TSCA Chemical Data Reporting: Preparing and Submitting a Petition

EPA #: EPA 705-G-2021-3736 OMB Control No.: 2070-0162 Date Issued: August 16, 2021 This document provides guidance on Chemical Data Reporting (CDR) rule requirements related to its applicable petition processes, specifically for:

- Full exemption of byproduct substances that are recycled or otherwise used within site-limited, physically enclosed systems (40 CFR 711.10(d)(1)) and
- Partial exemption of chemicals for which the CDR processing and use information has been determined to be of "low current interest" by the Agency (40 CFR 711.6(b)(2)).

The primary goal of this document is to help the regulated community comply with the CDR rule requirements in relation to its applicable petition processes. This document does not substitute for that rule, nor is it a rule itself. It does not impose legally binding requirements on the regulated community or on the U.S. Environmental Protection Agency (EPA).

The CDR rule, issued under the Toxic Substances Control Act (TSCA), requires manufacturers (including importers) to disclose to EPA certain information on the chemicals they manufacture domestically or import into the United States. EPA uses these data, which serve as important screening-level exposure-related information, to help assess potential effects these chemicals may have on human health and the environment. Some of the data submitted under the CDR rule is claimed as confidential business information (CBI) and will not be disclosed except as provided under applicable law. That which is non-confidential business information is made available to the public.

Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it has been approved by the Office of Management and Budget (OMB) and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR, part 9, and included on the related collection instrument, or form, as applicable.

The information collection activities contained in CDR are approved by OMB under the PRA and have been assigned OMB Control No. 2070-0162 (EPA ICR No. 1884). This guidance document does not contain any new or revised information collections or burden subject to additional OMB approval under the PRA. Burden is defined in 5 CFR 1320.3(b). The public burden for reading this guidance is estimated to be 1 hour per respondent.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form, petitions or other information to this address.

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Part I. CDR Petition Description and Process Overview

The CDR data include information on the manufacture (including import), industrial processing and use, and consumer and commercial use of certain chemicals currently included on the *TSCA Inventory*. Manufacturing, processing, and use information helps EPA screen and assess potential exposures to and risks of reported chemicals to human health and the environment. Certain chemicals for which this processing and use information has been determined to be of "low current interest" by the Agency are partially exempted from reporting and manufacturers of these chemicals are not required to provide information on the processing and use of their chemicals (only information on manufacturing (including import) is required). Additionally, certain chemicals, when produced as byproducts, may be fully exempted from reporting depending on how they are manufactured, processed, or used. Two separate petition processes exist for making amendments to the list of partially exempt chemical substances (40 CFR 711.6(b)(2)(iv)) or the list of processes and certain related byproduct substances (40 CFR 711.10(d)(1)(i)) that are fully exempted when they are recycled or otherwise used within site-limited, physically enclosed systems.¹ However, certain procedural aspects of the petition processes are similar or identical, as described below.

1. Who can submit a petition?

A petition may be submitted by any person, regardless of whether the person manufactures, imports, or uses the chemical, or is otherwise interested in the chemical. When evaluating the petition, EPA may consider any existing information for all manufacturing or importing sites, all uses of the chemical, and interest in the reportable information from those outside of EPA. See Part II. Section 2. and Part III. Section 2. for details on the requirements and/or considerations of both types of petition processes.

2. How do I submit a petition?

Your petition to amend the partial exemption chemical list at 40 CFR 711.6(b)(2)(iv) or the exemption list at 40 CFR 711.10(d)(1)(i) must be submitted in writing and must contain the identity of the chemical in question, as well as its Chemical Abstract Service (CAS) Registry Number. If a CAS Registry Number is not known to or reasonably ascertainable by you (the petitioner), an EPA-designated Accession Number for confidential substances can be submitted in lieu of a CAS Registry Number.

Your petition must also contain a written rationale for the request that provides sufficient specific information addressing the requirements and considerations listed in 40 CFR 711.6(b)(2)(ii) or 711.10(d)(1)(ii)(B) and (C), as applicable, including citations and relevant documents. If a request related to a chemical or particular process/byproduct combination is resubmitted, any subsequent request must clearly identify new information contained in the request. EPA may request other information that it believes necessary to evaluate the request.

EPA recommends submitting your petition in an electronic format (*i.e.*, as downloadable e-mail attachments, files on a USB drive, or CD). Your submission can be sent by e-mail to <a href="ecdpress: ecdpress: ecdpres

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¹ The CDR petition processes described in this guidance document are separate from the TSCA Section 21 petition process that can affect reporting requirements under TSCA Section 8, including the CDR rule. Information about the TSCA section 21 petition process, including guidance, is available on the TSCA Section 21 webpage.

