Review Report for Aluminum (CASRN 7429-90-5) Partial Exemption

May 2019: The Aluminum Association

Docket Identifier: EPA-HQ-OPPT-2019-0224

Summary of Decision: In response to a petition from the Aluminum Association[1] (hereinafter "petitioner") requesting that aluminum (CASRN 7429-90-5) be added to the 40 CFR 711.6(b)(2)(iv) list of specific chemical substances for which the Environmental Protection Agency (EPA, "the Agency") has a low current interest in the processing and use information, EPA has determined that the Agency does not have a low current interest in the processing and use information collected under the Chemical Data Reporting (CDR) rule (see 40 CFR Part 711) for aluminum. This determination is based on the totality of information available for the chemical substance, including an evaluation of all the considerations listed in 40 CFR 711.6(b)(2)(ii), as well as additional considerations.

Background: EPA received a petition from the Aluminum Association on January 30, 2019, requesting that aluminum (CASRN 7429-90-5) be added to the 40 CFR 711.6(b)(2)(iv) list of specific chemical substances that are exempt from the reporting requirements of 40 CFR 711.15(b)(4) (*i.e.*, exempt from requirements to report industrial processing and use and commercial/consumer use information). EPA has a low current interest in the substances on this "partial exemption" list and thus in the related CDR processing and use information. EPA emphasizes that low current interest is not synonymous with low hazard or low risk. As EPA stated in the preamble to the Inventory Update Reporting Amendments rule (the previous name for the Chemical Data Reporting rule), "[t]he inclusion of a chemical substance under this partial exemption is not itself a determination of the potential risks of a chemical. This partial exemption is solely intended to provide a tool to assist the Agency in better managing the collection of processing and use information under [the CDR rule]." (68 FR 848, 854, January 7, 2003). This determination is based on the Agency's interest in the chemical generally and in the processing and use information specifically: "[i]n determining whether there is low current interest in [CDR] processing and use information related to a specific chemical substance, EPA will look to the specific circumstances surrounding the chemical in question, and may use one or more of the considerations identified [in 40 CFR 711.6(b)(ii)], and/or considerations not identified [in 40 CFR 711.6(b)(ii)], to make an informed decision."[2]

The considerations used by EPA in reviewing this petition and an analysis of how those considerations relate to aluminum are set forth below.

In reviewing this petition, EPA considered information submitted, as well as other information, including, but not limited to: whether the petitioned chemical substance is listed on the Emergency Planning and Community Right-to-Know Act, Section 313 list of Toxic Chemicals and is thus reportable to the Toxics Release Inventory (TRI); 2012 and 2016 CDR submissions for the chemical substance; evaluations available through EPA's Integrated Risk Information

[1] The Aluminum Association. "RE: Partial Exemption Request for Elemental Aluminum (CASRN 7429-90-5)." December 28, 2018. Received January 30, 2019 with attachments.

[2] As updated in 40 CFR § 711.6(b)(ii).

(A) Referred to the older reg number. And included the following: "(i.e., at least one site manufactures 300,000 pounds or more of the chemical)."

(F) ". . . adequately managed by EPA or another agency or authority."

System, the International Agency for Research on Cancer, Organisation for Economic Co-operation and Development's (OECD) High Production Volume Screening Information Data Set program, and other relevant TSCA-related programs. EPA also considered whether the substance is subject to other regulatory programs administered by EPA.

Discussion on Considerations: Petitioner references information on aluminum from a variety of sources and linked it to specific considerations cited in 40 CFR 711.6(b)(2)(ii). Petitioner did not provide significant amounts of new information for EPA's consideration in this petition; rather, petitioner included their prior petition, from 2003. EPA reviewed that information, petitioner's other attachments, and publicly available sources of information. EPA's assessment of each consideration is below, with an indication of whether each consideration reflects a low current interest in this chemical and thus weighs in favor of granting or denying this petition for partial exemption.

