ENVIROMENTAL PROTECTION AGENCY

40 CFR Chapter I

EPA-HQ-OPPT-2021-0174; FRL-10023-55

Petition for Rulemaking under TSCA; Reasons for Agency Response; Denial of Requested Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition for rulemaking; denial; reasons for Agency response.

SUMMARY: This document announces the availability of EPA’s response to a portion of the petition it received February 8, 2021, from People for Protecting Peace River, Center for Biological Diversity, and 16 other organizations. While the petition requested three actions related to TSCA, EPA has determined that only one of those actions is an appropriate request: a request to issue a test rule under TSCA requiring testing of phosphogypsum and process wastewater from phosphoric acid production. EPA is treating the other portions of the petition involving TSCA as a petition under the Administrative Procedure Act (APA); those other portions request EPA to initiate the prioritization process for designating phosphogypsum and process wastewater as high-priority substances for risk evaluation, and to make a determination by rule under TSCA that the use of phosphogypsum in road construction is a significant new use. Therefore, this document does not provide EPA’s response to these two TSCA-requested actions. Also, this document does not address the petitioners’ requests under the Resource Conservation and Recovery Act (RCRA). After careful consideration, EPA has denied the TSCA section 21 portion of the petition for the reasons set forth in this document.

DATES: EPA’s response to this TSCA section 21 petition was signed May 5, 2021.

ADDRESSES: The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0174, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Public Reading Room are closed to visitors with limited exceptions. The EPA/DC staff continue to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

**FOR FURTHER INFORMATION CONTACT:** For technical information contact: Brooke Porter, Existing Chemicals Risk Management Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6388; email address: porter.brooke@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: TSCA-Hotline@epa.gov.

**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 manufacture (including import), distribute in commerce, process, use, or dispose of phosphogypsum and process wastewater. 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. *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 is 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.

C. What criteria apply to a decision on this 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 in the provisions under which actions have been requested in evaluating this TSCA section 21 petition.


EPA must make several findings in order to require testing under TSCA section 4(a)(1)(A)(i) through 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).

EPA must make several findings in order to require testing under TSCA section 4(a)(1)(A)(ii) through a rule or order. 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, and/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).

4. Legal standard regarding TSCA section 26.

TSCA section 26(h) requires EPA, in carrying out TSCA sections 4, 5, and 6, to make science-based decisions 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 other considerations, including the relevance of information and any uncertainties. 15 U.S.C. 2625(h). TSCA section 26(i) requires that decisions under TSCA sections 4, 5, and 6 be “based on the weight of scientific evidence.” 15 U.S.C. 2625(i). TSCA section 26(k) requires that EPA consider information that is reasonably available in carrying out TSCA sections 4, 5, and 6. 15 U.S.C. 2625(k).

5. Legal standard regarding mixtures under TSCA section 4(a)(1)(B) and 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.

II. Summary of the TSCA Section 21 Petition

A. What action was requested?

On February 8, 2021, the People for Protecting Peace River, Atchafalaya Basinkeeper, Bayou City Waterkeeper, Calusa Waterkeeper, Center for Biological Diversity, Cherokee Concerned Citizens, Healthy Gulf, ManaSota-88, Our Santa Fe River, RISE St. James, Sierra Club’s Florida and Delta chapters, Suncoast Waterkeeper, Suwanee Riverkeeper, Tampa Bay Waterkeeper, Waterkeeper Alliance, Waterkeepers Florida, and WWALS Watershed Coalition (the petitioners) requested EPA to take several actions under section 7004(a) of RCRA; section 21 of TSCA; and section 553 of the APA related to phosphogypsum and process wastewater from phosphoric acid production (process wastewater). With respect to TSCA, the petition asks EPA to (1) initiate the prioritization process for designating phosphogypsum and process wastewater as high-priority substances for risk evaluation under TSCA section 6(b)(1)(B)(i), (2) issue a test rule under TSCA section 4(a)(1)(A) requiring phosphogypsum and process wastewater manufacturers to develop information with respect to health and environmental effects relevant to a determination that the disposal of these chemical substances does or does not present an unreasonable risk of injury to health or the environment, and (3) make a determination by rule under TSCA section 5(a) that the use of phosphogypsum in road construction is a significant new use. This Federal Register document specifically addresses the petitioners’
TSCA section 21 petition, requesting EPA to issue a test rule under TSCA section 4(a)(1)(A). As described in Unit II.A.1 and II.A.2, this Federal Register document does not address the TSCA-requested actions which cannot be addressed under TSCA section 21 (i.e., action under TSCA section 6(b)(1)(B)(i) and section 5(a)), and EPA will consider taking such action in response to those requests, as appropriate, under the APA. This Federal Register document also does not address the petitioners’ requests under section 7004(a) of RCRA.

