American Forest & Paper Association

June 24, 2019

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Docket ID No.: EPA–HQ–OPPT–2018–0321

Dear Assistant Administrator Dunn,

The American Forest and Paper Association (AF&PA) appreciates the opportunity to submit comments in response to the U.S. Environmental Protection Agency's (EPA) proposed rule for revising the Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) program under section 8(a) of TSCA.[1]

AF&PA serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative *Better Practices, Better Planet 2020*. The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures over $200 billion in products annually and employs approximately 950,000 men and women. The industry meets a payroll of approximately $50 billion annually and is among the top 10 manufacturing sector employers in 45 states.

AF&PA's sustainability initiative — *Better Practices, Better Planet 2020* — comprises one of the most extensive quantifiable sets of sustainability goals for a U.S. manufacturing industry and is the latest example of our members' proactive commitment to the long-term success of our industry, our communities and our environment. We have long been responsible stewards of our planet's resources. We are proud to report that our members have already achieved the greenhouse gas reduction and workplace safety goals of this initiative. Our member companies have also collectively made significant progress in each of the following goals: increasing paper recovery for recycling; improving energy efficiency; promoting sustainable forestry practices; and reducing water use.

[1] TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a); Proposed Rule. 84 Fed. Reg. 17692 (April 25, 2019).

The following comments are provided to help clarify certain aspects of pulp processing and are relevant to EPA's efforts to alleviate chemical reporting obligations under TSCA section 8(a) through the proposed updates to the CDR rule. In addition to supporting EPA's determination that two streams in the Kraft recovery cycle should be classified and exempt from CDR as recycled byproducts, these comments explain how the Kraft cycle meets EPA's definition of a closed, continuous manufacturing process. On this basis, AF&PA on behalf of its members respectfully seeks additional exemption determinations from EPA. We believe that further regulatory relief is warranted at this time, before the next CDR reports come due in 2020. The CDR reports that EPA has collected from the pulp and paper industry in the past are an inaccurate representation of production and exposure, in that these reports do not adequately demonstrate that chemicals are being recycled in a closed system.

I. EPA correctly determined that black liquor and calcium carbonate are byproducts and should be exempted from the CDR.

AF&PA thanks EPA for recognizing the appropriateness of exemptions from CDR reporting for the continuous, closed Kraft recovery cycle. In the proposed rule, EPA finds that *sulfite liquors and cooking liquors, spent* (Chemical Abstracts Service Registry Number (CASRN) 66071-92-9) (*i.e.*, black liquor) and *carbonic acid calcium salt (1:1)* (CASRN 471-34-1) (*i.e.*, calcium carbonate) are byproduct streams that are exempt from CDR reporting because they meet the following criteria: (1) they are 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, and (2) the site is submitting CDR reports for the byproduct substance or a different chemical substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process.[2]

This proposed exemption will reduce duplicative reporting associated with the Kraft recovery process, whereby the same chemicals are being continuously recovered and reused on a daily basis. The public will benefit from a more accurate representation of chemical recycling (vs. chemical production) in the pulp and paper industry that will result from this change. The proposed rule also reduces the regulatory burden associated with tracking these two substances for purposes of making reports under CDR.

As explained further below, we do not think that a determination that these substances are exempt should hinge on or be contingent with consideration (2), *i.e.*, the reporting of the byproduct substance or another substance manufactured from the byproduct or manufactured in the same overall manufacturing process. Nevertheless, we appreciate

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[2] 84 Fed. Reg. at 17709. This exemption is codified in the proposed rule at 40 C.F.R. § 711.10(c)(2)(i)(B).

EPA's acknowledgement that regulatory relief is warranted and enthusiastically support the final adoption of the exemption.

II. Current CDR reporting for the Kraft process does not result in accurate, transparent, or effective risk communication to the public.

During the last two years, AF&PA and the National Council for Air and Stream Improvement, Inc. (NCASI), a scientific association organized to serve the forest products industry as a center of excellence,[3] have shared technical information with EPA staff concerning inorganic chemical recovery and reuse cycles used in Kraft and other pulping processes. As the agency is aware, CDR reporting for these sustainable operations has unintentionally created an inaccurate, overstated, and unflattering view of our industry. The specific chemicals at issue are aqueous inorganic solutions of sodium, calcium and sulfur, described as "liquors," and calcium oxide (*e.g.*, lime). The Kraft process is depicted in Figure 1.

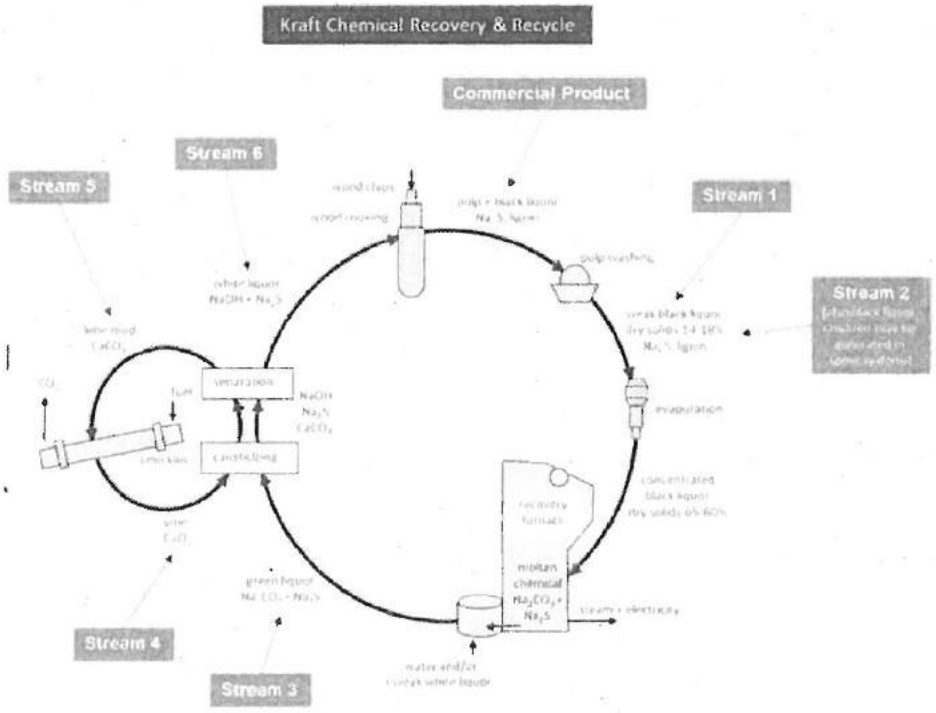

Figure 1. Kraft Pulping and Recycling Process

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[3] NCASI is an independent, non-profit research institute that focuses on environmental topics of interest to the forest products industry. Members of NCASI represent approximately 90% of the pulp and paper production in the United States. In its capacity as a research organization, NCASI has a long history of working with both its members and regulatory agencies to provide technical information helpful in managing environmental programs related to the forest products industry including the reporting of chemical substance production and release.

As illustrated above, the reason why the information our members currently submit through CDR portrays an inaccurate representation of production and exposure is that the chemicals identified in the process diagram are being recycled rather than newly manufactured. Although we believe that EPA recognizes the cyclical nature of the Kraft chemical recovery process, CDR does not account for the ongoing regeneration of the pulping chemicals in how these streams must be counted. Consequently, essentially the same pulping chemicals are counted hundreds of times for purposes of calculating annual production volumes.

The materials for which we seek an exemption are not sold in commerce and are reused entirely within the facility mill fence line in an enclosed system, yet the reporting of these chemicals fails to recognize the on-site recovery practices or closed system employed by Kraft pulp mills. As a result, the current level of CDR reporting and the quantities being reported represent an unnecessary, arbitrary, and disproportionate burden on our industry. The very nature and benefits of the industry's highly-efficient closed loop recycle process, perversely, in this case, result in an overstated and inaccurate view of chemical manufacturing in our industry.

The proposed rule would exempt only Streams 1 and 5 in Figure 1. So long as other process streams remain subject to reporting, the inaccuracies and burdens created by reporting the same chemicals each time they are recovered and reused on a daily basis continue to persist. Even with these exemptions, the paper industry would still be artificially ranked as among the highest generators of chemicals in the entire United States, surpassing the combined manufacture of the petroleum and chemical industries, as shown in Figure 2.

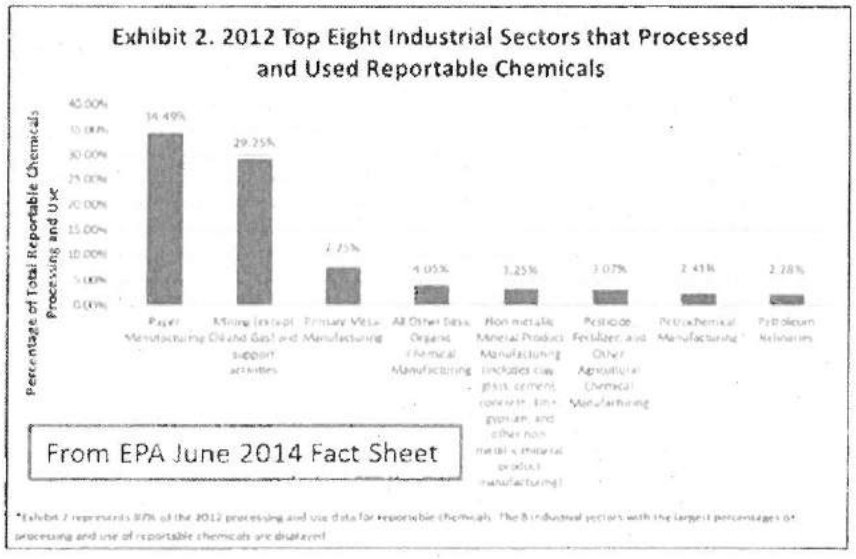

Figure 2. Exhibit of Top Eight Industrial Sectors Reporting Chemicals

For the 2016 CDR exercise, the pulp and paper industry reported about 1 trillion pounds of liquors and lime. Excluding black liquor and lime, about 620 billion pounds of these chemicals will still need to be reported. Thus, even this 37% reduction in reporting leaves pulp and paper as the #2 chemical producer, second to mining.

As already noted, this incongruous result stems from the fact that the same chemicals EPA is proposing to exempt continue to cycle through other parts of the recovery process on a daily basis. CDR requires companies that manufacture or process chemicals to provide information on each chemical and the amount produced. Therefore, the paper industry is required to report chemical constituents that are recovered and reused in a fully enclosed process on contiguous mill property and continuously re-used for turning wood chips into a useful product (pulp) that results in paper.

While AF&PA acknowledges EPA's effort to provide some relief, it is unfortunately the case that the proposed rule will provide no meaningful reduction in our reporting burden for this reason. We respectfully submit that artificially inflated manufacturing figures for chemicals that are actually confined in closed recycling systems fails to advance Administrator Wheeler's goal to provide accurate, transparent, and effective risk communication to the public. Without additional relief for other parts of the system, the CDR program will continue to propagate the myth that chemical recycling is the equivalent of chemical production in the pulp and paper industry.

On top of the foregoing, we were surprised and disappointed that the proposed rule did not include or respond to the extensive information our industry has provided to EPA concerning how the operational practices at pulp mills qualify other components of the Kraft cycle, such as green liquor, white liquor, and lime (Streams 3, 4, and 6 in Figure 1) for the non-isolated intermediate exemption. The proposed rule describes these streams as "intentionally manufactured substances" that "would therefore continue to be reportable under CDR" and is silent on why they would not qualify as exempt under the non-isolated intermediate exemption. We are concerned there is a misunderstanding about the nature of the process cycle with respect to this portion of our deregulatory request that we seek to address in these comments.