Partial Exemption Request (as applicable). If opting to send a physical (non-e-mail) petition by delivery service or mail, follow the directions in this guidance and send to the appropriate address listed at 40 CFR 700.17(a).

If your petition contains CBI, you must also provide a redacted version of your petition with any CBI masked.

3. What are the timing requirements of submitting a petition?

The timing requirements of submitting a petition are the same for the two types of petitions covered in this document:

- To assist EPA in reaching a decision regarding a particular request prior to a given principal reporting year, petitions must be submitted to EPA no later than 12 months prior to the start of the next principal reporting year.
 - For example, petitions to amend the list of partially exempt chemicals or exempt industrial processes and associated byproducts (respectively at 40 CFR 711.6(b)(2)(iv) and 40 CFR 711.10(d)(1)(i)) for the 2024 CDR submission period are due before January 1, 2022.
- 40 CFR 711.6(b)(2)(iii)(A) and 711.10(d)(1)(ii)(A) provide that EPA will issue a written response to each petition within 120 days of receipt of the petition and will maintain copies of these responses in a docket for each reporting cycle. The initial response may not have EPA's final decision, though EPA may make a final decision before the 120 days have passed.

These regulatory deadlines for submission of petitions are specified in 40 CFR $\frac{711.6}{(b)(2)(iii)(C)}$ and $\frac{711.10}{(d)(1)(ii)(E)}$.

4. What happens to my petition once I submit it?

EPA has established a process for reviewing petitions. There are several steps in this review process and, at any place in this process, EPA may contact the petitioner for clarification or additional information. The petitioner may also submit additional information relevant to the petition at any time before EPA issues a final decision.

In making its determination of whether a partial exemption should apply to a particular chemical substance or if a full exemption should apply to a specific process and byproduct substance combination, EPA will consider the information submitted and the totality of information available for the chemical substance in question or for the process and related byproduct substance in question, including but not limited to, respectively, the considerations listed at § 711.6(b)(2)(ii) or the requirements and considerations listed at § 711.10(d)(1)(ii)(B) and (C).

EPA plans to establish a docket for each petition. Information that is submitted to EPA in connection with the petition would be placed in this docket, along with other information such as the petition review report and information that is exchanged with you as the petition submitter. If submitted information contains content that is claimed as CBI, the petitioner must submit a redacted version that can be placed in the public record (Part IV. Section 1. of this document provides additional information on asserting a confidentiality claim when submitting a petition).

5. What happens if my petition is granted?

After granting a petition, the Agency will initiate rulemaking to make revisions to the list of partially

exempt substances at 40 CFR 711.6(b)(2)(iv) or the list of exempt processes and related byproduct substances at 40 CFR 711.10(d)(1)(i). This rulemaking could be a rule specific to a particular petition or done in combination with another rule (*i.e.*, before the next reporting cycle).

6. What happens if my petition is denied?

Upon denying a petition, the Agency will send a final response to the petitioner and place the denial in a public docket. Any subsequent petition for the same substance or process must clearly indicate new information contained in the request. It would be helpful to also indicate specific information that may change the previous determination.

Part II. Petitions for Full Exemption of Certain Byproducts and Processes under CDR

The public may petition EPA to make amendments to the list of industrial processes and associated byproducts at 40 CFR 711.10(d)(1)(i) when those byproducts are recycled or otherwise used in a site-limited², enclosed system that is part of the manufacturing process from which the byproduct was generated, and the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled byproduct or manufactured in the same overall manufacturing process. Petitions should be submitted using the procedures under 40 CFR 711.10(d)(1)(ii). EPA's intent in providing this petition process is to provide a mechanism for modification of the substances or industrial processes listed under this reporting exemption based upon information provided by the petitioner and specifically analyzed by the Agency, as appropriate.

Because there may be other manufacturing processes and related byproduct substances that meet the criteria for this exemption, and because EPA's interest in these byproduct substances may change, EPA may amend the list of byproduct substances and processes that have been included in this exemption. The Agency may do this on its own initiative or in response to a request from the public based on EPA's determination of whether the manufacturing process and related byproduct substance described meet the criteria in 40 CFR 711.10(d)(1), based on the requirements and considerations listed at 40 CFR 711.10(d)(1)(ii)(B) and (C).