1. Request for prioritization under TSCA section 6 and related testing under TSCA section 4(a)(2)(B)

With respect to actions under section 6 of TSCA, TSCA section 21 provides only for the submission of a petition seeking the initiation of a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 6(a). Prioritization under TSCA section 6(b) is distinct from rulemaking under TSCA section 6(a). Because TSCA section 21 does not provide an avenue for petitioners to request the initiation of the prioritization process for phosphogypsum and process wastewater, EPA is treating this portion of the request as a petition for action under the APA.

Petitioners also assert that “should EPA initiate prioritization but find that the development of new information is necessary to finalize a prioritization decision for phosphogypsum and process wastewater, EPA should exercise its authority under section 4(a)(2)(B) to obtain that information and establish priority” (Ref. 1, page 41). Because EPA is not addressing the request for prioritization as part of this petition response and has not otherwise initiated prioritization on phosphogypsum or process wastewater, the Agency is not in a position to exercise its authority under TSCA section 4(a)(2)(B) in the manner and for the reason described by petitioners.

2. Request for significant new use rule under TSCA section 5

TSCA section 21 does not provide for the submission of a petition seeking the initiation of a rule under TSCA section 5. Significant new use rules are issued under the authority of TSCA section 5(a)(2). Since TSCA section 21 does not provide an avenue for petitioners to
request the initiation of a proceeding to make a determination by rule under TSCA section 5(a), EPA is treating this portion of the request as a petition for action under the APA.

3. Request for issuance of a test rule under TSCA section 4(a)(1)(A)

TSCA section 21 does provide for the submission of a petition seeking issuance of a test rule under TSCA section 4(a)(1)(A). Therefore, this Federal Register document specifically addresses the only request permissible under TSCA section 21, requesting EPA to issue a test rule under TSCA section 4(a)(1)(A).

4. Request under RCRA section 7004(a)

This Federal Register document does not address the petitioners’ requests under section 7004(a) of RCRA.

5. Request under APA section 553(e).

This Federal Register document does not address the petitioners’ requests under section 553(e) of the APA.

B. What support did the petitioners offer?

The petitioners are not clear as to the provision of TSCA section 4(a)(1)(A) under which they are seeking a test rule. On pages 13 and 14 of the petition, for example, petitioners list the criteria to evaluate the request for testing under TSCA section 4(a)(1)(A)(i). However, in addition, the petition also includes reference to TSCA section 4(a)(1)(A)(ii). Because the petitioners were not clear whether they were seeking testing under TSCA section 4(a)(1)(A)(i) or 4(a)(1)(A)(ii), EPA considered the criteria in both sections in evaluating the petition. Additionally, because petitioners did not indicate whether the requested testing would pertain to mixtures or to individual chemical substances within a mixture, EPA considered both in evaluating the petition.

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

The petitioners claim that phosphogypsum and process wastewater located across the
United States may present an unreasonable risk of injury to human health and the environment under TSCA section 4(a)(1)(A)(i)(I). The petitioners claim that in EPA’s 1991 regulatory determination under the Bevill Amendment to RCRA (section 3001(b)(3)(A) of RCRA), regarding the exemption of processing ores and minerals, including phosphate rock, EPA indicated that phosphogypsum and process wastewater were more appropriate to address under a TSCA regulatory program. The petitioners make a general assertion that “EPA’s investigation of a TSCA regulatory program to manage phosphogypsum and process wastewater means these substances not only may, but do, pose an unreasonable risk of injury to human health and the environment” (Ref. 1, page 40). The petitioners point to the following studies and contend that worker exposure at phosphate fertilizer plants is associated with adverse health effects, however, an exposure-response relationship could not be established in these studies:

- Yiin, JH *et al*., 2016 (Ref. 2); and
- Kim, Kwang Po *et al*., 2006 (Ref. 3).

In addition, petitioners include information regarding the toxicity of several chemical substances they indicate are “phosphogypsum constituents” (arsenic, lead, nickel, cadmium, chromium, silver, antimony, copper, mercury, and thallium), as well as information on radionuclides (uranium, thorium, and radium) (Ref. 1, pages 19-23).