For the foregoing reasons, we continue to explain and advance our case in these comments that *black liquor, oxidized, black liquor furnace smelt, green liquor, lime (calcium oxide), and white liquor* (Streams 2, 3, 4, and 6 in Figure 1) qualify for an exemption from the CDR requirements as non-isolated intermediates. Our evaluation of the eligibility of these streams for the exemption is contained in the legal memorandum that we are submitting with these comments. We respectfully ask for EPA's consideration and determination that the Kraft cycle and these specific process streams qualify as non-isolated under the conditions described.

III. Related comments on the proposed byproduct exemption.

AF&PA respectfully requests that EPA revise its proposed factors for consideration of a byproduct exemption because we are concerned it requires additional analysis, tracking, and reporting than what is required today, and therefore would not accomplish the regulatory relief that it was EPA's intention to provide. We do not think the second consideration for a byproduct exemption is necessary. This consideration asks whether the site is reporting under CDR a chemical substance other than the byproduct substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process. It appears to be viewed by the agency as an indicia to ascertain exposure; if no other substances are reported, EPA appears concerned that the agency will not have any exposure-related information about the manufacturing site. However, the first consideration for this exemption requires the byproduct substance to be 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. Therefore, we think the agency's concern about potential exposures if the byproduct is part of an enclosed system should be correspondingly low, and sufficient to warrant dropping this condition. Given that TSCA section 8(a)(5)(A) limits EPA's CDR collection authority to only information that is necessary, that consideration does not contribute substantially as a part of the exemption process.

In response to EPA's request for comment, AF&PA supports reporting production volumes in ranges instead of two significant figures, because this will greatly reduce the reporting burden for submitters while continuing to provide the information needed by EPA for implementation of TSCA.

With further regard to the reporting burden on submitters, we respectfully ask for reconsideration of EPA's proposal to add the requirement to report the percent total production volume for a chemical substance that is a byproduct. EPA stated that this data element would help the agency "better understand" the manufacturing of byproduct chemical substances and the impact of current or future exemptions to reporting.[4] It places an onerous burden on our members to analyze the recycling streams we have described in these comments. To run analyses, identify all of the byproducts, and calculate individual percentages for each byproduct would require significant time, staff, and equipment resources. This highly burdensome mandate (1) would impact production costs and timelines, (2) is currently not feasible for commercial-scale production, and (3) runs counter to Congress' mandate to the agency to explore regulatory relief through negotiated rulemaking for these same byproduct streams. AF&PA supports keeping the rule as is in this regard. If EPA decides to go forward, we urge the agency to bifurcate the exemption from the production volume reporting, and delay production volume reporting until the next CDR cycle to provide companies time

[4] 84 Fed. Reg. 17692, at 17702.

to identify how best to comply. These comments are specifically provided in relation to the following request for comment by EPA:

> "EPA is soliciting comment on whether submitters should identify the percentage of total production volume of their chemical substance that is recycled instead of only designating whether recycling occurred, the burden associated with providing such an estimate, and any difficulties industry might encounter in estimating such a percentage (either to the nearest 10 percent or more accurately)."

Finally, AF&PA supports EPA's determination to propose an exemption from reporting under CDR for byproducts manufactured due to the use of pollution control equipment and boilers that generate heat or electricity on-site, when such equipment is not part of the main production process.

IV. Summary of request for additional relief as part of this rulemaking.

In closing, AF&PA appreciates and supports a proposed, new category for exempt recycled byproducts and EPA's determination that black liquor and calcium carbonate qualify for this exemption. As explained in these comments, this exemption is insufficient alone to provide adequate regulatory relief or accomplish accurate reporting for this industry. Also, in the current form in which it is drafted, the proposed exemption does not account for the fact that the identified streams represent only a portion of the Kraft recovery process. We ask that the proposed language be revised to read:

> " (B) Certain Kraft Pulping Process Streams (~~i.e.~~, CASRN 66071–92–9, Sulfite liquors and Cooking liquors, spent; and CASRN 471–34–1, Carbonic acid calcium salt (1:1))"

We also request that EPA revise the factors for qualifying for this byproduct exemption to eliminate the need to consider whether the site is reporting a chemical substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process. This provision is not necessary for the administration of CDR or the underlying purpose of the exemption. AF&PA respectfully submits that the proposal to require reporting of the percent total production volume for a chemical substance that is a byproduct would be complex to comply with and it is not consistent with the purpose of the rule to make CDR reporting burdens for byproducts more manageable for companies.

Because some Kraft pulp mills conduct oxidation of black liquor to facilitate odor reduction during combustion in the recovery furnace, AF&PA requests a determination by EPA that the following chemical qualifies for exemption from CDR requirements as a non-isolated intermediate pursuant to 40 C.F.R. § 711.10(c) (in accordance with § 720.30(h)(8)): black liquor, oxidized (CASRN 6814-09-0). We also seek non-isolated determinations for black liquor furnace smelt, green liquor (CASRN 68131-30-6),

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calcium oxide (CASRN1305-78-8), and white liquor (CASRN 68131-033-9). Finally, AF&PA supports changing the CDR to report quantities in ranges and support the exemption for byproducts manufactured due to the use of pollution control equipment and boilers that generate heat or electricity on-site, when such equipment is not part of the main production process.

The additional relief we seek from this reporting burden comports with EPA's current framework for CDR exemptions and embodies sound public policy. Closed systems consistently and historically have been interpreted by EPA as resulting in low or no exposure. There is still a disproportionate and arbitrary burden on the industry associated with reporting the same chemicals over and over. These are not in practice newly manufactured, and we think the reporting burden that still would remain if this rule is finalized as proposed continues to create an inaccurate representation of chemical manufacturing compared to other industries. We ask EPA to not delay in concluding that the remaining substances that are part of our request in these comments should also be excluded from CDR as non-isolated intermediates when pulp mills are designed and operated as described in these comments. We believe this rulemaking and submission serve as an adequate record and that a determination on the other streams in this enclosed, continuous system would represent a logical outflow of the rulemaking. Particularly since CDR reporting is around the corner and will not happen again until 2024, our industry respectfully asks EPA to consider our request at this time.

Respectfully submitted,

American Forest and Paper Association

Stewart E. Holm
Chief Scientist

Enclosures

Wiley Rein LLP

MEMORANDUM

TO: Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and
Pollution Prevention, Environmental
Protection Agency

CC: Matthew Z. Leopold, Esq.
General Counsel
Office of General Counsel,
Environmental Protection Agency

FROM: Martha E. Marrapese, Partner

DATE: June 24, 2019

RE: Toxic Substances Control Act; Chemical Data Reporting, 40 C.F.R. Part 711; Applicability of Non-Isolated Intermediate Exemption; Basis for Exempting Oxidized Black Liquor, Energy Recovery Furnace Smelt, Green Liquor, White Liquor, and Lime

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This legal memorandum was prepared to evaluate the eligibility of certain process streams in the Kraft recovery cycle qualify for the exemption for non-isolated intermediates from Chemical Data Reporting at 40 C.F.R. 711.10(c) under the Toxic Substances Control Act (TSCA). As explained below, we conclude that each element of the definition of a non-isolated intermediate is met for Oxidized Black Liquor, Energy Recovery Furnace Smelt, Green Liquor, White Liquor, and Lime, and that the Kraft recovery cycle qualifies as a continuous, flow-through process that qualifies for the exemption.

I. Description of the Kraft recovery cycle and the process chemicals reviewed.

EPA recently recognized the appropriateness of exemptions from CDR reporting for the Kraft recovery cycle in the proposed rule for updating CDR reporting for the 2020 cycle. The agency is proposing to exempt sulfite liquors and cooking liquors, spent (Chemical Abstracts Service Registry Number (CASRN) 66071-92-9) (i.e., black liquor) and carbonic acid calcium salt (1:1) (CASRN 471-34-1) (i.e., calcium carbonate) as byproduct streams that meet the following criteria: (1) they are 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, and (2) the site is submitting CDR reports for the byproduct substance or a different chemical substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process.

It is our understanding that over 100 million lbs./yr. of several inorganic compounds such as sodium sulfide, sodium sulfate, sodium carbonate, sodium hydroxide, calcium carbonate and calcium oxide are reported under CDR by a typical Kraft mill. However, there is some confusion as to what really is manufacturing in this context. We were asked to review the following additional pulping chemicals, which also have been the subject of determination requests that AF&PA has made to EPA. They are generated and used within the same process as the above two streams and are of similarly variable composition. These chemicals are classified and named under TSCA as UVCBs (substances of unknown or variable compositions, complex reaction products, and biological materials), and they are, in the order they are generated in the Kraft cycle:

- Black liquor, oxidized (CASRN. 68514-09-0); Sulfite liquors and cooking liquors, spent, oxidized. The substance resulting from the oxidation of the black liquor byproduct, an aqueous solution resulting from the reaction of lignocellulosic substances (wood or other agricultural fiber sources) with one or more pulping chemicals including those used in Kraft, sulfite, semichemical or other pulping processes by the oxidation of the desugared component of the black liquor.

- Energy Recovery Furnace Smelt: The substance resulting from the chemical reactions occurring when black liquor or black liquor, oxidized is burned for energy recovery in the Kraft cycle.

- Green liquor (CASRN 68131-30-6); Sulfite liquors and cooking liquors, green. A solution obtained by dissolving the chemicals recovered in the alkaline pulping process in water. Green liquor consists primarily of Na_2S and Na_2C0_3.

- Calcium oxide (CASRN 1305-78-8) or lime. Formed when the calcium carbonate byproduct is heated in a lime kiln.

- White liquor (CASRN 68131-33-9); Sulfite liquors and cooking liquors, white. The solution formed by reacting the sodium salts of green liquor with calcium oxide. White liquor consists primarily of NaOH, Na_2S, and Na_2S0_4.

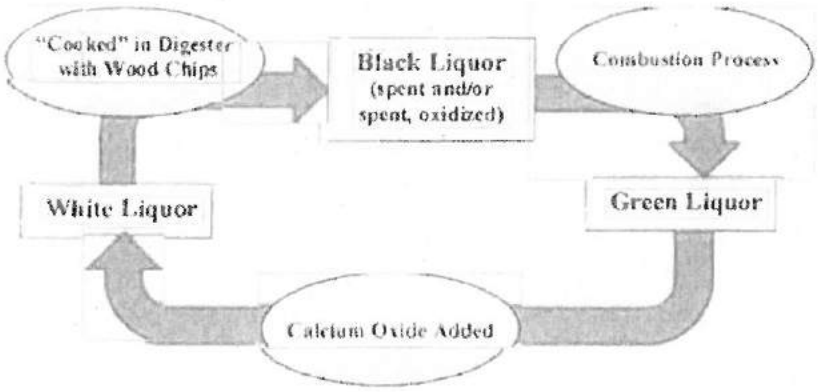

Figure 1. Process for Kraft recovery showing process streams reviewed for non-isolated intermediate status under TSCA

In AF&PA's information submissions to EPA for a non-isolated intermediate exemption determination, the relatedness of these streams has been emphasized as illustrated in Figure 1. However, for purposes of TSCA, AF&PA understand that each intermediate stream must independently qualify on the merits for exemption. Therefore, following an explanation of our understanding of how this exemption is interpreted by EPA, each process stream is presented and evaluated separately in turn below for why their attributes qualify them for non-isolated intermediate exemption status under TSCA and CDR.