1. What is a byproduct and when is it reportable?

A *byproduct* is "a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s)." See 40 CFR 704.3, referenced by 40 CFR 711.3. A byproduct is generally reportable when it is *used* for a non-exempt commercial purpose.³

² Site-limited means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a chemical substance or as part of a mixture or article outside the site. Imported chemical substances are never site-limited. Although a site-limited chemical substance is not distributed for commercial purposes outside the site at which it is manufactured and processed, the chemical substance is considered to have been manufactured and processed for commercial purposes. (40 CFR 711.3)

³ See 40 CFR 711.10(c) (explaining that a person is not subject to CDR reporting when the person manufactured the chemical substance in a manner described in 40 CFR 720.30(g) (describing byproducts with limited commercial purposes) or 720.30(h)(2) (listing "[a]ny byproduct which is not used for commercial purposes")). Note that "commercial purpose" refers to the broad definition in 40 CFR 704.3 ("the purpose of obtaining an immediate or eventual commercial advantage"). It is not synonymous with the narrower definition of "commercial use" at 40 CFR 711.3, which is only intended for further subcategorizing reportable uses between industrial, commercial, and consumer settings.

There are other circumstances where a byproduct may be exempt, as described in detail in Section A of Part 1 of the Byproducts, Impurities, and Recycling Scenarios document. The petition process is associated with the exemption at 40 CFR 711.10(d)(1): for certain listed manufacturing processes. the listed byproducts are exempt when recycled or otherwise used within a sitelimited, physically enclosed system that is part of the same overall manufacturing process from which the byproduct substance was generated, and when the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled byproduct or manufactured in the same overall manufacturing process.

<u>Listed Substances and Associated Manufacturing</u> Processes:

As of August 1, 2021, the manufacturing processes and certain related byproduct substances listed are:

- Portland cement manufacturing
 - CASRN 68475-76-3, Flue dust, portland cement (commonly referred to as cement kiln dust or CKD)
- Kraft pulping process
 - CASRN 66071-92-9, Sulfite liquors and Cooking liquors, spent (often comprised of what is referred to as black liquor)
 - CASRN 68514-09-0, Sulfite liquors and Cooking liquors, spent, oxidized (often comprised of what is referred to as oxidized black liquor)
 - CASRN 471-34-1, Carbonic acid calcium salt (1:1)
 (commonly referred to as calcium carbonate)

2. Submitting a Byproduct Exemption Petition under 40 CFR 711.10(d)(1)(ii)

Petitions must be in writing; identify the process and byproduct chemical substance(s) that are the subject of the request; and contain a written rationale that provides sufficient specific information, addressing the requirements and considerations listed at 40 CFR 711.10(d)(1)(ii)(B) and (C) respectively, including citations and relevant documents, to demonstrate to EPA that the byproduct substance(s) and manufacturing process(es) in question either would or would not meet the criteria for this reporting exemption. In addition to information addressing the requirements and considerations listed in 40 CFR 711.10(d)(1)(ii)(B) and (C), a petition may include additional information relevant to the request, and EPA may request other information that it believes necessary to evaluate the request.

 a) Requirements and Considerations for determining whether a byproduct substance is recycled or otherwise used within site-limited, physically enclosed systems (40 CFR 711.6(b)(2)(ii)(B) and (C))

There are two requirements at 40 CFR 711.10(d)(1)(ii)(B) which must be met in order for EPA to amend the list at 40 CFR 711.10(d)(1)(i). There are also two considerations at 40 CFR 711.10(d)(1)(ii)(C) which EPA will use to evaluate petitions. EPA will consider the totality of information available for the process and related byproduct substance in question, including but not limited to, one or both of these considerations. In other words, EPA is not limited to these four items when petitions are evaluated and may rely on additional information or internal decision criteria.

Requirements (§ 711.10(d)(1)(ii)(B)):

- (1) The byproduct substance is recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured.
- (2) The site is reporting under CDR other chemical substance(s), in particular a chemical substance other than the byproduct substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process.⁴

Considerations (§ 711.10(d)(1)(ii)(C)):

- (1) Whether EPA has a current interest in the byproduct substance.
- (2) Whether the byproduct substance must have already been reported under CDR, or would be expected to be reported if not exempted by this exemption.

Regarding enclosed systems (Requirement 1)

For the purposes of CDR, EPA considers an enclosed system to be a system of equipment directly connected to the production process that is designed, constructed, and operated in a manner which prevents emissions, or the release of any chemical substance into the facility or environment during the production process. Such emissions, including fugitive emissions, could lead to exposures to workers, the public, or the environment. For an enclosed system, exposure and release could only occur due to loss of integrity or failure of the manufacturing process equipment or control systems.

To meet the requirements for the EPA enclosed system scenario, any equipment that the byproduct is present in at any point during the process sequence, such as tanks, reaction vessels, reactors, processing units (e.g., a drum filter), and/or connecting lines, need to: (1) be of high structural integrity and contained on all sides, (2) pose no foreseeable potential for escape of constituents to the facility or environment during normal use, and (3) be connected directly by pipeline or similarly enclosed device to a production process. Also, any transfers or holding steps occurring in this system must be necessary to the recycling process and must take place within physically enclosed equipment that meet the aforementioned criteria. For example, hard piping or completely sealed (i.e., welded) equipment would meet these criteria if connected directly to other enclosed equipment, preventing potential releases, including fugitive emissions.