As support for the claim that phosphogypsum and process wastewater are produced in substantial quantities under TSCA section 4(a)(1)(A)(ii)(I), petitioners provide information about the size of phosphogypsum stacks, the amount of phosphogypsum produced annually, and the volume of process wastewater that can be stored in stacks (Ref. 1). Regarding production in substantial quantities, petitioners point to an EPA webpage indicating that phosphogypsum is produced in quantities of 5.2 tons for every ton of phosphoric acid produced (Ref. 4). In addition, petitioners cite to information indicating that approximately 46 million tons of phosphogypsum are created in the United States annually (Ref. 5).

2. Insufficient information and experience.
Without providing supporting rationale, the petitioners assert that updated information is needed, including:

- Information on “population-level exposure risks” for radionuclides and radon emissions for phosphogypsum stacks; and
- Information on the number and size of the phosphogypsum stacks.

The petitioners also state that the majority of the available phosphogypsum and process wastewater research is focused on potential commercial uses, rather than toxicity and other health and environmental effects relevant to an unreasonable risk finding (Ref. 1, page 40).

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

The petitioners claim that a TSCA section 4 “testing rule is necessary to fill gaps in current science and to better inform a future risk evaluation,” citing the need for updated information on “population-level exposure risks” for radionuclide and radon emissions for phosphogypsum stack systems since the population around each phosphogypsum stack has likely increased (Ref. 1, page 40). The petitioners also claim it is necessary to update toxicity information using the Toxicity Characteristic Leaching Procedure (TCLP) method (Ref. 1, page 40). The petitioners provide no further information identifying specific gaps in the TCLP information already available, or why additional testing is necessary under TSCA section 4(a)(1)(A).

III. Disposition of TSCA Section 21 Portion of the Petition

A. What is EPA’s response?

After careful consideration, EPA has denied the TSCA section 21 portion of the 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/tscasection-21#reporting. The response, the petition (Ref. 1), and other information is available in the docket for this TSCA section 21 petition (see
B. What was EPA’s reason for this response to the request for testing under TSCA section 4?

TSCA section 21 does provide for the submission of a petition seeking the initiation of a proceeding for the issuance of a rule under TSCA section 4. The petition must “set forth the facts which it is claimed establish that it is necessary to issue” the requested rule. 15 U.S.C. 2620(b)(1). When determining whether the petition meets that burden, EPA will consider whether the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or any combination of such activities, may present an unreasonable risk of injury to health or the environment under TSCA section 4(a)(1)(A)(i)(I), or whether 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 under TSCA section 4(a)(1)(A)(ii)(I). In addition, EPA will consider whether “information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or mixture.” 15 U.S.C. 2620(b)(4)(B)(i)(I) (see also 15 U.S.C. 2603(a)(1)). Furthermore, EPA’s decision to grant a petition for the promulgation of a TSCA section 4 rule requires a finding that “testing of such substance or mixture with respect to such effects is necessary to develop such information.” 15 U.S.C. 2603(a)(1). In the case of a mixture, the petitioners must set forth facts to establish that the effects of the mixture would 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).

EPA evaluated the information presented or referenced in the petition and considered that information in the context of the applicable authorities and requirements of TSCA sections 4, 21, and 26. 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 also considered relevant information that was reasonably available to the Agency
during the 90-day petition review period. As detailed in Unit III.B.2 and III.B.3, EPA finds that
the petitioners have not met their burden as defined in TSCA sections 4(a)(1)(A) and 21(b)(1)
because the petitioners have not provided the facts necessary for the Agency to determine for
phosphogypsum and process wastewater that existing information and experience are insufficient
and testing 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 phosphogypsum or process wastewater 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 testing with respect to
such effects is necessary to develop such information, as described in more detail below.
However, EPA agrees that phosphogypsum and process wastewater are or will be produced in
substantial quantities under TSCA 4(a)(1)(A)(ii)(I).

2. Insufficient information and experience.

The petition does not set forth the facts necessary to demonstrate that there is
“insufficient information and experience” on which the effects of phosphogypsum and process
wastewater on health or the environment can reasonably be determined or predicted. The
petitioners only claim that updated toxicity information using the TCLP method is necessary and
assert that information available is from an outdated “Extraction Procedure.” However, EPA has
found that there are TCLP data related to phosphogypsum and process wastewater available in
the public domain (Ref. 6). The petitioners failed to present facts indicating the nature and extent
of existing TCLP data and articulate why this data is insufficient. The petitioners do not provide
an assessment of existing data to support a finding of insufficient information and experience.
The petitioners present no evidence that they undertook efforts such as a literature search of
publicly available information, an analysis and characterization of the results of such a literature search, or an inventory of information they claim is missing from the public domain.