A. Process description - the Kraft recovery cycle.

Based on information provided to us by the American Forest and Paper Association (AF&PA) and the National Council for Air and Stream Improvement, Inc. (NCASI) on the Kraft recovery process, we understand these systems are operated to run 24 hours/day, 7 days/week. It is our understanding that in the Kraft process, inorganic chemicals are continuously extracted in the form of a smelt product by burning black liquor in a recovery furnace. These chemicals continually exit the recovery furnace and are dissolved in weak wash to make green liquor, which is continuously pumped to a green liquor clarifier. From the clarifier, the clarified green liquor is continuously sent to a series of causticizers where it is reacted with slaked lime. The slaked lime is obtained continuously in a separate lime cycle by hydrating reburned lime in a slaker, the reburned lime product being continuously generated in a lime kiln. The chemicals that are generated continuously from the causticizing process are white liquor and a lime mud byproduct. The causticizing white liquor product is continuously pumped to the white liquor clarifier. The clarified white liquor product is sent continuously either directly or via single or multiple "flow-through" tanks to the digester for preparing cooking liquor which is then fed continuously to the digesters to cook the wood. The digesters produce a mixture of pulp and weak black liquor. The black liquor is continuously generated by washing and separation from pulp in the brown-stock washers from where it is continuously concentrated to strong liquor before being fired in the energy recovery furnace. The lime mud product is continuously pumped from the bottom of the white liquor clarifier to the mud washer from where the washed mud is continuously sent to mud tank(s). From the mud storage tank(s), the lime mud is continuously de-watered. The dewatered lime mud is fed to

the lime kiln(s). Reburned lime (CaO) product is continuously generated from the CaCO3 in the lime mud. The lime product is continuously withdrawn from the kiln and sent to a lime silo from where it is continuously sent to the lime slaker.

To support the conclusion that the Kraft cycle is continuous, AF&PA and NCASI provided us a summary of responses from mills pertaining to how the cooking and spent liquors, lime mud and reburned lime product flow in their respective mills (Appendix A). These responses confirm that, typically, the entire Kraft process is a continuous one with material flowing into and out of various tanks and/or silos, which operate as "flow-through" tanks/silos or "flow modulators." The process streams (black liquor, green liquor, white liquor, lime mud and reburned lime) are rarely isolated from the process and stored in vessels, or even pumped to vessels with no corresponding continuous drawdown. Thus, most situations appear to meet the definition of "non-isolated intermediate" chemicals and, as such, are not reportable if they were never "intentionally removed from the equipment in which they were manufactured ".

These systems employ the use of *"flow-through process tanks"* and *"surge tanks"* that remain in the direct line of flow; again, portions of these chemical streams are not diverted to such vessels, but rather then entire quantity of flow is directly processed through them. The term *"flow-through process tank"* is not defined in the CDR rule, but an understanding of these vessels is absolutely critical to a proper analysis of the Kraft system. We have located the following description elsewhere in EPA's regulations which AF&PA agrees appropriately describes these vessels for purposes of the pulping process:[1] A flow-through process tank is a tank that forms an integral part of a production process through which there is a steady, variable, recurring, or intermittent flow of materials during the operation of the process. Flow-through process tanks do not include tanks used for the storage of materials prior to their introduction into the production process or for the storage of finished products or by-products from the production process. Specifically, in the Kraft cycle, flow-through tanks (as well as surge tanks) are used primarily for buffering and controlling the continuous-flow of fluids.

Further support for the conclusion that there is no intentional removal from the equipment for storage when flow through tanks are part of the direct line of operation in a continuous manufacturing operation is provided by the successful settlement agreement reached by AF&PA with EPA on its petition for judicial review of a March 2000 EPA interpretive memorandum stating that the Subpart Kb NSPS for volatile organic liquid storage tanks did not apply to "flow-through process tanks". In this agreement, EPA cited and relied on the interpretation stated in its 1998 "guidance letter" which said:[2]

> the definition of "storage vessel" in Subpart Kb does not include "flow-through process tanks", defined in the Underground Storage Tank Program (40 CFR 280.12) as tanks that form an integral part of a production process through which there is a steady, variable, recurring or intermittent flow of materials during the operation of the process, and that are not used for the storage of materials prior to their introduction into the production process or for the storage of finished products or byproducts from the production

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1 40 C.F.R. § 280.12.

2 68 Fed. Reg. 8577 (February 24, 2003).

process.

B. Worker exposure considerations.

The Kraft process chemicals are generally characterized as having high pH, and the enclosed system in which the cycle operates serves to avoid human contact with these chemicals. EPA defines "reasonably likely to be exposed" for purposes of CDR as exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use, is more likely to occur than not occur. Such exposures would normally include but are not limited to activities such as charging reactor vessels, drumming, bulk loading, cleaning equipment, maintenance operations, materials handling and transfers, and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact, absorption, etc.), but excludes accidental or theoretical exposures.[3] Under the CDR rule, there is no minimum duration or frequency of exposure for determining the number of workers reasonably likely to be exposed to a chemical substance. If it is determined that a worker is reasonably likely to be exposed at any time during the year for any length of time, this worker should be included in the estimate.[4] However, as described above, charging reactor vessels in the Kraft cycle is done mechanically in an enclosed manner and the pulping chemicals involved are reused and recycled. The pulping chemicals are not drummed or bulk loaded manually into the system. Because the mills are run 24 hours/day, 7 days/week, cleaning is rare, and maintenance operations take place while the chemicals remain contained in the vessels and piping. Materials handling and transfers are performed by mechanical means, and analytical operations whereby samples may be taken for analysis are performed using appropriate worker protection.

II. <u>The CDR Exemption for Non-isolated intermediates.</u>

The CDR exemption at 40 C.F.R. § 711.10(c) for "non-isolated intermediates" states as follows:

> § 711.10 Activities for which reporting is not required.
>
> A person described in § 711.8 is not subject to the requirements of this part with respect to any chemical substance described in § 711.5 that the person solely manufactured or imported under the following circumstances:
>
> (a) The person manufactured or imported the chemical substance described in § 711.5 solely in small quantities for research and development.
>
> (b) The person imported the chemical substance described in § 711.5 as part of an article.
>
> (c) The person manufactured the chemical substance described in § 711.5 in a manner described in 40 CFR 720.30(g) or (h).

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[3] 40 C.F.R. §711.3; 2016 Chemical Data Reporting Frequent Questions (Updated July 11, 2016), No. 29.1, available at: https://www.epa.gov/sites/production/files/2016-07/documents/cdr_fq_final_july_11_2016.pdf. (Hereinafter 2016 CDR Frequent Questions).

[4] Id., No. 29.2.

The above-referenced 40 C.F.R. § 720.30(h) provisions incorporated by operation of § 711.10(c) include the non-isolated intermediate exemption:

> § 720.30 Chemicals not subject to notification requirements.
>
> The following substances are not subject to the notification requirements of this part:
>
> * * *
>
> (h) The chemical substances described below: (Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)
>
> * * *
>
> (8) Any nonisolated intermediate.

Because § 711.10(c) incorporates this Part 720 exemption, we turn to Part 720 for the definitions for our analysis. First, each process stream has to qualify as an "intermediate" chemical as defined at § 720.3(n):

> (n) *Intermediate* means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions.

Next, to determine if the non-isolated intermediate elements also are met, we look to § 720.3(w):

> (w) *Non-isolated intermediate* means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous-flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers "isolates" the substance by removing it from process equipment in which it is manufactured.

To evaluate these definitions in the context of CDR, EPA has instructed companies to consider the entire process sequence from manufacture to use of an intermediate to determine whether or not an intermediate chemical substance is a "non-isolated intermediate."[5] The agency advises companies to consider and respond to the following questions in making these determinations:

1) Does the chemical substance function as an intermediate?

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[5] *TSCA Chemical Data Reporting Fact Sheet: Non-Isolated Intermediates.* EPA. April 2016. (Hereinafter 2016 CDR Fact Sheet).

2) Was the intermediate "intentionally removed from the equipment in which it was manufactured"?
3) Was the intermediate "stored after its manufacture"?
4) Which pieces of equipment can be considered "ancillary to the reaction vessel"?

On the first question, the 2016 CDR Fact Sheet cautions that "if the chemical substance is not partially or totally consumed for the intentional manufacture of another chemical substance or a mixture (or intentionally present for the purpose of altering the rate of such a chemical reaction), then it is not an intermediate."[6] This evaluation is dependent on an accurate assessment of the nature of the chemical reactions involved and can be complex in the case of UVCBs.

The other three questions above are typically grounded by past agency interpretations of qualifying and non-qualifying processes, whether a particular process presents a case of intentional removal or storage, and whether ancillary equipment constitutes "is equipment in which the intermediate is manufactured. Since the CDR exemption stems from the exemption from listing a chemical on the Inventory,[7] the following agency interpretations associated with the process conditions that qualify as non-isolated are routinely applied in either case:

- The *"equipment"* to be evaluated for whether the intermediate is consumed in whole or in part (or is intentionally present for the purpose of altering the rate of chemical reaction) includes (1) the reaction vessel itself, (2) equipment which is *"ancillary"* to the reaction vessel, and (3) and *any equipment through which the substance passes during a continuous-flow process,* excluding those in which the substance is stored after its manufacture.[8]

- *"Ancillary"* equipment is further explained by EPA as "auxiliary or supplemental to the reaction vessel and is used for performing necessary or important parts of the manufacturing process involving the intermediate, such as filtration, distillation, drying, size (volume) reduction, heating or cooling. Equipment that provides primary operational support to the reaction vessel itself, such as equipment for metering or controlling the reaction within the vessel, is also considered ancillary and needs to be considered in evaluating a chemical's eligibility for this exemption.[9] It further includes "equipment that is auxiliary or supplemental to the reactor and is used for such purposes as filtration, distillation, drying, size reduction, *heating*, cooling, or dehydration."[10] In guidance, EPA has used the term auxiliary equipment to describe the

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6 2016 CDR Fact Sheet, page 2.

7 42 Fed. Reg. 13133 (March 1977); re-proposed at 42 Fed. Reg. 39182, 39191 (Aug. 2, 1977); finalized at 42 Fed. Reg. 64572, 64576 (Dec. 23, 1977).

8 2016 CDR Fact Sheet (p. 2) and § 720.3(w). Emphasis added.

9 2016 CDR Fact Sheet (p. 3). *See also* 40 CFR 710.3 (emphasizing that such equipment must be "strictly ancillary")."

10 *Id.* at p. 3 (emphasis added).

following as ancillary in a continuous-flow process: pipes, pumps, valves, etc.

- From the enclosed agency letter addressing the use of surge tanks with respect to Inventory determinations,[11] when auxiliary equipment is out of the direct line of flow, storage in such equipment may constitute isolation.[12] However, as previously determined by EPA in the attached letter from Rebecca Cool, then Chief of the New Chemicals Prenotice Branch, the use of surge tanks within the direct line of flow in the production process does not negate the use of this exemption.

- The term *"continuous-flow process"* is given a broad interpretation so that it may include multiple and interconnected process phases. Specifically, according to the agency "[t]his term is <u>not</u> considered by EPA to solely represent synthetic reactions that actually produce intermediate and product substances in a continuous manner; nor is it considered to just include reactions involving only one reaction vessel with its ancillary equipment. The Agency's concept of a continuous-flow process also includes *sequential reaction processes that may occur in different reaction vessels, and that may involve transfer of an intermediate substance between various reaction or processing vessels.* Consequently, <u>any</u> mechanical manufacturing process in which an intermediate is moved from one piece of equipment to another, using enclosed auxiliary equipment (pipes, pumps, valves, etc), [sic] without intentional storage or removal of the intermediate, is considered by EPA to be a continuous flow process."[13] In other words, if a substance is caused to react in one vessel and is subsequently mechanically transferred through closed equipment to a second vessel for further reaction or processing, no isolation is deemed to have occurred.[14] We believe that the concept of sequential reaction vessels can encompass the use of flow through tanks for the purpose of buffering or controlling the continuous-flow of material in the system. In numerous cases in published guidance, EPA recognizes a series of interconnected reaction vessels as continuous-flow processes rather than a serious of batch operations.[15]

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11 Letter from Rebecca S. Cool, Chief, New Chemical Notification Branch, January 24, 2000 (concurring that surge tanks in question are part of a process, thereby permitting a non-isolated intermediate conclusion to be drawn. Underscoring the point that the quantity of the intermediate does not present a barrier to qualifying for the exemption, EPA noted in this response that "the amount of material involved is substantial").