Though there may be some potential for exposures and releases (e.g., through non-routine cleaning of equipment, or maintenance operations) associated with such enclosed, site-limited systems, the potential exposures and releases related to such systems are likely less than the potential exposures and releases associated with recycling systems that are not enclosed (e.g., systems that transfer the byproduct to a different site for recycling or other use). For example, on-site recycling systems that rely on open troughs for moving material have an increased opportunity for exposures due to dusting or splashing as compared to the use of an enclosed pipe for moving material from one part of the manufacturing process to another.

In the circumstance where a portion of the volume of byproduct is not recycled and is instead used for a commercial purpose distinct from its manufacture as a byproduct, that circumstance should be identified within the petition and, if the petition is granted, that portion would remain reportable (e.g., volumes that are created and/or recycled in systems that are open or not consistent with the above criteria). Also, volumes that are removed from the enclosed systems, such as those that are stored in an open tank or

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⁴ EPA expects to be able to ascertain typical exposure scenarios for an exempted byproduct's manufacturing process based on information for other substances that are reported at the facility in the same manufacturing process. If no other substances are reported, EPA would not otherwise have any exposure-related information associated with the manufacturing site (84 FR 17709, April 25, 2019).

pit, or stored in any non-connected tank or vessel, are excluded from this exemption and would remain reportable. In other words, this exemption is both process- and substance-dependent.

Regarding "current interest" (Consideration 1)

In general, EPA determines current interest based on both current and anticipated future needs. For example, chemicals that are the subject of TSCA rules or activities, such as chemicals for which prioritization was initiated and/or priority designations were proposed, could be expected to be considered of current interest. To inform its determination of current interest, the Agency may utilize its current knowledge and understanding of the individual chemical's structure, properties, indications of hazards and potential exposures (e.g., potential for persistence, bioaccumulation, health effects, or environmental effects). The Agency may also consider whether the potential risks of the chemical substance are already adequately managed by EPA or another agency or authority, and take into account the information needs of EPA, other Federal agencies, Tribes, States, and local governments, as well as members of the public. This list is not exhaustive.

b) Types of information you may include in a petition under 40 CFR 711.10(d)(1)(ii)

Below are examples of the types of information petitioners could provide to EPA that may help demonstrate that exemption criteria are met and that an exemption should apply to a particular process and associated byproduct substance(s). This list is not exhaustive.

- 1. Descriptive background on the subject process, including information on the industry status of their specific process (state of the art process, industry standard, legacy process, etc.). The background should describe pollution and exposure control measures, as well as the specific chemicals involved, including those that meet the definition of a *byproduct* under CDR (see page 6 of this document or 40 CFR 704.3, referenced by 40 CFR 711.3).
- Detailed process flow diagram(s) With appropriate annotations and descriptions that are responsive to the criteria/considerations of the exemption (including potential points of exposure/fugitive emissions/release):
 - a. Potential points of exposure: sampling points;
 - b. Fugitive emissions: pumps, valves, piping connections;
 - c. Releases (e.g., stack emissions, discharges to water, disposal to land): vents, drains, etc.; and
 - d. Process conditions (*e.g.*, the processing of a non-volatile liquid at low temperature, and pressure, processing of a volatile liquid at high temperature).
- 3. Detailed mass balance to illustrate a materials flow that supports the "enclosed system" criterion.
- 4. Detailed descriptions of worker activities, which inform EPA's understanding of potential points of exposure/emission.
- 5. Video or photo facility/process schematic walkthroughs.
- 6. Reference past, current, or upcoming reporting under CDR:
 - a. Specific data elements that will help identify that the chemical is a byproduct, that it never left the manufacturing site, and that it is recycled, include:
 - i. Percent manufactured as a byproduct (voluntarily reported element);
 - ii. Volume used on-site; and
 - iii. Whether the chemical is recycled or otherwise used instead of treated as a waste.
 - b. Identify other reportable substances associated with the process/byproduct in question.

- 7. Reference relevant past, current, or future reporting (or lack thereof) under other programs/statutes, or to other federal or state agencies (e.g., other TSCA Section 8(a) reporting, TSCA Section 5 reporting (i.e., premanufacture notices), or reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA)/Toxics Release Inventory (TRI), RCRA (Resource Conservation and Recovery Act), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Federal Food Drug and Cosmetic Act (FFDCA), etc.).
- 8. Identify whether or not the byproduct or a component of the byproduct is undergoing risk evaluation, is being considered for prioritization, has particular uses or attributes that are of interest, and/or is the subject of certain TSCA actions (a rule proposed or promulgated under TSCA sections 4, 5(a)(2), 5(b)(4), or 6, or an enforceable consent agreement (ECA) developed under the procedures of 40 CFR part 790, or an order issued under TSCA sections 4, 5(e) or 5(f), or relief that has been granted under a civil action under TSCA section 5 or 7).

