ENIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2011-0683; FRL-9339-4]

Chemical Substances and Mixtures Used in Oil and Gas Exploration or Production; TSCA Section 21 Petition; Reasons for Agency Response

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: On August 4, 2011, Earthjustice and 114 other organizations petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA) to use: TSCA section 8(a) to require manufacturers and processors of oil and gas exploration and production (E&P) chemical substances and mixtures to maintain certain records and submit reports on those records; TSCA section 8(d) to require manufacturers, processors, and distributors to submit to EPA existing health and safety studies related to E&P chemical substances and mixtures; TSCA section 8(c) to request submission of copies of any information related to significant adverse reactions to human health or the environment alleged to have been caused by E&P chemical substances and mixtures; and TSCA section 4 to require manufacturers and processors of E&P chemical substances and mixtures to conduct toxicity testing of E&P chemical substances and mixtures. In a letter dated November 2, 2011, EPA informed petitioners that it denied the TSCA section 4 request and in a letter dated November 23, 2011, EPA informed petitioners that it granted in part the TSCA section 8(a) and 8(d) requests. This document sets forth EPA’s reasons for denying in part the petitioners’ requests. In addition, EPA has concluded that TSCA section 21 does not apply to requests for a TSCA section 8(c) data call-in.
FOR FURTHER INFORMATION CONTACT: For technical information contact:
Mark Seltzer, Chemical Control Division (7405M), Office of Pollution Prevention and
Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,
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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, however, may be of
interest to you if you manufacture (including import), process, or distribute chemical
substances or mixtures used in hydraulic fracturing to create fractures in geologic
formations, such as shale rock, allowing enhanced natural gas or oil recovery. Since other
entities also may be interested, the Agency has not attempted to describe all the specific
entities that may be affected by this action. If you have any questions regarding the
applicability of this action to a particular entity, consult the technical person listed under

FOR FURTHER INFORMATION CONTACT.

B. How Can I Access Information About this Petition?

The docket for this TSCA section 21 petition, identified by docket identification
(ID) number EPA-HQ-OPPT-2011-0683, is available at http://www.regulations.gov or at
the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental
II. TSCA Section 21

A. What is a TSCA Section 21 Petition?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8 or an order under TSCA sections 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the Federal Register. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of the denial, if the denial occurs prior to the expiration of the 90-day period, or within 60 days after the expiration of the 90-day period.

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

Section 21(b)(1) of TSCA requires that the petition “set forth the facts which it is claimed establish that it is necessary” to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that
apply to the requested actions. In addition, TSCA section 21 establishes standards a court
must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit
filed by the petitioner. 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA has relied on the
standards in TSCA section 21 and in the provisions under which actions have been
requested to evaluate this petition. The standards that apply to actions under TSCA
sections 4 and 8 (Ref. 1) are available in the docket established for this TCSA section 21
petition.

III. Summary of the TSCA Section 21 Petition

A. What Action was Requested?

On August 4, 2011, Earthjustice and several other organizations petitioned EPA to:

1. Adopt a rule pursuant to TSCA section 4 to require manufacturers and
processors of E&P chemical substances and mixtures to develop test data sufficient to
evaluate the toxicity and potential for health and environmental impacts of all E&P
chemical substances and mixtures that they manufacture and process. The petitioners
request the rule include a requirement for the manufacturer or processor to identify any
E&P chemical substance and mixture for which testing is required (Ref. 2).

2. Adopt a rule pursuant to TSCA section 8(a) requiring manufacturers and
processors of E&P chemical substances and mixtures to maintain records and submit
reports to EPA disclosing the identities, categories, and quantities of E&P chemical
substances and mixtures, descriptions of byproducts of E&P chemical substances and
mixtures, all existing data on potential or demonstrated environmental and health effects
of E&P chemical substances and mixtures, and the number of individuals potentially exposed to E&P chemical substances and mixtures (Ref. 2).

3. Request call-in of all allegations of significant adverse reactions received and maintained by manufacturers, processors, and distributors of E&P chemical substances and mixtures pursuant to TSCA section 8(c) and 40 CFR part 717 (Ref. 2).