12 2016 CDR Fact Sheet, p. 3.

13 Emphasis added. TSCA Inventory Representation Policy – Non-Isolated Intermediate Exclusion, p. 4 (emphasis in original). EPA. 1986. (Hereinafter TSCA Inventory Representation Policy).

14 2016 CDR Fact Sheet, *p. 5, Case Study A.* Historically, the issue of closed mechanical transfers was additionally addressed by EPA in a letter dated July 15, 1986 addressed to Geraldine Cox of the then-Chemical Manufacturers Association (copy enclosed). The examples in the 2016 CDR Fact Sheet as well as this letter are referenced to underscore EPA's longstanding adherence to the interpretation that a closed system is not limited in terms of the size of the system, the quantity of the intermediate, or the number of connected equipment components. If this were not the case, the agency would have told us by now.

15 These examples may be found in the case studies in the 2016 CDR Fact Sheet, the TSCA Inventory Representation Policy, and the Geraldine Cox letter previously cited in this memorandum. We suggest that isolation is required for a batch system determination; otherwise the "batch" interpretation runs counter to the non-isolated intermediate definition. Theoretically any continuous system could be described as a series of batch operations if this were not the case and the matter of isolation were not considered.

- An operation with *fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process* so long as measures are taken to prevent worker exposure to and environmental contamination from the releases."[16]
- Accidental release due to equipment failure also does not affect the non-isolated status of the intermediate.[17, 18]
- A substance may be held for purposes clearly related to the requirements of the manufacturing process in a closed, continuous operation, such as flow or process control, without the holding being deemed to be storage that would take it outside of the non-isolated intermediate exemption.[19] This understanding dates back to a 1978 Federal Register notice,[20] in which EPA clarified that the storage of a chemical for a period of two or three hours was not sufficient to interrupt the "continuous-flow process" or qualify as isolation. For the record, the agency's response states that "[i]n general, any chemical substances which are held temporarily in an otherwise continuous-flow process for purposes that are clearly related to the necessity of the manufacturing process – such as heating, cooling, filtration or reaction -- are not considered reportable, while those that are held principally for purposes of storage would be considered reportable." Examples of temporary holding that EPA would generally consider having a clear technical relationship to the needs of the overall manufacturing process (such as heating, cooling, filtration, or reaction) and therefore not negate the use of this exemption include:[21]
    - holding to accommodate different reaction rates and varying flow rates or transfer times;
    - holding during repair or maintenance of the intermediate's manufacturing equipment; and
    - holding that is necessary for analytical sampling.

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16 40 C.F.R. § 704.3. Enclosed process means a manufacturing or processing operation that is designed and operated so that there is no intentional release into the environment of any substance present in the operation. An operation with fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases.

17 TSCA Inventory Representation Policy, p. 5.

18 In addition, a substance that is intended to be a non-isolated intermediate, when inadvertently isolated because of an unexpected disruption to the manufacturing process, does not trigger CDR requirements so long as the substance is disposed of as a waste in accordance with applicable federal, state and local requirements. Under that circumstance, the isolated substance was not "manufactured for commercial purposes" since it was not "manufactured with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer". 40 C.F.R. § 720.3(r).

19 Id. at p. 7.

20 43 Fed. Reg. 9254, 9256 (March 6, 1978).

21 2016 CDR Fact Sheet, p. 3; TSCA Inventory Representation Policy, p. 7.

III. How each of these process streams meet the conditions of the exemption.[22]

In general, the pulping cycle results in the manufacture of several different materials. We now turn to each process stream, evaluate each one from manufacture to use, and respond to EPA's recommended questions for purposes of assessing their status under the non-isolated intermediate exemption in turn. For illustration purposes each section below corresponds to the identified process stream in Figure 2.

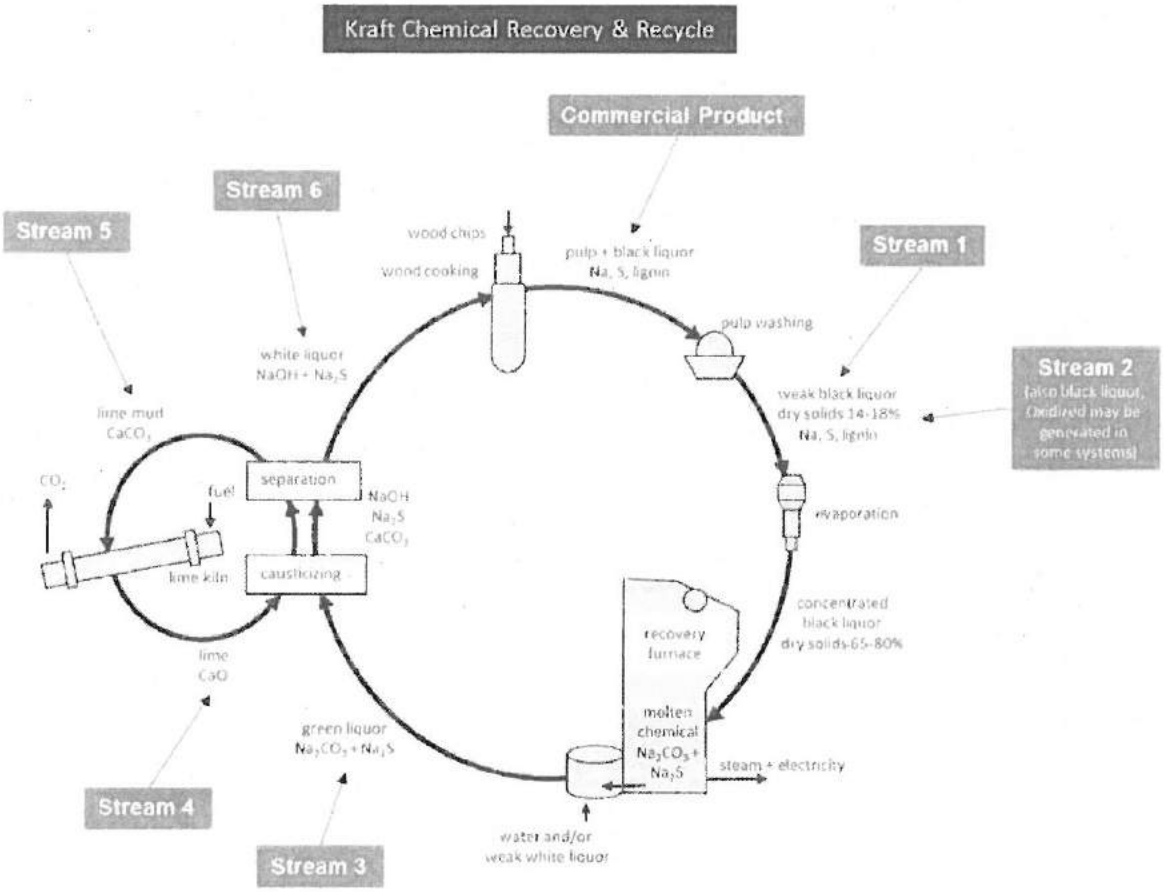

Figure 2. Kraft Pulping and Recycling Process

1. Black liquor, oxidized (CASRN 6814-09-0)(Stream 2).

At some mills, the black liquor byproduct generated from the cooking phase is sent through and oxidized in a black liquor oxidation system *before* being concentrated in the direct-

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[22] AF&PA and its members understand that certain activities that fall outside of the normal operations described in this memorandum that would result in isolation may cause these streams to be reportable under CDR. Examples include off-site transfers, extended hold times, or diversion to a side storage tank. It is not our intent to discuss those circumstances further here. Only a small fraction of the continuously generated black, green and white liquor, lime mud and reburned lime product seem to be truly "isolated" from the process during the calendar year and stored in tanks and vessels (for reasons other than maintenance or repair).

contact evaporator (DCE) and burned in a recovery furnace. Approximately 20% of the mills oxidize and send their black liquor to a DCE; however, in those cases the entirety of the black liquor byproduct passes through this unit before passing through the DCE. The oxidation reaction results in the conversion of reduced sulfides to thiosulfides and sulfates. The process is closed: (1) all process equipment is interconnected with piping; (2) there are only minimal, carefully controlled fugitive emissions; and (3) no intermediates are isolated or removed from the cycle.

a. Does the chemical substance function as an intermediate?

An *intermediate* is any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures. *Black liquor, oxidized* meets this definition because it is in large part consumed when it undergoes combustion, a type of oxidation reaction where components are combined chemically with oxygen in an exothermic reaction that releases heat energy. Burning for energy recovery is not the only commercial purpose for this chemical. The combustion residue is used for the intentional manufacture of other substances or mixtures, in this case as a process input for green liquor. Therefore, black liquor, oxidized meets the definition of a chemical intermediate under TSCA. The intentionally oxidation of black liquor converts this exempt byproduct into a different chemical substance that is black liquor, oxidized. As a result of the dual use of this chemical for energy recovery and as a process input, the chemical substance is totally consumed for the intentional manufacture of another chemical substance or a mixture and therefore is an intermediate.

b. Was the intermediate "intentionally removed from the equipment in which it was manufactured"?

Black liquor, oxidized results from a reaction process that takes place in an oxidization vessel, from which point it is transferred in closed pipes through the DCA, recovery furnace, and the green liquor process stream. This movement takes place via mechanical or gravitational means, using enclosed auxiliary equipment (pipes, pumps, valves, etc.). There is no intentional removal of the intermediate from the system leading up to and including conversion to heat energy and the combustion residues continue to pass through the Kraft recovery system. This chemical does not leave the Kraft pulping and recovery cycle during normal operations. There is a steady, variable, recurring flow of the chemical through the enclosed system during the operation of the process.

c. Was the intermediate "stored after its manufacture" and which pieces of equipment can be considered "ancillary to the reaction vessel"?

Black liquor, oxidized is transferred from the oxidation system to the DCA and then to the energy recovery unit. Kraft recovery includes sequential reaction processes in different reaction vessels that cause the transfer of this intermediate substance between various reaction or processing vessels on a flow-through basis. The digester, oxidation unit, evaporator and recovery furnace operate 24 hours a day, 7 days per week, and under normal operating conditions there are no chemical releases or worker exposures to this intermediate. Overall, this intermediate is handled is consistent with EPA's guidance that "if a substance is caused to

react in one vessel and is subsequently mechanically transferred through closed equipment to a second vessel for further reaction or processing, no isolation is deemed to have occurred."

As such, it is consistent with EPA's published guidance and examples given above to view this process as a continuous, enclosed process rather than a series of batch processes. As explained above, EPA's 2016 CDR Fact Sheet states that certain activities are not deemed to be storage and has determined that storage of a chemical for a period of two or three hours is normally not sufficient to disqualify a system as a continuous-flow process or to qualify as isolation. The types of temporary holding that can and do occur in the Kraft cycle are those that have a clear technical relationship to the necessity of the manufacturing process, such as holding to accommodate different reaction rates and varying flow rates or transfer times, holding during repair or maintenance of the intermediate's manufacturing equipment, or holding that is necessary for analytical sampling.