To assist in evaluating whether your petition under 40 CFR 711.10(d)(1)(ii) includes types of information that will be useful for EPA's determination, **Table 1** matches the above examples with the Requirement and/or Consideration that each example may help inform. EPA emphasizes that these are <u>not requirements</u> in order to have a petition granted, but *suggestions* for improving the robustness and completeness of your petition. **Including these types of information in a petition is <u>not</u> a guarantee that a petition will be granted. Likewise, an omission of most of these types of information does <u>not</u> guarantee that a petition will be denied (if meeting the Requirements and Considerations can be sufficiently displayed by other means).**

Table 1: Expectations of where Example Information would Inform Requirements/Considerations for Petitions under 40 CFR 711.10(d)(1)

		Petition Requirements and Considerations					
Information Example		Require	ements	Considerations			
		1	2	1	2		
1: Descriptive Background		+	+	+	0		
2: Process Flow Diagram		+	+	0	0		
3: Mass Balance		+	+	0	0		
4: Worker Activities		+	0	+	0		
5: Facility/Process Walkthrough		+	+	0	О		
6: CDR Data	а	+	0	0	+		
	b	0	+	0	0		
7: Other Programs/Statutes		0	0	+	0		
8: Risk / Interest / Certain TSCA Actions		o	o	+	+		
Legen		+ = Likely to Inform					
	3	o = Not Likely to Inform					

Part III. Petitions for Partial Exemption of Certain Chemicals under CDR

The public may petition EPA to make amendments to the list of partially exempt chemical substances at 40 CFR 711.6(b)(2)(iv). Petitions should be submitted using the procedures under 40 CFR 711.6(b)(2)(iii). EPA's intent in providing this petition process is to provide a mechanism for modification of this reporting exemption based upon information provided by the petitioner and specifically analyzed by the Agency, as appropriate.

Because there may be other substances with processing and use information of low current interest, and because EPA's interest in these substances may change over time depending on future uses or scientific findings of risk for any given chemical that is already partially exempt, EPA may amend the list of substances that have been included in this exemption. The Agency may do this on its own initiative or in response to a request from the public based on EPA's determination of whether substance(s) described meets the criteria in 40 CFR 711.6(b)(2), based on the considerations listed at 40 CFR 711.6(b)(2)(ii).

1. What is a partially exempt substance and what data reporting is still required?

If a chemical substance qualifies for a partial exemption from reporting requirements, a company must report the information required by 40 CFR 711.15(b)(1)-(3); however, a company is not required to report the information described in 40 CFR 711.15(b)(4). In other words, manufacturers of partially exempted chemicals continue to report manufacturing information for those chemicals, but not processing and use information. Note that these partial exemptions are negated if the chemical substance is the subject of any of certain TSCA actions.⁵

Chemical substances in the following two groups qualify for a partial exemption from reporting requirements:

- Petroleum process streams listed in 40 CFR 711.6(b)(1) and
- Specific chemical substances listed in 40 CFR 711.6(b)(2)(iv)

2. Submitting a Partial Exemption Petition under 40 CFR 711.6(b)(2)(iii)

Petitions must be in writing; identify the chemical substance(s) that are the subject of the request; and contain a written rationale that provides sufficient specific information, addressing the considerations at 40 CFR 711.6(b)(2)(ii), including cites and relevant documents, to demonstrate to EPA that the collection of the information in 40 CFR 711.15(b)(4) for the chemical in question either is or is not of low current interest. In addition to information addressing the considerations listed in 40 CFR 711.6(b)(2)(ii), a petition may include additional information relevant to the request, and EPA may request other information that it believes necessary to evaluate the request.

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⁵ The subject of a rule proposed or promulgated under TSCA sections 4, 5(a)(2), 5(b)(4), or 6, or the subject of an ECA developed under the procedures of 40 CFR part 790, or the subject of an order issued under TSCA sections 4, 5(e) or 5(f), or the subject of relief that has been granted under a civil action under TSCA section 5 or 7. Instructions for determining subject chemicals are provided on the CDR website and in CDR guidance.

a) Considerations for whether the processing and use information of a chemical may be of low current interest (40 CFR 711.6(b)(2)(ii))

In making its determination of whether this partial exemption should apply to a particular chemical substance, EPA will consider the totality of information available for the chemical substance in question, including but not limited to, one or more of the considerations listed below. In other words, EPA is not limited to these six items when petitions are evaluated and may rely on additional information or internal decision criteria.