Consideration A: Whether the chemical qualifies or has qualified in past Inventory Update Reporting (IUR) or CDR collections for the reporting of the information described in 40 CFR 711.15(b)(4).

Petitioner states that aluminum (CASRN 7429-90-5) was reported to the 2012 and 2016 CDR. EPA reviewed the 2012 and 2016 CDR data for aluminum and found that 145 and 161 sites, respectively, reported domestic manufacture or importation of aluminum, with a nationally aggregated production volume of 10 to 15 billion lbs. from 2010 to 2015.

EPA has concluded that at least one manufacturing site would likely have a production volume sufficient to trigger the need to report processing and use information under the 2020 CDR (25,000 lb threshold). Thus, the petition is eligible for consideration.

Consideration B: The chemical substance's chemical and physical properties or potential for persistence, bioaccumulation, health effects, or environmental effects (considered independently or together).

Petitioner provides some information for this consideration, stating that aluminum occurs naturally in food and the environment and that it does not bioaccumulate to a significant extent. Notwithstanding, EPA found this information insufficient for a decision and reviewed additional sources of data.

Human Health Effects. While aluminum does not meet OECD/Canada Domestic Substance List (DSL) categorization results criteria for human health concerns,[3] there is evidence of a concern due to inhalation of fume or dust forms of aluminum. Specifically, the Agency for Toxic Substances and Disease Registry (ATSDR),[4] describes concerns that exposure to high levels of aluminum may result in respiratory and neurological problems, and airborne particulates from aluminum have the ability to remain airborne for long periods of time.

[3] OECD; Canada DSL Categorization Results. https://canadachemicals.oecd.org/ChemicalDetails.aspx?ChemicalID=996B8A65-9713-4991-B136-C98310E6D92E.

[4] ATSDR (2008). Toxic Substances Portal – Aluminum. https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=190&tid=34. Accessed April 10, 2019.

The European Union's Toy Safety Directive 2009/48/EC acknowledged that aluminum occurs naturally in food and incorporated this into a new threshold limit to lower (strengthen) the migration limits of aluminum that in children's toys. This updated threshold, which is by 2.5 times lower than the previous limit, was based on a recommendation from the Scientific Committee on Health, Environmental and Emerging Risks, which noted that "exposure to aluminium from sources others than toys, in particular from diet, which is by far the major source of chronic exposure, may already exceed the reference value for tolerable weekly intake as derived by [Joint Food and Agricultural Organization/World Health Organization Expert Committee on Food Additives]. Therefore, the [Scientific Committee on Health, Environmental and Emerging Risks] recommends that the additional exposure from toys should be minimised."[5]

Environmental Effects. While Aluminum does not meet OECD/Canada's DSL categorization results criteria for environmental concerns, EPA published in December 2018 final updated aquatic life ambient water quality criteria recommendations for aluminum in freshwater under the Clean Water Act, stating that aluminum can inhibit an aquatic organism's ability to regulate salt concentrations and clog fish gills, potentially resulting in death or affecting growth and reproduction.[6] Based on the available information for aluminum, EPA continues to have an interest in this chemical, and this information thus weighs against granting the partial exemption.

Environmental Fate. The data and associated research available for aluminum indicate a concern for environmental fate. Available information from OECD/Canada's DSL categorization results indicates that aluminum is persistent (as is the case for all elemental metals) in the environment. These categorization results are not determinative on whether aluminum is bioaccumulative or not.

The data contributing to EPA's consideration of this factor do not support a low current interest in aluminum. This consideration weighs against establishing a partial exemption.

Consideration C: The information needs of EPA, other federal agencies, tribes, states, and local governments, as well as members of the public.