In the case of the Kraft recovery process, worker exposure is prevented by maintaining the chemicals that are being used and generated within the equipment itself, by ensuring that the system is properly managed to avoid unintentional, accidental release, and through the use of appropriate PPE during quality control sampling. The equipment through which *black liquor, oxidized* flows is designed for performing necessary parts of the manufacturing process involving the intermediate, specifically evaporation and heating. The flow through each component is necessary for the commercial purpose of the operation. For example, heating and dehydration are specifically identified in EPA guidance as acceptable operations that will qualify as ancillary to the reaction vessel and qualify for non-isolated intermediate status. All of the equipment is in the direct line of flow in that all quantities of this intermediate pass through the equipment. Therefore, the use of any one of these operational units does not qualify as isolation. They are not located adjacent to or merely within the same process sequence. The DCE step is necessary to drive off moisture and concentrate the *black liquor, oxidized* to ensure efficient combustion of the solids portion of the intermediate, and the energy recovery unit is necessary to accomplish the use of the intermediate for energy generation and recovery of the combustion residue for use in green liquor. Moreover, EPA has agreed that the ancillary components of a continuous-flow process that are covered by the exemption include the pipes, pumps, valves, etc. designed to mechanically transfer the intermediate through these pieces of equipment.

2. **Recovery furnace smelt and green liquor (CASRN 68131-30-6, *sulfite liquors and cooking liquors, green*) (Stream 3).**

This stream is a solution obtained once *black liquor* or *black liquor, oxidized* is fed into the recovery furnace to produce heat/energy. Figure 3 illustrates the portion of the Kraft recovery cycle associated with the manufacture of green liquor.

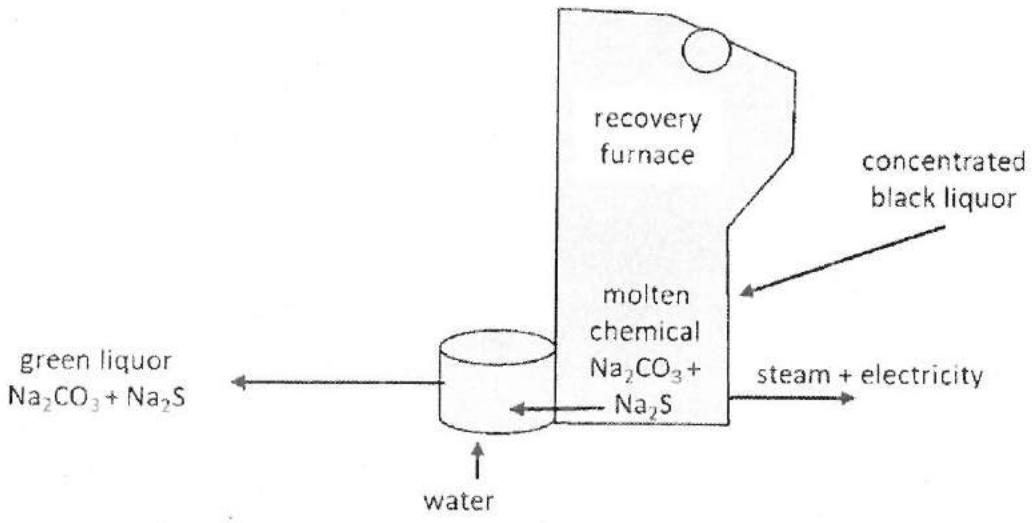

Figure 3. Furnace smelt and green liquor in the Kraft recovery cycle

As noted, the combustion of *black liquor* or *black liquor, oxidized* produces heat energy from the organic lignin that supplies well over half of the energy required for mill operations. It also produces combustion residues (or smelt) from the inorganic constituents in the black liquor byproduct stream which undergo oxidation-reduction reactions. The smelt is not simply comprised of component chemical substances from the *black liquor, oxidized* because it is produced as a result of chemical reactions occurring when burning the black liquor. Green liquor is formed when the resulting furnace smelt (the liquefied inorganics drained from the bottom of the furnace, *i.e.*, the remaining portion of the *black liquor* and *black liquor, oxidized*) is dissolved in water in an enclosed manner in an adjacent tank to form green liquor. From there, the green liquor is piped through an enclosed system to the causticizer shown in Figures 4 and 5. In the causticizer, the sodium salts in green liquor react with calcium oxide to form white liquor.

a. Does the chemical substance function as an intermediate?

An *intermediate* is any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures. Both the furnace smelt and *green liquor* meet this definition. The furnace smelt is used to manufacture *green liquor*, which subsequently undergoes reaction with calcium oxide to form *white liquor*, which is then sent into the digester to manufacture pulp. The intentional reaction of green liquor with calcium oxide also generates the byproduct calcium carbonate. As a result of these process steps, the furnace smelt and green liquor are transformed in whole or part to intentionally manufacture another chemical substance and therefore are intermediates. These chemicals do not leave the Kraft pulping and recovery cycle to be stored in tanks, etc. during normal operations.

b. Was the intermediate "intentionally removed from the equipment in which it was manufactured"?

The Kraft cycle includes sequential reaction processes that occur in different reaction vessels and that cause the transfer of this intermediate substance between various reaction or processing vessels. Specifically, these chemicals are transferred from the energy recovery furnace to mixing tanks immediately adjacent and connected to the recovery furnace and then go on in an enclosed manner to the causticizer. All movement takes place via mechanical or gravitational means, using enclosed auxiliary equipment (pipes, pumps, valves, etc.). There is no intentional removal of these intermediate from the system leading up to and including the subsequent conversion reactions. There is a steady, variable, recurring flow of the chemical through the enclosed system during the operation of the process. Green liquor may flow through large surge tanks; providing all of the chemical flows through these tanks rather than a portion of it, the agency has ruled that the use of surge tanks does not constitute storage.[23]

c. Was the intermediate "stored after its manufacture" and which pieces of equipment can be considered "ancillary to the reaction vessel"?

Green liquor is transferred from the mixing tank immediately following the energy recovery unit to the causticizer. This intermediate is not diverted in between these process flow steps. Between units associated with green and white liquor systems, green and white liquor are continuously processed under normal operating conditions through pipes and other vessels, in what is generally referred to in the industry as "flow-through" tanks, that facilitate a continuous process operation. Process flow is regulated to accommodate different reaction rates and varying flow rates or transfer times, a function that is clearly related to the requirements of the manufacturing process in these closed, continuous operations. Similar to the design of most flow-through tanks, whose primary purpose is to buffer or regulate the flow from one process to another, the vessels in the pulping industry are equipped with vents that allow for level control and process protection under upset conditions. They are conventional and necessary for the safe operation of industrial processes. Based on CDR and the agency's TSCA Inventory Representation Policy, as well as Federal Register statements on the scope of this exemption, "holding to accommodate different reaction rates and varying flow rates or transfer times" is not deemed to be storage in a continuous process, and periods of up to two or three hours normally will not be sufficient to interrupt a continuous-flow process or otherwise qualify as isolation.

Therefore, this system qualifies as a continuous system[24] and as an enclosed process.[25] These operations may include fugitive, inadvertent, or emergency pressure relief releases, which will not cause the system to be disqualified from non-isolated intermediate status so long as measures are taken to prevent worker exposure to and environmental contamination from the releases. Worker exposure is prevented during this phase of the process by maintaining the chemicals that are being used and generated within the equipment itself and by ensuring that

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23 *See* footnote 9.

24 TSCA Inventory Representation Policy, p. 4 (emphasis in original).

25 40 C.F.R. § 704.3.

the system is properly managed to avoid unintentional, accidental release. Under normal operating conditions there are no chemical releases or exposure to the green liquor, and if applicable, federal permitting requirements are followed to prevent inadvertent or fugitive air release. Overall, this intermediate is handled consistent with EPA's guidance that "if a substance is caused to react in one vessel and is subsequently mechanically transferred through closed equipment to a second vessel for further reaction or processing, no isolation is deemed to have occurred."[26]

The equipment at this process stage is all ancillary to and a part of the Kraft cycle because it is used to perform necessary parts of the manufacturing process. None of these units qualify as diversion or isolation. The mixing tank is required for the liquification of the furnace smelt for flow-through purposes, and the causticizer serves as the reaction vessel for white liquor. These functions are integral to the success of the Kraft cycle and therefore qualify the equipment as ancillary to the reaction vessel (for this stream, we submit the role of the reaction vessel is served by the energy recovery unit). The mixing tank and causticizer are both in the direct line of flow-through – and not located adjacent to or merely within the same process sequence. As noted, EPA has previously agreed that the ancillary components of a continuous-flow process include the pipes, pumps, valves, etc. designed to mechanically transfer the intermediate through these pieces of equipment.

3. Calcium oxide (CASRN1305-78-8) or lime (Stream 5).

Green liquor is causticized using calcium oxide to form *white liquor* with the resulting byproduct of *calcium carbonate*. The *calcium carbonate* and *white liquor* are continuously removed from the causticizing area and continuously fed to their next downstream process.

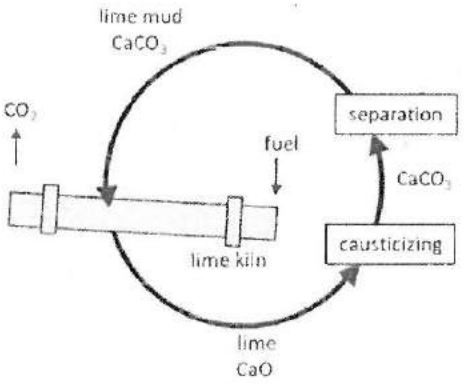

Figure 4. Calcium Oxide in the Kraft Recovery Process

As shown in Figure 4, the calcium carbonate byproduct is recovered in a separation vessel and transferred to a lime kiln. The calcium carbonate byproduct is heated in the kiln to drive off CO_2, retaining the calcium in the form of calcium oxide. From the lime kiln, the lime is continuously transported though lime silos to the causticizing area of the mill where it is

[26] 2016 CDR Fact Sheet, *p. 5, Case Study A*. Historically, the issue of closed mechanical transfers was additionally addressed by EPA in a letter dated July 15, 1986 addressed to Geraldine Cox of the then-Chemical Manufacturers Association (copy enclosed).

reacted with green liquor. This flow-through process accomplishes the recovery and recycling of calcium in the Kraft cycle by way of the lime kiln that converts the *calcium carbonate* byproduct back into *calcium oxide*. The equipment associated with this process phase runs continuously under normal operations and in closed vessels.

a. Does the chemical substance function as an intermediate?

An *intermediate* results when a chemical substance is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures. Calcium oxide in the Kraft cycle meets this definition by undergoing reaction with *green liquor* to form *white liquor* and *calcium carbonate* as a recycled byproduct. That calcium oxide is completely consumed is evident from the nature of this process phase, which requires the use of a lime kiln to convert the recycled byproduct to the form necessary to react with *green liquor* in the causticizer. As a result of this reaction, calcium oxide is transformed to intentionally manufacture another chemical substance and therefore is an intermediate. This chemical does not leave the Kraft pulping and recovery cycle to be stored in tanks, etc. during normal operations. There is a steady, variable, recurring flow of the chemical through the enclosed system during the operation of the process.

b. Was the intermediate "intentionally removed from the equipment in which it was manufactured"?