4. Adopt a rule pursuant to TSCA section 8(d) to require submittal of all existing, not previously reported health and safety studies related to the health and/or environmental effects of all E&P chemical substances and mixtures (Ref. 2).

B. What Support Do the Petitioners Offer?

The petitioners believe that there are potential risks to human health, terrestrial and aquatic life, and the environment from E&P chemical substances and mixtures, and that there is currently insufficient information about these potential risks. The petitioners believe rulemakings under TSCA section 4 and section 8 are necessary to fill information gaps so that Federal and State regulators can appropriately assess and regulate E&P chemical substances and mixtures and provide information to the public about E&P chemical substances and mixtures. To support their requests, the petitioners discussed the following information sources which focus mostly on hydraulic fracturing chemical substances and mixtures, and assert the limitations of these sources:

• EPA’s current study to examine the relationship between hydraulic fracturing and drinking water resources (Ref. 3).

• FracFocus.org (http://fracfocus.org), a website (operated jointly by the Ground Water Protection Council (GWPC) and the Interstate Oil and Gas Compact Commission (IOGCC)) that serves as a voluntary chemical substance registry for
companies to report publically available information on chemicals used in hydraulic fracturing operations.

- Current Federal and State regulations requiring the disclosure of E&P chemical substances and mixtures.
- Two reports published by The Endocrine Disruption Exchange (TEDX) (Ref. 4) and the New York State Department of Environmental Conservation (NYSDEC) (Ref. 5) that analyze the health effects of chemical substances and mixtures for which TEDX and NYSDEC could locate a Chemical Abstracts Service Registry Number (CASRN).
- Reports of potential harm to human and environmental health from exposure to E&P chemical substances and mixtures.

**IV. Disposition of TSCA Section 21 Petition**

For the purpose of making its decision, EPA evaluated the information presented or referenced in the petition and the Agency’s authority and requirements under TSCA sections 4, 8, and 21. EPA has also evaluated the comments in response to the petition received from the American Petroleum Institute (Ref. 6), the American Chemistry Council (Ref. 7), and Halliburton Energy Services (Ref. 8). After careful consideration, EPA has granted in part and denied in part the petition. In a letter dated November 2, 2011 (Ref. 9), EPA informed petitioners that it denied the TSCA section 4 request. In a subsequent letter dated November 23, 2011 (Ref. 10), EPA informed petitioners that it granted in part the TSCA section 8(a) and 8(d) requests.

By virtue of partially granting the TSCA section 8(a) and 8(d) requests, EPA plans to initiate rulemaking under TSCA sections 8(a) and 8(d) to obtain data on
chemical substances and mixtures used in hydraulic fracturing. Although EPA has partially granted the TSCA section 8(a) and 8(d) requests, the Agency is not committing to a specific rulemaking outcome. EPA’s response to the petition describes a principle that will guide EPA’s efforts: “given efforts underway [in states, industry and other federal agencies], our expectation is that the TSCA proposal would focus on providing aggregate pictures of the chemical substances and mixtures used in hydraulic fracturing. This would not duplicate, but instead complement, the well-by-well disclosure programs of states” (Ref. 10).

EPA plans first to develop an Advance Notice of Proposed Rulemaking (ANPRM) and initiate a stakeholder process to provide input on the design and scope of the TSCA reporting requirements that would be included in a proposed rule. EPA anticipates that States, industry, public interest groups, and members of the public will be participants in the process. The stakeholder process will bring stakeholders together to discuss the information needs and help EPA to ensure any reporting burdens and costs are minimized, ensuring information already available is considered in order to avoid duplication of efforts. The dialogue will also assist EPA in determining how information that is claimed Confidential Business Information could be aggregated and disclosed to maximize transparency and public understanding.

Section 9(d) of TSCA provides that the EPA Administrator shall consult and cooperate with other Federal agencies “for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements.” 15 U.S.C. 2608(d). Consistent with TSCA section 9(d), in the development of these actions, EPA will consult and cooperate with other agencies (e.g., Bureau of Land
Management (BLM) and the U.S Department of Energy (DOE)). Consistent with TSCA section 9(b), EPA will consult and cooperate with multiple offices within the Agency.