- (A) Whether the chemical substance qualifies or has qualified in the past for Inventory Update Reporting (IUR)/CDR collections for the reporting of the information described in § 711.15(b)(4).
- (B) The chemical substance's chemical and physical properties or potential for persistence, bioaccumulation, health effects, or environmental effects (considered independently or together).
- (C) The information needs of EPA, other Federal agencies, Tribes, States, and local governments, as well as members of the public.
- (D) The availability of other complementary risk screening information.
- (E) The availability of comparable processing and use information.
- (F) Whether the potential risks of the chemical substance are adequately managed. (40 CFR 711.6(b)(2)(ii))

b) Types of information you may include in a petition under 40 CFR 711.6(b)(2)(iii)

Below are examples of the types of information petitioners could provide to EPA that may help demonstrate that exemption criteria are met or addressed and that a partial exemption should apply to a particular chemical substance. This list is <u>not</u> exhaustive:

- Descriptive background on the subject chemical, including information on its chemical and physical properties and/or potential for persistence, bioaccumulation, health effects, or environmental effects:
 - a. Are there potential adverse human health effects (*e.g.*, if exposure may result in respiratory and/or neurological problems)?
 - b. Are there potential adverse environmental effects (e.g., have hazards to aquatic and/or terrestrial organisms been identified)?
 - c. Are there potential bioaccumulative or persistent characteristics?
 - d. Is there evidence that particular hazards require certain engineering controls such that human or environmental exposures are not expected (e.g., chemicals that are explosive or highly flammable)?
 - e. Consider activities undertaken by
 - i. EPA (e.g., EPCRA/TRI, Clean Water Act, Clean Air Act),
 - Other US agencies (e.g., Occupational Safety and Health Administration (OSHA), National Institutes of Health (NIH), Agency for Toxic Substances and Disease Registry (ATSDR)),
 - iii. Other countries or international organizations (*e.g.*, Organisation for Economic Cooperation and Development (OECD), Canada's Domestic Substance List (DSL) and National Pollutant Release Inventory (NPRI)).
- Process flow diagram(s) for processing and use scenarios With appropriate annotations and descriptions displaying how potential exposures to the chemical substance are managed (including potential points of exposure/fugitive emissions/release):

- a. Potential points of exposure: sampling points;
- b. Fugitive emissions: pumps, valves, piping connections;
- c. Releases (e.g., stack emissions, discharges to water, disposal to land): vents, drains, etc.; and
- d. Process conditions (*e.g.*, the processing of a non-volatile liquid at low temperature, and pressure, processing of a volatile liquid at high temperature).
- 3. Detailed descriptions of worker activities for processing and use scenarios.
- 4. Reference past, current, or upcoming reporting under CDR:
 - a. Production volume(s).
 - b. Specific data elements that will help identify potential exposure scenarios of the chemical:
 - i. Industrial Processing and Use Data:
 - 1. Type of Process or Use Operation;
 - 2. Industrial Sector; and
 - 3. Function Category.
 - ii. Consumer and Commercial Use Data:
 - 1. Product Category;
 - 2. Function Category;
 - 3. Whether the use is consumer and/or commercial; and
 - 4. Whether the chemical is in products intended for use by children.
 - c. Using trends associated with the above data, identify if the number of unique exposure scenarios for the substance in question are expanding or decreasing:
 - i. Have several CDR cycles of processing & use information been reported already?
 - ii. Are there minimal or no emerging uses? Provide supporting information.
 - iii. Is the trend in uses stagnant/unlikely to change over time? Provide supporting information.
- 5. Reference relevant past, current, or future reporting (or lack thereof) under other programs/statutes, or to other federal or state agencies (e.g., other TSCA Section 8(a) reporting, TSCA Section 5 reporting (i.e., premanufacture notices), or reporting under EPCRA/TRI, RCRA (Resource Conservation and Recovery Act), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Federal Food Drug and Cosmetic Act (FFDCA), etc.).
- 6. Identify whether or not the chemical is undergoing risk evaluation, is being considered for prioritization, has particular uses or attributes that are of interest, and/or is the subject of certain TSCA actions (a rule proposed or promulgated under TSCA sections 4, 5(a)(2), 5(b)(4), or 6, or an enforceable consent agreement (ECA) developed under the procedures of 40 CFR part 790, or an order issued under TSCA sections 4, 5(e) or 5(f), or relief that has been granted under a civil action under TSCA section 5 or 7).