Extensive information on the heavy metal chemical substances contained in phosphogypsum and process wastewater is readily available. For example, EPA has published Integrated Risk Information System (IRIS) assessments, which review existing information and characterize the hazards of chemicals, that are available for all of the heavy metals mentioned in the petition, as well as uranium (Ref. 7). Furthermore, the Agency for Toxic Substances and Disease Registry (ATSDR) has published Toxicological Profiles, which characterize the toxicologic and adverse health effects information for hazardous substances, for all of the metals, as well as for radon and the radionuclides referenced in the petition (Ref. 8). The petitioners make no mention of the IRIS assessments, nor have they provided the facts necessary to show that this extensive body of existing information on toxicological effects, including the ATSDR Toxicological Profiles cited in the petition, is insufficient. TSCA section 21 requires the petitioner, not EPA, to “set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under TSCA sections 4, 6, or 8, or an order under TSCA sections 4 or 5(e).” 15 U.S.C. 2620. Therefore, petitioners have failed to meet their burden.

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

The petition did not include any data, information, or analysis related to the need for testing of phosphogypsum and process wastewater or for the chemical substances, including the heavy metals and radionuclides contained in phosphogypsum and process wastewater. A petition without such information is facially incomplete because it fails to provide minimum factual information for EPA to make the threshold findings needed to respond to and act on the petition as contemplated by TSCA section 21. Even if the petitioners had successfully demonstrated the insufficiency of existing information, they still failed to demonstrate that testing of phosphogypsum and process wastewater is needed to develop the necessary information that they
claim does not exist. Importantly, the petitioners provided no information regarding how testing by manufacturers of phosphogypsum and process wastewater would provide the sort of health and environmental effects data that petitioners believe is necessary. 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. Beyond an assertion that TCLP data is not available, the petitioners did not include any information on what type of testing they claim is needed.

4. Testing as a mixture.

Petitioners do not indicate whether the requested testing would pertain to mixtures or to individual chemical substances within a mixture. With regard to testing phosphogypsum and process wastewater as a mixture, petitioners have not set forth facts sufficient to support the required finding for mixtures under TSCA section 4(a)(1): That the effects of phosphogypsum and process wastewater would 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). EPA has broad discretion to make this finding, and although petitioners did not specify whether their request was for testing of phosphogypsum and process wastewater as a mixture, EPA does not, at this time, believe this finding is warranted.

5. Environmental justice considerations.

Petitioners express environmental justice concerns and include examples of a phosphogypsum and process wastewater facility near a historic Black neighborhood, and another facility in a region of Louisiana which they state has environmental justice concerns related to impacts from a variety of industrial activities (Ref. 1, pages 36-38).

As a general matter, EPA shares the petitioners’ concerns regarding the potential for disproportionate impacts in communities with environmental justice concerns. However, petitioners must set forth the facts which it is claimed establish that it is necessary to issue a rule
or order requiring testing under TSCA section 4(a)(1)(A). As petitioners have not set forth facts sufficient for EPA to make these findings, EPA is not able to issue a test rule under TSCA section 4 in response to this TSCA section 21 petition.

6. What were EPA’s conclusions?

EPA denied the request to initiate a proceeding for the issuance of a rule under TSCA section 4 because the TSCA section 21 petition does not set forth the facts establishing that it is necessary for the Agency to issue such a rule. In particular, the petition does not demonstrate that existing information and experience on the effects of phosphogypsum and process wastewater are insufficient or that testing of phosphogypsum and process wastewater with respect to such effects is necessary to develop such information. Therefore, the petitioners have not demonstrated that the rule they requested is necessary.

IV. 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. Curran, Rachael, People for Protecting Peace River, and Lopez, Jaclyn, Center for Biological Diversity to the Administrator of the Environmental Protection Agency. Re: Petition for Rulemaking Pursuant to Section 7004(a) of the Resource Conservation and Recovery Act; Section 21 of the Toxic Substances Control Act; and Section 553 of the Administrative Procedure Act Concerning the Regulation of Phosphogypsum and Process Wastewater from Phosphoric Acid Production. Received February 8, 2021.

https://doi.org/10.1080/02786820600643313.


https://www.epa.gov/enforcement/mosaic-fertilizer-llc-settlement.


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