Regarding the TSCA section 4 request, EPA has concluded that the petition does not set forth sufficient facts to support the petitioners’ assertion that it is necessary to initiate the requested rulemaking under TSCA section 4. The discussion in this unit provides the reasons for EPA’s decisions to deny the petition in part.

A. Partial Denial of the TSCA Section 8(a) Request

Although EPA is granting the TSCA section 8(a) request in part, the petitioners’ request is overly broad, and they have not demonstrated that the broad rule they requested is necessary. The petitioners request that for all chemical substances and mixtures used throughout all E&P operations, EPA require by rule submission of essentially all of the information identified in TSCA section 8(a) for rules under that section. (The petitioners request all information for the chemical substances and mixtures generally, even beyond their use in the E&P industry.) The E&P industry is a large industry involving a range of varied operations and classes of chemical substances and mixtures (Refs. 11 and 12). EPA, other Federal agencies, and States, have focused attention on hydraulic fracturing due to specific concerns raised about this practice, and most of the incidents and information sources referenced in the petition pertain to hydraulic fracturing. EPA believes information collection under TSCA could significantly advance the Federal Government’s understanding of potential risks associated with this practice. EPA notes that it already has broad regulations under TSCA section 8(a) requiring periodic reporting of extensive information with respect to chemical substances (Ref. 1) including chemical substances used in the E&P industry. Before proposing a TSCA section 8(a) rule specific
to the E&P industry as a whole, EPA would want a better understanding of the incremental value of individual information elements.

B. Partial Denial of TSCA Section 8(d) Request

EPA is partially granting the TSCA section 8(d) request in this petition. EPA intends first to issue an ANPRM regarding the submission of unpublished health and safety studies and lists of ongoing and initiated studies from companies manufacturing (including importing), processing, and distributing certain chemical substances and mixtures, used in hydraulic fracturing. As part of the stakeholder process discussed in Unit IV., EPA plans to seek input on the range of chemical substances and mixtures that may be subject to the TSCA section 8(d) rulemaking. For the reasons set out in Unit IV.A., EPA does not believe a broader TSCA section 8(d) rule is needed or appropriate at this time.

C. Denial of TSCA Section 4 Request

The petitioners requested a TSCA section 4 test rule covering all chemical substances and mixtures used in oil and gas E&P. Specifically, the petitioners requested that EPA promulgate a rule under TSCA section 4 requiring “manufacturers and processors of E&P [chemical substances and mixtures] to develop test data to evaluate the toxicity and potential for health and environmental impacts of all chemical substances and mixtures they manufacture and process” and that the TSCA section 4 rule require the manufacturers and processors to identify all chemical substances and mixtures tested (Ref. 2). EPA is denying this request as the petitioners have not set forth sufficient facts to support their assertion that it is necessary to issue a TSCA section 4 rule requiring testing of all chemical substances and mixtures used in all oil and gas E&P, as required
by TSCA section 21(b)(1). Further, to the extent that the petition could be read to articulate a somewhat narrower request (that only some chemical substances and mixtures should be tested, as necessary to evaluate the potential impacts of those chemical substances and mixtures), this is not a request for an identifiable rule under TSCA section 4, as required by TSCA section 21 (e.g., the petition does not identify specific chemical substances or mixtures for which inadequate data exist, or the data gaps or endpoints for which testing is necessary).

The petitioners have not set forth sufficient facts for EPA to find that information available to the EPA Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of all E&P chemical substances and mixtures, or that testing is necessary to develop such information. The petitioners identified two reports that discuss health effects from some chemical substances and mixtures used during oil and gas operations with some specific discussion on hydraulic fracturing. The reports are an information source that EPA might review in developing a TSCA section 4 rulemaking to determine whether data are lacking for specific health endpoints for specific chemical substances. However, EPA believes the analysis conducted for the reports are not comprehensive because not all E&P chemical substances and mixtures were reviewed in either report (Ref. 2). Therefore, the petitioners do not demonstrate that data are insufficient for all E&P chemical substances and mixtures.