To assist in evaluating whether your petition under 40 CFR 711.6(b)(2)(iii) includes types of information that will be useful for EPA's determination, **Table 2** matches the above examples with the Consideration that each example may help inform. EPA emphasizes that these are <u>not requirements</u> in order to have a petition granted, but *suggestions* for improving the robustness and completeness of your petition. **Including these types of information in a petition is <u>not</u> a guarantee that a petition will be granted. Likewise, an omission of most of these types of information does <u>not</u> guarantee that a petition will be denied (if meeting the Considerations can be sufficiently displayed by other means).**

Table 2: Expectations of where Example Information would Inform Considerations for Petitions under 40 CFR 711.6(b)(2)

	Petition Considerations						
Information Example	Α	В	С	D	E	F	
1: Descriptive Background	0	+	+	+	+	+	
2: Process Flow Diagram	0	+	+	0	0	+	
3: Worker Activities	0	+	+	0	0	+	
4: CDR Data	+	0	+	0	0	+	
5: Other Programs/Statutes	0	+	+	+	+	+	
6: Risk / Interest / Certain TSCA Actions	+	+	+	0	0	+	
Legend:	+ = Likely to Inform o = Not Likely to Inform						

c) What is currently exempted under 40 CFR 711.6(b)(2)?

To see the full list of chemical substances that are partially exempt, see <u>Title 40</u>, <u>Part 711</u>, <u>§711.6(b)(2)(iv) – Table 2 (PDF)</u>. Examples from the list include: Limestone, Carbon, Graphite, Charcoal, certain cooking oils, certain sugars/sweeteners, Lanolin, Tallow, Lard, and others. Specific chemical identities are included in the referenced Table 2.

Since the initial list was created, petitions have been granted for substances that:

- Have essentially no possibility of exposure or release except under emergency/catastrophic circumstances (e.g., substances that are highly reactive and/or pyrophoric and implicitly require extensive safety measures), or
- Generally present a low risk of adverse human health or environmental effects and have no identified unmet information needs for CDR processing and use information.

Example additions to the partially exempt chemicals list:

- March 22, 2016 EPA added six chemicals: certain fatty acids/oils/methyl esters (FRN; EPA-HQ-OPPT-2014-0809).
- November 10, 2014 EPA added six chemicals: three types of propanetricarboxylic acid; D-Fructose (CASRN 57-48-7); Corn, steep liquor (CASRN 66071-94-1); and Soybean oil, epoxidized (CASRN 8013-07-8) (FRN; EPA-HQ-OPPT-2014-0347).
- June 19, 2014 EPA added three chemicals: 1,3-Propanediol (CASRN 504-63-2); Oils, palm kernel (CASRN 8023-79-8); and Bentonite, acid-leached (CASRN 70131-50-9) (FRN; EPA-HQ-OPPT-2012-0221).

Example petition denials:

 May 30, 2019 – EPA denied petitions for two chemicals: Aluminum (CASRN 7429-90-5) and Aluminum oxide (Al₂O₃) (CASRN 1344-28-1) (Read the Aluminum Association's petitions, EPA's petition review reports, and EPA's response to the petitions; EPA-HQ-OPPT-2019-0224).

Part IV. Additional Considerations

1. Confidential Information

If the petition contains competitively sensitive information, the submitter may assert confidentiality claims at the time the petition is submitted (see 40 CFR 711.30(a)). For such information, you must submit with your petition detailed written answers to the questions listed at 40 CFR 711.30(b)(1) – (b)(6) (40 CFR 711.30(b)). Note: the questions at 40 CFR 711.30(c) may also apply.

There are certain types of information which cannot be claimed as confidential (see 40 CFR 711(a)(2)).

There are certain types of information for which substantiation of the confidentiality claim at the time of submission is not required. Specifically, information described in TSCA section 14(c)(2) is exempt from the substantiation requirement at the time of submission (see 40 CFR 711.30(a)(3)(iv)). Note that substantiation may be required at a later date.

If a petition submitted under § 711.6(b)(2)(iii)(A) or § 711.10(d)(1)(ii)(A) includes any information claimed as confidential, the petitioner must also include a certification statement signed and dated by an authorized official and a version of the petition that redacts the information claimed as confidential (see 40 CFR 711.30(a)(5) and 40 CFR 711.30(d)(2), respectively). EPA expects to include the redacted version of the petition in the docket that the Agency plans to establish for each petition.

2. For further information:

For general CDR information, visit www.epa.gov/cdr. These specific webpages and documents might be of particular interest:

- To access additional fact sheets and other CDR information, visit the <u>How To Report Under CDR</u> page.
- For additional information and to see the most recent responses to submitted CDR petitions, refer to the *CDR Petitions* page.
- For additional information about byproducts, see the <u>Byproduct, Impurities, and Recycling</u> Scenarios.
- For additional information about byproducts and associated processes that meet the criteria of the exemption at 40 CFR 711.10(d)(1), see the <u>Kraft Pulp and Paper Process</u> fact sheet.

If you have questions about CDR, you can visit the <u>CDR Contact Us</u> page, contact the TSCA Hotline (<u>tsca-hotline@epa.gov</u> | 202-554-1404), or e-mail your question to <u>eCDRweb@epa.gov</u>.