This sequential reaction process occurs in different reaction vessels and that cause the transfer of this intermediate substance between various reaction or processing vessels in a continuous, flow-through cycle. Specifically, *calcium oxide* is transferred into the causticizer and the resulting byproduct is sent to a lime kiln that re-generates calcium oxide for transfer and use in the causticizer. All movement takes place via mechanical or gravitational means, using enclosed auxiliary equipment (pipes, pumps, valves, etc.). There is no intentional removal of the intermediate from continuous[27] and enclosed process.[28] The operations may include fugitive, inadvertent, or emergency pressure relief releases, but these do not disqualify the system from non-isolated intermediate status so long as measures are taken to prevent worker exposure to and environmental contamination from the releases. Worker exposure is prevented during this phase of the process by maintaining the chemicals that are being used and generated within the equipment itself and by ensuring that the system is properly managed to avoid unintentional, accidental release. Under normal operating conditions there are no chemical releases or exposure to the calcium oxide, and if applicable, federal permitting requirements are followed to prevent inadvertent or fugitive air release. Overall, this intermediate is handled is consistent with EPA's guidance that "if a substance is caused to react in one vessel and is subsequently mechanically transferred through closed equipment to a second vessel for further reaction or processing, no isolation is deemed to have occurred."[29]

c. Was the intermediate "stored after its manufacture" and which pieces

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27 TSCA Inventory Representation Policy, p. 4.

28 40 C.F.R. § 704.3.

29 2016 CDR Fact Sheet, *p. 5, Case Study A.* Historically, the issue of closed mechanical transfers was additionally addressed by EPA in a letter dated July 15, 1986 addressed to Geraldine Cox of the then-Chemical Manufacturers Association (copy enclosed).

of equipment can be considered "ancillary to the reaction vessel"?

Calcium oxide is continuously transferred from the lime kiln to the causticizers via the use of lime silos. The process flow of calcium oxide is regulated through the use of the silos to accommodate different reaction rates and varying flow rates or transfer times, a function that is clearly related to the requirements of the manufacturing process. Their primary purpose is to buffer or regulate the flow from one process to the other, and they flow directly from one process to the other. The use of a flow-through silo system is conventional and necessary for the safe operation of the Kraft cycle. Based on CDR and the TSCA Inventory Representation Policy, as well as Federal Register statements on the scope of this exemption, "holding to accommodate different reaction rates and varying flow rates or transfer times" is not deemed to be storage in a continuous process, and periods of up to two or three hours normally will not be sufficient to interrupt a continuous-flow process or otherwise qualify as isolation.

The ancillary equipment at this phase includes the separation tank, lime kiln, silos and causticizer. All of these are used to perform necessary parts of the manufacturing process. The separation tank permits calcium carbonate to be diverted from the white liquor and sent for recovery. The kiln serves this recovery purpose. The silos allow the recovered calcium oxide to flow through to the causticizer in metered fashion and the causticizer itself is where calcium oxide is consumed to form white liquor. These functions are integral to the success of the Kraft cycle and therefore qualify the equipment as ancillary to the reaction vessel (for this stream, we submit the role of the reaction vessel is served by the energy recovery unit). All vessels, including the silos, are in the direct line of flow-through operation. As a result, the silos do not represent diversion or storage. As already noted, EPA has previously agreed that the ancillary components of this phase of the process include the pipes, pumps, valves, etc. used to mechanically transfer the calcium oxide intermediate through the equipment.

4. **White liquor (CASRN 68131-33-9, *sulfite liquors and cooking liquors, white*) (Stream 6).**

White liquor is generated from the reaction of *green liquor* and *calcium oxide*, with a resulting calcium carbonate byproduct. This solution is formed by reacting the sodium salts in green liquor with calcium oxide. Calcium oxide produced from an interconnected lime kiln is continuously slaked with water in a lime slaker and mixed, continuously, with the green liquor. The reaction occurs in closed vessels called causticizers. Figure 5 shows this portion of the Kraft cycle.

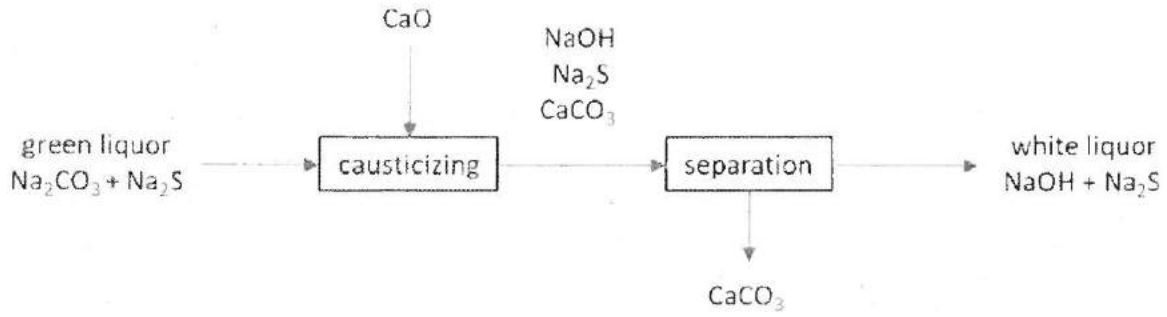

Figure 5. White Liquor in the Kraft Recovery Process

The balance of the process also occurs in what are considered to be closed vessels where, under normal operating conditions, there are no intentional chemical releases or exposure of personnel to *white liquor*. Wood is pulped in the digester using white liquor in the process of "cooking" the wood chips at elevated temperature and pressure. The cooking process results in the separation of cellulose fibers from lignin and other wood components. The lignin and other wood components remain in the spent pulping liquor, referred to as black liquor.

a. Does the chemical substance function as an intermediate?

An *intermediate* results when a chemical substance is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures. *White liquor* in the Kraft cycle meets this definition by undergoing reaction with wood to form pulp and the recycled *black liquor* byproduct. The *white liquor* is completely consumed, as evident from the distinct chemical identities assigned to the pulp reactant and the *black liquor* byproduct. The use of high temperature and pressure is necessary to accomplish the conversion reactions that transform the wood to form pulp, which is the commercial product that is isolated from this process. As a result of the reactions in the cooking phase in the digester, *white liquor* is transformed to intentionally manufacture another chemical substance and therefore is an intermediate. This chemical does not leave the Kraft pulping and recovery cycle to be stored in tanks, etc. during normal operations. There is a steady, variable, recurring flow of the chemical through the enclosed system during the operation of the process.

b. Was the intermediate "intentionally removed from the equipment in which it was manufactured"?

The Kraft cycle, as explained above, includes different reaction vessels and the transfer of the intermediate substances between reaction vessels. Specifically, *white liquor* is transferred from the causticizer and separation tank to the digester in a continuous and flow-through manner. All movement takes place via mechanical or gravitational means, using enclosed pipes, pumps, valves, etc. There is no intentional removal of the intermediate from the system leading up to and including conversion of the wood into pulp. Therefore, this

system qualifies as a continuous system[30] and as an enclosed process.[31] These operations may include fugitive, inadvertent, or emergency pressure relief releases, which will not cause the system to be disqualified from non-isolated intermediate status so long as measures are taken to prevent worker exposure to and environmental contamination from the releases. Worker exposure is prevented during this phase of the process by maintaining the chemicals that are being used and generated within the equipment itself and by ensuring that the system is properly managed to avoid unintentional, accidental release. Under normal operating conditions there are no chemical releases or exposure to the *white liquor*, and if applicable, federal permitting requirements are followed to prevent inadvertent or fugitive air release. Overall, this intermediate is handled is consistent with EPA's guidance that "if a substance is caused to react in one vessel and is subsequently mechanically transferred through closed equipment to a second vessel for further reaction or processing, no isolation is deemed to have occurred."[32]

c. Was the intermediate "stored after its manufacture" and which pieces of equipment can be considered "ancillary to the reaction vessel"?

White liquor is transferred in a direct manner from the separation tank to the digester. This intermediate is not diverted in between these process steps; rather it is continuously processed under normal operating conditions through pipes and other vessels in what is generally referred to in the industry as a "flow-through" process that facilitates a continuous process operation like the Kraft process. Process flow may be regulated to accommodate different reaction rates and varying flow rates or transfer times, a function that is clearly related to the requirements of the manufacturing process in these closed, continuous operations. Similar to the design of most flow-through tanks, whose primary purpose is to buffer or regulate the flow from one process to another, the vessels in the pulping industry are equipped with vents that allow for level control and process protection under upset conditions. These are conventional and necessary for the safe operation of industrial processes. Based on CDR and the TSCA Inventory Representation Policy, as well as Federal Register statements on the scope of this exemption, "holding to accommodate different reaction rates and varying flow rates or transfer times" is not deemed to be storage in a continuous process, and periods of up to two or three hours normally will not be sufficient to interrupt a continuous-flow process or otherwise qualify as isolation.

Moreover, the equipment at this process stage is fully ancillary to the Kraft cycle because it is used to perform necessary parts of the manufacturing process. The causticizer, separation tank and digester are required for generating the *white liquor*, byproduct separation, and pulp manufacture, respectively. These functions are integral to the success of the Kraft cycle and therefore qualify the equipment as ancillary to the reaction vessel (for this stream, we submit the role of the reaction vessel is served by the energy recovery unit). These

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30 TSCA Inventory Representation Policy, p. 4.

31 40 C.F.R. § 704.3.

32 2016 CDR Fact Sheet, *p. 5, Case Study A.* Historically, the issue of closed mechanical transfers was additionally addressed by EPA in a letter dated July 15, 1986 addressed to Geraldine Cox of the then-Chemical Manufacturers Association (copy enclosed).

units are in the direct line of each other and do not involve diversion of the *white liquor* away from the digester at any point. As noted, EPA has previously agreed that the ancillary components of a continuous-flow process include the pipes, pumps, valves, etc. designed to mechanically transfer the intermediate through these pieces of equipment.

IV. Summary of Non-Isolated Intermediate Analysis

In summary, the manner in which the Kraft cycle operates demonstrate clearly that pulp manufacture is a continuous-flow process and that the chemicals in question are not diverted from the process cycle at any time during normal operations. EPA guidance states that when an intermediate chemical is caused to react in one vessel and is subsequently mechanically transferred through closed equipment to a second vessel for further reaction into another intermediate, the agency does not segment these process steps into batches for purposes of analysis under TSCA, because no isolation is deemed to occur. EPA also provides guidance on holding times and allowable holding purposes to remain eligible for the non-isolated intermediate exemption. It is up to each mill to evaluate its own process conditions in relation to that guidance.

In general, we have demonstrated in the case of each of these process phases how the non-isolated intermediate exemption from CDR reporting may be applied based on our understanding of how the exemption is interpreted by EPA in public guidance and pronouncements in both the new chemical and CDR programs.

We would be happy to respond to any questions or comments you may have concerning the information and analysis in this memorandum. Please do not hesitate to contact me at mmarrapese@wileyrein.com or 202-719-7156.

Attachments (4)

TSCA Chemical Data Reporting
Fact Sheet: Non-Isolated Intermediates

This fact sheet provides information on the reporting exemption applicable to non-isolated intermediate chemical substances for purposes of the Chemical Data Reporting (CDR) rule (40 CFR 711).

The primary goal of this document is to help the regulated community comply with the requirements of the CDR rule. 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 give EPA information on the chemicals they manufacture domestically or import into the United States. EPA uses the data, which provides important screening-level exposure related information, to help assess the potential human health and environmental effects of these chemicals and makes the non-confidential business information it receives available to the public.

What is an intermediate?

The CDR rule defines an intermediate as "any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions." See 40 CFR 704.3, referenced by 40 CFR 711.3.

What is a non-isolated intermediate?

A non-isolated intermediate is "any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers isolates the substance by removing it from process equipment in which it is manufactured." See 40 CFR 704.3, referenced by 40 CFR 711.3.

How do I determine if my chemical substance is a non-isolated intermediate that is exempt from CDR reporting requirements?

The manufacture of a non-isolated intermediate is exempt from reporting requirements under CDR. See 40 CFR 711.10(c) and 40 CFR 720.30(h)(8).

You must consider the entire process sequence from manufacture to use of an intermediate to determine whether or not an intermediate chemical substance is a "non-isolated intermediate." Evaluating the following questions will help you make this determination.

a. Does the chemical substance function as an intermediate?