Petitioner did not provide sufficient evidence to support their statement that EPA and other agencies no longer have information needs; in their 2003 petition, petitioner refers to reviews by other federal and international agencies and claims that CDR information would not be relevant. Specifically, petitioner cites studies from ATSDR, Environment Canada, Health Canada, and the International Programme on Chemical Safety with the assertion that aluminum is well-studied and there are no information needs. However, some of the agencies identified by petitioner have stated the need for more comprehensive studies. For example, researchers affiliated with the National Institutes of Health (NIH) identified research needs to further improve risk assessments on aluminum, specifically recommending studies on:

- Air-borne aluminum exposure of workers in the aluminum industry;

[5] Directorate-General for Health and Food Safety (European Commission). *Final opinion on tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys.* March 28, 2018. https://publications.europa.eu/en/publication-detail/-/publication/f55246b3-32fb-11e8-b5fe-01aa75ed71a1/language-en. Accessed May 13, 2019.

[6] U.S. EPA (2018). Fact Sheet: Final 2018 Aquatic Life Ambient Water Quality Criteria for Aluminum in Freshwaters. https://www.epa.gov/sites/production/files/2018-12/documents/aluminum-criteria-final-factsheet.pdf. Accessed April 24, 2019.

- Aluminum-containing aerosols and the bioavailability of the inhaled aerosols;
- The potential for respiratory tract disease/illness and neurological effects (i.e., possibility for very specific neurological deficits observed to lead to more severe illness such as Alzheimer's) due to occupational exposure via inhalation to aluminum and aluminum compounds; and
- The potential link between aluminum and aluminum in drinking water and neurological disorders and cognitive impairment.[7]

More importantly, petitioner did not justify that there are not any potential information needs from EPA, such as needs under TSCA for processing and use information reported to CDR as part of chemical prioritization, risk evaluation, and risk management under TSCA section 6.

The above factors weigh against establishing a partial exemption.

Consideration D: The availability of other complementary risk screening information.

Petitioner provides little evidence demonstrating that complementary risk screening information is available for aluminum. Though petitioner cites a report prepared by Environment Canada and Health Canada, which included a risk characterization for aluminum salts (i.e., aluminum chloride, aluminum nitrate, and aluminum sulfate), it does not provide information specific to elemental aluminum.

Petitioner submitted their Aluminum Statistical Review, which contains information on the production, imports, exports, fabrication steps, markets, and ultimate commercial and consumer uses for aluminum. While petitioner believes it provides a more accurate representation of domestic processing and use of aluminum, the review is very limited in usability compared to CDR. For example, the review lacks the level of detail of exposure-related information that CDR provides on sites, workers, processing and use scenarios, and associated percent production volume.

Aluminum is on Canada's DSL, but risk screening information complementary to CDR is limited. Aluminum in the form of fume or dust is on Canada's National Pollutant Release Inventory (NPRI) with a use reporting threshold (10 tons). These data do not necessarily reflect activities in the U.S., and the available NPRI information (e.g., pollutant releases, disposals, and recycling) is more comparable to TRI than processing and use information under CDR.

The above factors lead EPA to conclude that the partial availability of complementary risk screening information is insufficient, which weighs against partially exempting aluminum from CDR reporting.

Consideration E: The availability of comparable processing and use information.

Though petitioner claims that processing and use information collected under CDR would be available from other sources (specifically, the U.S. Geological Survey), that information is not as current nor is it comparable to the level of detail in the exposure-related information provided in CDR. The European Chemicals Agency is collecting data regarding aluminum use in Europe;

[7] Krewski, D. et al. "Human Health Risk Assessment for Aluminium, Aluminium Oxide, and Aluminium Hydroxide". *J Toxicol Environ Health B Crit Rev*. 2007; 10(Suppl 1): 1–269. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2782734/. Accessed April 10, 2019.

while recent processing and use information for this chemical is available, albeit in a very generalized manner, it does not specify the amounts of aluminum for each use, nor does it provide any quantitative value in regard to releases and/or exposures, and does not necessarily reflect processing and use activities in the U.S. Regarding potential information that could be comparable to the number of exposed workers reported under CDR, occupational employment stats are available from the Bureau of Labor Statistics, but this information is not site-specific or exposure-related.