The petitioners also failed to show it is necessary to issue a TSCA section 4 rule by failing to support the other findings under TSCA section 4. 15 U.S.C. 2603(a)(1)(A)(i) and (B)(i). The petitioners made a minimal attempt to show that any individual E&P chemical substance is produced in “substantial quantities” and provided no production
volume information for any individual chemical substance. While the petitioners do make
general statements that E&P chemical substances and mixtures are used in large
quantities (Ref. 2), this does not provide a basis for EPA to conclude that all E&P
chemical substances and mixtures are produced in substantial quantities. The term
“substantial quantities” has been interpreted by EPA to generally be one million pounds
or more per year (Ref. 13). Nor have the petitioners shown that any specific chemical
substance or mixture enters or may reasonably be anticipated to enter the environment in
substantial quantities or that there is or may be significant or substantial human exposure
to any specific chemical substance or mixture. Individual chemical substances and
mixtures used in E&P operations may well be produced and released in small volumes.

Furthermore, the petitioners have not shown that all E&P chemical substances and
mixtures may present an unreasonable risk (Refs. 4 and 5). The oil and gas E&P industry
is broad and engages in a wide variety of activities and uses many different chemical
substances and mixtures depending on site characteristics. Although petitioners provided
examples of spills and releases and cited existing databases collecting health effects data,
they did not show that any individual chemical substance or mixture, or the entire class of
chemical substances and mixtures used in all phases of the E&P industry, may present an
unreasonable risk. While it is possible that such a finding could be made for some
chemical substances and mixtures used in some operations, it is also likely that many are
benign, and petitioners did not provide sufficient information for the broad finding they
request. For these reasons, the petitioners have not demonstrated that it is necessary to
issue the requested TSCA section 4 rule.

With respect to E&P mixtures, petitioners have not made any attempt to show that
evaluating the effects of mixtures would be reasonable and more efficient than testing chemical substances in the mixtures. 15 U.S.C. 2603(a)(2). EPA is not prepared to make this finding without more complete information regarding the chemical substances and mixtures currently in use and the existing available information regarding potential health effects. EPA understands that mixtures can change frequently in hydraulic fracturing operations, and in the E&P industry more broadly, and the petition does not provide sufficient information to enable EPA to effectively identify what mixtures, or classes of mixtures, if any, might most efficiently be tested. Any existing mixture tested might not still be in use once testing has been completed, and additional mixtures might be in use at that point. A requirement to test certain representative mixtures might be reasonable and more efficient than testing individual chemical substances, but petitioners did not provide sufficient information to support such a finding.

EPA is in the process of evaluating information in its possession and plans to request additional information as described in this document. While EPA agrees with petitioners that the Office of Research and Development (ORD) study focuses on the potential impacts on drinking water resources and does not require companies to conduct testing or to develop health and safety data, EPA plans to summarize the available data (including data the Agency may already have collected) on the toxicity of chemical substances and mixtures used in hydraulic fracturing, and to identify and prioritize data gaps for further investigation. This information will aid in EPA’s understanding of potential effects beyond drinking water impacts. EPA also plans to review the results from the Agency’s other activities and those from other Federal agencies (Ref. 3).

V. References
The following is a list of the documents that are specifically referenced in this document and placed in the docket that was established under docket ID number EPA-HQ-OPPT-2011-0683. For information on accessing the docket, refer to Unit I.B.

1. Legal Standards on TSCA Section 4, 8(a), 8(c), 8(d) and Applicability to a Section 21 Petition. May 24, 2012.

2. Earthjustice and 114 other organizations. Letter from Deborah Goldberg, Earthjustice to Wendy Cleland-Hamnett, Director, Office of Pollution Prevention and Toxics (OPPT), EPA. “Re: Citizen Petition Under Toxic Substances Control Act Regarding the Chemical Substances and Mixtures Used in Oil and Gas Exploration or Production.” August 4, 2011.


7. Letter from Christina Franz, Senior Director, Regulatory & Technical Affairs, American Chemistry Council (ACC) to Wendy Cleland-Hamnett, Director OPPT, EPA: “Comments of the American Chemistry Council on the TSCA Section 21 Petition Concerning Oil and Gas Exploration and Production Chemicals.” October 20, 2011.


13. EPA. TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for
List of Subjects Chapter I

Environmental protection, Exploration and production (E&P), Hydraulic fracturing, Oil and gas, Toxic Substances Control Act (TSCA).


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