If the chemical substance is not partially or totally consumed for the intentional manufacture of another chemical substance or a mixture (or intentionally present for the purpose of altering the rate of such a chemical reaction), then it is not an intermediate. See 40 CFR 704.3, referenced by 40 CFR 711.3. If it is not an intermediate, it cannot be a non-isolated intermediate.

b. Was the intermediate "intentionally removed from the equipment in which it was manufactured"?

A non-isolated intermediate is an intermediate that is not intentionally removed from the equipment in which it was manufactured. The "equipment in which [the intermediate] was manufactured" is defined to include the following (40 CFR 704.3, referenced by 40 CFR 711.3):

- the reaction vessel in which the intermediate is manufactured,
- equipment which is ancillary to the reaction vessel, and
- any equipment through which the substance passes during a continuous flow process (not including tanks or other vessels in which the substance is stored after its manufacture).

If a particular volume portion of an intermediate is isolated, it is possible that the remaining volume portion of the intermediate may still be considered a non-isolated intermediate. The volume portion that is isolated is subject to CDR reporting requirements, while the remaining volume portion that is non-isolated is exempt from reporting.

c. Was the intermediate "stored after its manufacture"?

A chemical substance is considered to be stored if it has been "intentionally removed from the equipment in which it is manufactured" (such as a reaction vessel) and transferred into equipment where it is "stored after being manufactured." Such intentional storage of a chemical intermediate is considered isolation, regardless of the length of storage and whether the storage is termed "holding," and even if the transfer into the storage equipment is enclosed.

However, EPA generally would not consider an intermediate to have been isolated or stored when it is being temporarily held solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process – such as heating, cooling, filtration, or reaction. Other examples of holding that EPA would generally consider to have a clear technical relationship to the needs of the overall manufacturing process are:

- holding to accommodate different reaction rates and varying flow rates or transfer times;
- holding during repair or maintenance of the intermediate's manufacturing equipment; and
- holding that is necessary for analytical sampling.

In evaluating the particular facts of such cases, the absence of any storage purpose (see 40 CFR 704.3) is the key determining factor: if the chemical substance is being held for storage purposes, it has been isolated. Conversely, if the material is being held solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process, that is an indication that there is not a storage purpose and that the chemical substance has not been isolated.

***d.** Which pieces of equipment can be considered "ancillary to the reaction vessel"?*

EPA interprets the phrase "ancillary" as consisting of equipment that is auxiliary or supplemental to the reaction vessel and is used for performing necessary or important parts of the manufacturing process involving the intermediate, such as filtration, distillation, drying, size (volume) reduction, heating or cooling. Equipment that provides primary operational support to the reaction vessel itself, such as equipment for metering or controlling the reaction within the vessel, also would be considered as ancillary. See 40 CFR 710.3 (emphasizing that such equipment must be "strictly ancillary"). EPA does not consider equipment to be ancillary merely because it is located adjacent to or within the same process sequence as the reaction vessel. For example, EPA does not consider pipes and pumps used to transfer a chemical from the reactor to a storage vessel as equipment "ancillary to the reaction vessel." These pieces of equipment serve the purpose of storage and transfer; not the manufacturing purpose of the reaction vessel.

Examples of isolated and non-isolated intermediates

Example	Isolated, Reportable	Non-isolated, Not Reportable
An intermediate sent off-site for reclamation.	X	
An intermediate that is transferred into an open or closed tank for long-term storage.	X	
An intermediate that is transferred to a closed container for shipment or sale.	X	
An intermediate that is temporarily transferred to a closed vessel while the equipment in which it was manufactured is being repaired.		X
Quality control samples taken of an intermediate during the manufacturing process, or the intermediate being held in the reaction vessel in which it was manufactured during and solely for a quality control analysis of that intermediate.		X
Portion of an otherwise non-isolated chemical intermediate that is accidentally released due to equipment failure or necessary maintenance.		X
Portion of an otherwise non-isolated chemical intermediate that is left as a residue in the reaction vessel.		X
Intermediate is consumed in the same reaction vessel in which it was manufactured (provided that it hasn't been held there for storage purposes).		X
Intermediate is manufactured in a reaction vessel and subsequently transferred in an enclosed loop system to an enclosed processing unit (such as a drum filter used to remove impurities) and then to a reaction vessel to be consumed in a reaction.		X
Portion of an otherwise non-isolated chemical intermediate that is incidentally caught in the catalysts when the reaction catalysts are annually removed and replaced.		X
Portion of an otherwise non-isolated chemical intermediate that is incidentally caught in the filter media when the filters are exchanged during routine maintenance (i.e., removal of intermediate is limited to the quantities incidentally caught in the filter media).		X
Chemical intermediate that is recovered for subsequent commercial purposes such as a filter cake and then manually transferred to another piece of equipment.	X	

Specific Case Studies

Case Study A

Company A manufactures Chemical Intermediate X in Reactor 1. After manufacture, Chemical Intermediate X is transferred via mechanical means inside a closed system to a tank. From this tank, Chemical Intermediate X is then transferred to Reactor 2 where it is consumed in a subsequent reaction. The tank, reactors and connecting lines are all enclosed. Is the mechanical transfer from Reactor 1 to the tank considered an isolation step?

To determine whether or not the transfer to the tank is an isolation step, Company A must determine whether Chemical Intermediate X is being stored between being manufactured in Reactor 1 and being consumed in Reactor 2.

Suppose there is a closed vessel between Reactor 1 and Reactor 2 that temporarily accommodates the newly formed intermediate during its continuous flow from Reactor 1 to Reactor 2, solely to allow space for surges of intermediate-containing material out of Reactor 1. If that is the only hold, the transfer between Reactor 1 and Reactor 2 is not an isolation step, since any hold between Reactor 1 and Reactor 2 is solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process.

Alternatively, suppose there is a closed vessel between Reactor 1 and Reactor 2 that is being used solely to heat, cool, or filter Chemical X before transfer to Reactor 2. These are the sole purposes of the hold and they have a clear technical relationship to the needs of the overall manufacturing process. The hold would not be viewed as storage and isolation. If that is the only hold, the transfer between Reactor 1 and Reactor 2 is not an isolation step.

Finally, suppose there is a closed vessel between Reactor 1 and Reactor 2 that is being used to temporarily hold Chemical X for plant operation convenience or non-technical business reasons. This is viewed as storage and the transfer between Reactor 1 and Reactor 2 isolates the intermediate.

Case Study B

Company B operates a distillation column, which produces an intermediate stream in the overheads identified as "Distillates (petroleum), straight-run light." This overheads stream is then fed directly, through a closed system, to an enclosed unit in the plant that is used for alkylation reactions. Would the overheads stream that is the feed to this unit be considered a non-isolated intermediate?

The transfer of this overhead stream distillates from the distillation column to the alkylation reaction chamber occurs through enclosed equipment, without any holding steps, via a continuous flow process. Therefore, the intermediate stream produced in the distillation column and transferred to the reaction chamber is considered to be a non-isolated intermediate.

Case Study C

Company C operates a distillation column, which produces an intermediate stream in the overheads identified as "Distillates (petroleum), straight-run light." This overheads stream is then fed directly, through a closed system, to a drop tank until there is a volume of intermediate that is convenient to use in that plant's alkylation unit. Would the overheads stream that is the feed to this unit be considered a non-isolated intermediate?

Whether the intermediate stream is considered isolated or non-isolated is dependent on factors that were not included in the description. Depending upon the situation, the use of the drop tank could be for storage or it could be solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process.

Isolated intermediate: If the alkylation unit is intended to only be run occasionally, such as when an order for product is placed, then the drop tank would be used to store the intermediate stream until the alkylation unit is running. Although the transfer is accomplished through a closed system, the normal operation of the system includes a storage step and the intermediate is considered isolated in the drop tank.

Non-isolated intermediate: If the alkylation unit is run continuously, but the distillation column is run intermittently because the rate of reaction of the intermediate in the alkylation unit is lower than the rate of manufacture of the intermediate in the distillation column, there may be some intermediate that accumulates in the drop tank. Even though some intermediate may be held in the drop tank, this is done for reasons that have a clear technical relationship to the needs of the overall manufacturing process; the hold is not for business reasons or for plant operation convenience. The intermediate is considered to be non-isolated.

Case Study D

Company D manufactures chemical substance A, which will be reacted with other chemicals to manufacture product B. Chemical substance A, therefore, is an intermediate. The equipment used to manufacture A and B is enclosed and can be operated in a continuous flow manner. The process to manufacture A is slow, so that portion of the process runs continuously. The process to manufacture B is much faster, and therefore, the company typically waits until it has orders for product B before running the second half of the process. Is chemical substance A a non-isolated intermediate?

Although chemical substance A is held in part because of the different rates of reaction, it is also being held for reasons that do not have a clear technical relationship to the needs of the overall manufacturing process (i.e., the desire to not run the reactor to manufacture product B until Company D has orders). Therefore, the hold on chemical substance A constitutes storage and chemical substance A is isolated.

Case Study E

A reactor in which an intermediate substance is manufactured is equipped with a surge tank that temporarily and reversibly accommodates some of the reaction mixture that surges out of the reactor when there is an exothermic expansion, excessive foaming, or some other type of pressure build-up in the reaction mixture that forces some of it (already containing a portion of the newly-formed intermediate) to flow into the surge tank until the reaction conditions stabilize. All of the vessels and lines are enclosed and the transfer or flow of reaction mixture occurs by mechanical or gravitational means or as a spontaneous flow as part of releasing pressure in the reactor. After the surging reaction mixture returns to the reactor and the manufacture of the intermediate is completed, the intermediate will be consumed in the same reactor to manufacture the final product. Is the intermediate in the reaction mixture that flows into the surge tank considered non-isolated?

This surge tank performs a holding function for one purpose only, which bears a clear technical relationship to the needs of the overall manufacturing process (i.e., addressing pressure build-up in the course of the reaction). The intermediate is not isolated by being held in the surge tank.

Case Study F

Company F manufactures substance A and transfers a portion through an enclosed, continuous flow system to a second reactor to manufacture chemical substance B, which is subsequently used for a commercial purpose. The remaining portion of substance A is transferred to a storage tank for later use for a different commercial purpose. Is any portion of substance A considered a non-isolated intermediate?

The portion of substance A that is transferred through an enclosed, continuous flow system to a *second reactor* (where it is used to manufacture chemical substance B) is considered to be a non-isolated intermediate. The portion of substance A that is transferred to a storage tank is isolated. Reporting under CDR for the isolated portion of substance A would be required if the isolated portion of substance A meets the other reporting requirements.

For further information:

To access copies of additional fact sheets and other CDR information, visit www.epa.gov/cdr.

If you have questions about CDR, you can contact the TSCA Hotline by phone at 202-554-1404 or e-mail your question to eCDRweb@epa.gov.

after 7/15/86

TSCA INVENTORY REPRESENTATION POLICY - NON-ISOLATED INTERMEDIATE EXCLUSION

I. INTRODUCTION

Non-isolated intermediates are not reportable for the Chemical Substance Inventory (the Inventory) under Section 8(b) of the Toxic Substances Control Act (TSCA), and are therefore not subject to the Premanufacture Notice (PMN) requirements under Section 5(a) of TSCA. The purpose of this paper is to describe the policy that the Office of Toxic Substances (OTS) has followed in determining whether an intermediate substance, during its manufacture, processing and further reaction to convert it to another substance, is a non-isolated intermediate.