Additionally, TRI information does not supplant CDR processing and use information. Aluminum is listed on TRI, but only in the form of fume or dust. TRI provides limited information on quantities released potentially related to the processing and use of the chemical, but not the types of exposure-related information that CDR provides. Data from the non-confidential 2012 and 2016 CDR database identified numerous industrial, consumer, and commercial uses (see Consideration F).

Given that processing and use information comparable to what is collected under CDR is not available, this weighs against granting the partial exemption.

Consideration F: Whether the potential risks of the chemical substance are adequately managed by EPA or another agency or authority.

Petitioner claims that the risks of aluminum are adequately regulated by EPA and other agencies (i.e. the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA)). EPA has recommended a Secondary Maximum Contaminant Level of 0.05 to 0.2 milligrams per liter for aluminum in drinking water. EPA regulates aluminum and certain aluminum compounds under the Clean Air Act, though they are not designated as hazardous air pollutants. OSHA has established a PEL for aluminum dust of 15 milligrams per cubic meter of air as an 8-hour time-weighted average.[8] FDA has determined that aluminum cooking utensils, aluminum foil, antiperspirants, antacids, and other aluminum products are generally safe, and has designated a number of aluminum compounds used in foods, drugs, and toiletries as generally recognized as safe.[9]

While it is true that aluminum is regulated under other federal statutes, there are significant research gaps regarding the potential effects of exposure to aluminum. These gaps include the impacts of chronic aluminum fumes or dust exposure on a worker's neurological and respiratory system; further identification of those risks may lead to future regulation. CDR processing and use information has the potential to help fill these information gaps. Therefore, it is not a certainty that the potential risks are currently adequately managed. As an example, the previously-mentioned updates to the aquatic life ambient water quality criteria recommendations provide information for states to develop science-based standards that reflect site-specific factors and are protective against the effects of aluminum on aquatic life,[10] and may result in regulations to address risks.

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[8]U.S. Department of Labor; OSHA. Permissible Exposure Limits – OSHA Annotated Table Z-1. https://www.osha.gov/dsg/annotated-pels/tablez-1.html#osha_pel1, Accessed May 13, 2019.

[9] The Aluminum Association. "RE: Partial Exemption Request for Elemental Aluminum (CASRN 7429-90-5)". December 28, 2018. Received January 30, 2019 with attachments.

[10] U.S. EPA (2018). Fact Sheet: Final 2018 Aquatic Life Ambient Water Quality Criteria for Aluminum in Freshwaters. https://www.epa.gov/sites/production/files/2018-12/documents/aluminum-criteria-final-factsheet.pdf. Accessed April 24, 2019.

This is particularly true for many of the current uses of aluminum and possibly many new uses not yet reported. For example, according to petitioner, aluminum in additive manufacturing (3D printing) is expected to grow significantly. These processes, such as Directed Energy Deposition, Powder Bed Fusion, and Sheet Lamination, would rely heavily on aluminum in both fume and dust/powder forms; typical particle size distributions for these processes is between 10 and 75 microns. Because particles smaller than 10 microns are considered respirable, this use could and result in exposures and releases.

The overall number of unique scenarios reported to CDR for processing and use has increased over time. Trend analysis was completed from the available CDR processing and use information for aluminum (2012 – 2016). The results show that even though the number of unique scenarios reported for consumer and commercial use decreased slightly from 31 to 29, the number of unique scenarios reported for industrial processing and use increased from 66 to 82.

Given that the diversity of processing and use scenarios is changing and increasing overall, the variety of potential exposure pathways, and consequently the related risk, associated with the processing and use of aluminum is changing over time. These factors indicate a continued current interest in aluminum and weigh against granting the partial exemption.

