www.mdpi.com/1660-4601/18/11/6027.*
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Authority: 15 U.S.C. 2601 *et seq.*

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Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 211, 212, 245, and 252

[Docket DARS–2023–0017]

RIN 0750–AL14

Defense Federal Acquisition Regulation Supplement: Consolidation of DoD Government Property Clauses (DFARS Case 2020–D029)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to consolidate existing contract clauses for the management and reporting of Government property into a single contract clause, to replace references to legacy software applications used for reporting Government property within the DoD enterprise-wide eBusiness