Part V. Appendix

1. Background on Byproduct Exemption from CDR under 711.10(d)(1):

In April 2020, EPA added two new byproduct exemptions to the CDR rule, one of which lists specific industries and byproducts.⁶ As a result of activities associated with the <u>2017 negotiated rulemaking</u>, two industries brought to EPA's attention particular scenarios of processes and substances that included low-exposure potential similar to that of a non-isolated intermediate:

- a) Portland cement industry—Cement kiln dust.

 The Portland Cement Association (PCA) described scenarios where the manufacture and recycling of the byproduct, cement kiln dust (CKD) (CASRN 68475-76-3, Flue dust, portland cement), is similar to non-isolated intermediates (which are currently exempted from the need to report under CDR by 40 CFR 711.10, which references 40 CFR 720.30(h)(8), except that it may be temporarily stored before reintroduction into the Portland cement manufacturing process. Because the cement kiln dust is stored, it could not meet the requirements of the non-isolated intermediate exemption. In addition, the recycling operation uses the CKD to manufacture clinker (which consists of Portland cement), which is reported under CDR by its component substances and therefore would supply the Agency with exposure information from a similar production process.
- b) Kraft pulping cycle—black liquor, oxidized black liquor, and calcium carbonate. The American Forest & Paper Association (AF&PA) provided EPA with extensive information about the Kraft pulping cycle and chemicals manufactured as part of that cycle. AF&PA identified that the Kraft pulping cycle begins with the production of black liquor (both oxidized and nonoxidized forms) as a byproduct of pulping in the production of paper, and the black liquor is subsequently used to manufacture green liquor. Calcium oxide and green liquor are used to manufacture white liquor, which results in the production of calcium carbonate as a byproduct. The calcium carbonate is recycled to produce calcium oxide. From the information provided, black liquor (CASRN 66071-92-9, Sulfite liquors and Cooking liquors, spent), oxidized black liquor (CASRN 68514-09-0, Sulfite liquors and Cooking liquors, spent, oxidized), and calcium carbonate (CASRN 471-34-1, Carbonic acid calcium salt (1:1)) are byproducts and, in the Kraft pulping cycle, are typically recycled in site-limited, enclosed systems. The other substances in the cycle are intentionally manufactured substances and would therefore continue to be reportable under CDR. Because sites would be reporting these other non-exempt substances/liquors, the Agency would still receive exposure information from the same overall production processes.

⁶ Toxic Substances Control Act (TSCA) Chemical Data Reporting Revisions Under TSCA Section 8(a) (Docket ID No. EPA-HQ-OPPT-2018-0321-0118).

⁷ EPA's existing policy with respect to non-isolated intermediates excludes storage in tanks or other vessels (*e.g.*, shipping containers) even if the vessels are part of an enclosed system (see the *CDR Fact Sheet: Non-Isolated Intermediates*).

2. Background on Partial Exemptions from CDR under 711.6(b)(2):

In January 2003, EPA incorporated into the CDR rule (IUR at the time) a partial exemption for specific chemical substances where EPA identified that there was a low current interest in the CDR processing and use information related to the chemicals. EPA identified a list of chemicals that are covered by this partial exemption and provided a process for revising this list over time because interest in the CDR processing and use information for a particular chemical can change.

To create an initial list of specific chemical substances covered by this partial exemption, EPA started with:

- (1) The list of chemical substances identified as part of the High Production Volume (HPV) Challenge Program for which, based on a preliminary review of known hazard information, it was determined that the SIDS data set would not further EPA's understanding of the chemical's properties.
- (2) The list of the chemical substances that the European Union (EU) exempted from its reporting requirements for existing chemical substances.
- (3) Certain other chemicals identified during the rulemaking process, for which EPA was able to quickly determine, based on a review of their chemical structures, properties, existing hazard information, and available exposure information, that CDR processing and use information is of low current interest.

This list was then adjusted based on the totality of information available to EPA during the rulemaking period to ensure that the chemicals included in this partial exemption were those for which EPA determined that CDR processing and use information is of low current interest. EPA chose these chemicals because almost all previously underwent a review to be placed on the aforementioned lists. Along with the Agency's current knowledge and understanding of the individual chemical's structure, properties, indications of hazards and potential exposures, EPA was able to inform its determination that there is a low current interest in CDR processing and use information for these specific chemicals (IUR Amendments Final Rule Ref. 5 [USEPA, "Methodology Used for the Initial Selection of Chemicals for the Inventory Update Rule Amendments (IURA) 'Low Current Interest' Partial Reporting Exemption," OPPT, July 24, 2002.]).

Since this initial list was published, EPA has modified the list multiple times. Examples are provided in Part III of this document.