Additional Considerations:

Petitioner argues that EPA's original reasoning for denial has been resolved as reporting for aluminum (including processing and use) was conducted in 2012 and 2016. While EPA has collected processing and use information for aluminum for these two reporting cycles, there has been a stark increase in the number of processing and use scenarios, not to mention increased variability in these scenarios. As a result, exposure has changed as well. EPA continues to have interest in knowing and understanding the changes in these scenarios.

Petitioner requests that the partial exemption include imported aluminum alloys as well (to include the aluminum component and other metals making up the alloy). Alloys are considered mixtures under TSCA. The TSCA Inventory lists chemical substances, not mixtures, and the component chemical substances of a mixture would need to be reported individually (if meeting the reporting threshold). The partial exemption request pertains to the chemical substance aluminum, and thus alloys are outside the scope of the request. Each other component would require a separate petition as these substances are identified separately on the TSCA Inventory, and thus reported separately to CDR.

Petitioner claims that there are inaccuracies and challenges in CDR reporting. Petitioner claims that the 2011 and 2015 CDR data releases include inaccurate information regarding aluminum, arguing that reporting entities are sometimes reporting aluminum when an aluminum compound should be reported instead. It is unclear how this potential problem would be addressed by granting this petition for partial exemption.

Petitioner also contends that even though the 2011 CDR data release indicated that aluminum is the #2 chemical used in children's products, that is likely to be in error as it is used in some products that are marketed to children, such as juice box packaging and aluminum baseball bats, but the vast majority of products containing aluminum (e.g., aluminum cans, ladders, wheels) are

not specifically intended or marketed for use by children age 14 or younger. Petitioner asserts that this is an example of how difficult it is to draw sound conclusions regarding aluminum from the CDR data. Any argument of this sort does not get to the heart of whether a chemical's processing and use information is of low current interest to EPA.

The petitioner identifies that CDR's Industrial Function Category codes are not well suited to materials like aluminum. EPA has received other feedback concerning CDR's Industrial Function Category codes. As a result of this input from submitters, in EPA's currently proposed TSCA section 8(a) CDR Revisions Rule (84 FR 17692, April 25, 2019), EPA proposes to harmonize these category codes with the Organisation for Economic Co-operation and Development's (OECD) functional, product, and article use categories, expanding the function categories from the 35 codes currently used by CDR to 117 codes. Harmonizing CDR use codes with the OECD codes would provide submitters to CDR with international uniformity in use and exposure information reporting. This would not only enable submitters to streamline their different country-specific reporting requirements, but also would allow for more tailored reporting, which may address the concerns described in the petition.

Conclusion: EPA has determined that the Agency does not have a low current interest in the processing and use information collected under the CDR rule for aluminum. EPA considered the information included in the petition, but ultimately determined it to be insufficient for EPA's needs. EPA continues to maintain interest in the processing and use information for aluminum. This determination is based on the totality of information available for the chemical substance, including an evaluation of all the considerations listed in 40 CFR 7l1.6(b)(2)(ii), and additional considerations petitioner noted.

In reviewing this petition and available supplementary information in regard to the Agency's current interest in the processing and use information of aluminum, EPA determined that:

- The inhalation of fume or dust forms of aluminum may result in respiratory and neurological problems and the substance may also be harmful to aquatic organisms (primarily fish);
- Research gaps exist and may require CDR processing and use information;
- Risk screening information complementary to CDR is insufficient or does not exist;
- Processing and use information comparable to what CDR provides is not available from other sources;
- There is not enough evidence supporting that the potential risks are already adequately managed; and
- Based on trend analysis of available processing and use information, many uses for aluminum exist and possibly many new uses have not yet been reported. These new, unreported uses are important for EPA to know. The number of unique scenarios reported to CDR, and therefore the variety of potential exposure pathways, for aluminum's industrial processing and use has changed and increased considerably over time (2012 – 2016).