II. BACKGROUND AND POLICY

The TSCA Inventory Reporting Regulations (40 CFR 710) exclude from Inventory reporting those chemical substances which are not intentionally removed from the equipment in which they are manufactured [§ 710.4(d)(8)]. Although the term "non-isolated intermediate" does not appear in the Inventory Reporting Regulations, the term "intermediate" as defined under § 710.2(n) is implied to be a reportable, isolated type of substance. This definition states that an intermediate is:

> "any chemical substance (1) which is intentionally removed from the equipment in which it is manufactured, and (2) which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s)."

However, when an intermediate substance is not intentionally removed from the equipment used to produce it, the practice has been to call it a non-isolated intermediate.

In the Agency's response to comment 67 concerning intermediates and the Inventory Reporting Regulations (42 FR 64588), the term "intermediate" excludes intermediates that are technically isolatable (within production equipment) but never encountered in the environment. The response also included this statement:

> "Chemical substances which are not removed from the equipment in which they are manufactured are not considered "intermediates" for the purposes of these regulations and are excluded from the Inventory by § 710.4(d)(8)."

Such substances are referred to as "non-isolated intermediates" in the Premanufacture Notice (PMN) Rule, which also excludes such intermediates from reporting [40 CFR 720.30(h)(8)]. The PMN Rule [40 CFR 720.3(w)] also defines non-isolated intermediate as:

> "any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture."

The wording in this definition is largely adopted from a notation in the Inventory Reporting Regulations that immediately follows and clarifies the definition of "intermediate" (42 FR 64576).

The term "ancillary" refers to equipment that is auxiliary or supplemental to the reactor and is used for such purposes as filtration, distillation, drying, size reduction, heating, cooling, or dehydration.

The term "continuous flow process" used in the definition of non-isolated intermediate also was employed in the previously mentioned clarifying note in the Inventory Reporting Regulations. In response to questions from the chemical industry concerning whether short-term or temporary storage of an intermediate can still be considered part of a continuous flow process, EPA published the following statement in the March 6, 1978 Supplemental Clarification of the Inventory Reporting Regulations (43 FR 9256):

> "In general, any chemical substances which are held temporarily in an otherwise continuous flow process for purposes that are clearly related to the necessity of the manufacturing process -- such as heating, cooling, filtration or reaction -- are not considered reportable, while those that are held principally for purposes of storage would be considered reportable."

In an attempt to further clarify the definition of a non-isolated intermediate, OTS stated in its July 15, 1986 response to an industry inquiry:

> "The Agency intends to exclude from the Inventory and PMN requirements any chemical substance which is manufactured and consumed in the manufacture of another chemical substance without intentional removal from process equipment during its manufacture and use. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but the storage or transfer to shipping containers isolates the substance by removing it from process equipment in which it is manufactured.

As implied by this quotation, EPA exercises a broad interpretation of the definition of non-isolated intermediate. This quotation is also consistent with the Agency's broad interpretation of the term "continuous flow process". This term is not considered by EPA to solely represent synthetic reactions that actually produce intermediate and product substances in a continuous manner; nor is it considered to just include reactions involving only one reaction vessel with its ancillary equipment. The Agency's concept of a continuous flow process also includes sequential reaction processes that may occur in different reaction vessels, and that may involve transfer of an intermediate substance between various reaction or processing vessels. Consequently, any mechanical manufacturing process in which an intermediate is moved from one piece of equipment to another, using enclosed auxiliary equipment (pipes, pumps, valves, etc), without intentional storage or removal of the intermediate, is considered by EPA to be a continuous flow process.

III. EXAMPLES ILLUSTRATING THE POLICY

The following examples of processes will provide further clarification of this policy:

A. Manufacture of an intermediate and a product derived from it in the same reaction vessel:

An intermediate substance that is manufactured in a reaction vessel and then is further reacted to form another

substance, without intentional removal from the reaction vessel for processing or any other reason, is considered to be a non-isolated intermediate. This intermediate substance is considered to be consumed in the reaction vessel for the intentional purpose of producing another substance. However, even if a small amount of the intermediate is left as a residue in the reaction vessel, its non-isolated status will be maintained. Accidental release due to equipment failure also does not affect the non-isolated status of such an intermediate.

B. Manufacture of an intermediate in a reaction vessel with subsequent transfer to a processing unit, followed by return to the same vessel for further reaction:

After being produced in a reaction vessel, suppose that an intermediate substance is transferred through enclosed lines (pipes, pumps, valves, meters, gauges, etc.), by gravitational or mechanical means, to a drum filter that is also enclosed (one example of a processing unit). If the intent of this filtration is to remove insoluble impurities, byproducts, residual reactants or catalysts from a liquid or soluble intermediate, this intermediate comprises or is part of the filtrate. It is then transferred back to the reaction vessel by mechanical or gravitational means through enclosed lines. This intermediate, which has not been removed from the equipment used to manufacture it, is considered to be a non-isolated intermediate.

Suppose, on the other hand, that an intermediate is a solid substance that is intended to be collected by the filter as part of a filter cake. If the filter is opened to manually transfer the filter cake containing the intermediate back to the reaction vessel, this intermediate is considered to be isolated, since it is intentionally removed from the processing equipment. A similar interpretation would apply to other processing operations (e.g., distillation, drying, size reduction, etc.) that can be performed between the synthesis and subsequent reaction of an intermediate substance.

C. Reaction in one vessel with transfer to a processing unit, followed by transfer to a second reaction vessel:

An intermediate can be manufactured in one reaction vessel, transferred (by pumping or gravity feeding) to a processing vessel where it may be dehydrated, for example, and then transferred to a second reaction vessel to undergo further reaction that produces a final product. The intermediate is considered to be non-isolated if all of the vessels and the interconnecting lines are enclosed, if the transfers are made by gravitational or mechanical means, and no intentional removal of the intermediate occurs from the equipment used to manufacture it.

On the other hand, if the equipment is not completely closed, or if the transfer of the intermediate from one unit of the equipment to another has been accomplished by manual means

or by transfer via bags, drums, tank truck or tank car (even though mechanical equipment may have been used to handle this substance), the intermediate substance is considered isolated. In these situations, the intermediate is considered to have been removed from the equipment in which it was manufactured.

IV. OTHER CRITERIA FOR DETERMINING THE STATUS OF AN INTERMEDIATE

In processes using either one reaction vessel (examples A and B) or at least two reaction vessels (example C), the removal of samples of an intermediate strictly for (1) research or product/process development purposes, or (2) quality control testing does not itself affect the non-isolated status of the intermediate substance [refer to the EPA response to comment 70 in the Inventory Reporting Regulations (42 FR 64589)].

The manufacturing equipment used for a multi-reactor system may also include a vessel or a tank (a surge tank, for example) where the intermediate substance may be temporarily held to accommodate different reaction rates, varying flow rates or transfer times, etc. A substance held for a limited time in this type of vessel for purposes that are clearly related to the requirements of the manufacturing process (as opposed to storage) is not considered to be an isolated intermediate. Furthermore, holding an intermediate in a vessel to provide for maintenance or repair of equipment does not constitute isolation.

On the other hand, if an intermediate is transferred to a vessel or tank principally for the purpose of storing this intermediate for an extended period of time, the substance is isolated and reportable.

The Agency has not yet resolved the issue of whether it should establish a precise time limit defining how long an intermediate substance may be kept in a holding vessel before it is considered to be in storage and, therefore, isolated. Determinations regarding this specific issue have been made on a case-by case basis, utilizing information provided by each submitter.

In the future, an addendum will be attached to this paper. This will contain examples that illustrate new applications of policy or other types of policy applications that the Agency has frequently reviewed. Issues identified by EPA that cause future policy refinements to be made will also be presented in the addendum.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 15 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Geraldine V. Cox, Ph.D.
Vice President-Technical Director
Chemical Manufacturers Association
2501 M Street, N.W.
Washington, D.C. 20037

Re: Nonisolated Intermediate Definition

Dear Dr. Cox:

This replies to your June 16, 1986 letter requesting that the Agency clarify the definition of a nonisolated intermediate at 40 CFR 720.3(w) in light of the promulgation of the recent Inventory update reporting rule.

We have carefully reviewed the contents of your letter and agree that the Agency should provide a clear interpretation of what constitutes a nonisolated intermediate for purposes of determining what substances are excluded from the Inventory and premanufacture notification (PMN) requirements.

The Agency intends to exclude from the Inventory and PMN requirements any chemical substance which is manufactured and consumed in the manufacture of another chemical substance without intentional removal from process equipment during its manufacture and use. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers "isolates" the substance by removing it from process equipment in which it is manufactured.

The following examples offer further clarification:

(1) Reaction in the Same Vessel: Reactants A and B are charged to a reaction vessel to form a chemical substance X. Then C is added to react with X to form another substance Y which is then drummed for shipment. In this example X is considered to be nonisolated since it is not intentionally removed from the process equipment of manufacture. Y will be considered to be isolated since it is intentionally removed by drumming for transport.

Linda Travers

(2) Reaction in One Vessel with Purification in Another and Transfer to a Second Vessel: The reaction is carried out in one reactor and the reaction mixture is then pumped through an enclosed drum filter to another vessel for the next reaction step. The reaction intermediate is considered to be nonisolated since there is no intentional removal and all transfer is mechanical and through closed equipment. However, if the filtration is not closed or if the transfer is manual (for example, involving the removal of the intermediate as a filter cake), then the intermediate would be considered to be isolated since the transfer would not be through closed equipment. A similar interpretation applies to other processing steps between manufacture and subsequent reaction (e.g., distillation, drying, size reduction, etc.).

The Agency plans to publish a clarification of its policy on nonisolated intermediates in an advisory circular as soon as possible. Thank you for bringing this important matter to my attention. I hope that this letter clarifies the Agency's position on what constitutes a nonisolated intermediate and responds to your concerns regarding compliance with Inventory and PMN regulations. If you have further questions on this issue, please feel free to contact me.

Sincerely,

original signed by
Edwin F. Tinsworth

Edwin F. Tinsworth, Acting Director
Office of Toxic Substances

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Herbert Estreicher
Covington & Burling
1201 Pennsylvania Ave., N.W.
P.O. Box 7566
Washington, D.C. 20044-7566

JAN 24 2000
CBI
CONTAINS NO

Re: PC 3867

Dear Mr. Estreicher:

This letter responds to your letter, sent to David Schutz of my staff, and dated 29 October 1999. In that letter you described a commercial synthesis and the equipment (including surge tanks) in which it takes place, and asked the Agency's agreement with your conclusion that an intermediate formed in this equipment would be "nonisolated" as that term is defined at 40 Code of Federal Regulations §720.3(w):

> " (w) Nonisolated intermediate means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture."

You state that all process equipment is interconnected with piping, that no intermediates are isolated or removed from the system, and that emissions are minimal and any which occur are not intentional. You note that your client intends to use a continuous production process, and that it is using surge tanks to enable one part of the process to continue functioning if another part of the system is down or if yield fluctuates. The amount of material contained in one of these tanks can enable the downstream processing to continue for up to 6 days in event of a process upset. According to the flow diagram you have included with your letter, all process material flows through the surge tanks rather than bypassing the tanks unless there is excess material.

Essentially, you are asking that the Agency agree with you that it is appropriate to consider these surge tanks in the category of "equipment through which the chemical substance passes during a continuous flow process" rather than as "tanks or other vessels in which the substance is stored after its manufacture." The Agency agrees with your position based on your diagram showing that all of the material flows through the tanks. The amount of material involved is substantial, however, and if the tanks were out of the direct line of flow rather than flow-through and your process were otherwise the same, storage in the surge tanks would constitute isolation and premanufacture notice (PMN) would have to be filed.

If you have any questions on this matter, please contact Dave Schutz of my staff on 202 260 8994.

Sincerely,

Rebecca S. Cool

Rebecca S. Cool, Chief
New Chemicals Prenotice Branch
Mail Stop 7405, Chemical Control Division