

Prepublication Copy Notice:

The Director of Pollution Prevention and Toxics signed the following *Federal Register* document on March 22, 2016:

Title: **Partial Exemption of Certain Chemical Substances from Reporting Additional Chemical Data**
Action: Final Rule
FRL: 9941-19
Docket No.: **EPA-HQ-OPPT-2014-0809**

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 711

[EPA-HQ-OPPT-2014-0809; FRL-9941-19]

Partial Exemption of Certain Chemical Substances from Reporting Additional Chemical Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the list of chemical substances that are partially exempt from reporting additional information under the Chemical Data Reporting (CDR) rule.

EPA has determined that, based on the totality of information available on the chemical substances listed in this final rule, there is a low current interest in their CDR processing and use information. EPA reached this conclusion after considering a number of factors, including the risk of adverse human health or environmental effects, information needs for CDR processing and use information, and the availability of other sources of comparable processing and use information.

DATES: This final rule is effective [*insert date of publication in the Federal Register*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0809, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The

telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

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TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute at 15 U.S.C. 2602(7) to include import) the chemical substances contained in this rule. The North American Industrial Classification System (NAICS) codes provided here are not intended to be exhaustive, but rather provide a guide to help readers determine whether this document applies to them. Potentially affected entities may include chemical manufacturers subject to CDR reporting of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

II. Background

A. What Action is the Agency Taking?

This partial exemption eliminates an existing reporting requirement under 40 CFR 711.6(b)(2). EPA is adding the following chemical substances to the list of chemical substances that are exempt from reporting the information described in 40 CFR 711.15(b)(4): Fatty acids, C14-18 and C16-18 unsaturated, methyl esters (Chemical Abstract Services Registry Number (CASRN) 67762-26-9); fatty acids, C16-18 and C-18 unsaturated, methyl esters (CASRN 67762-38-3); fatty acids, canola oil, methyl esters (CASRN 129828-16-6); fatty acids, corn oil, methyl esters (CASRN 515152-40-6); fatty acids, tallow, methyl esters (CASRN 61788-61-2); and soybean oil, methyl esters (CASRN 67784-80-9). However, by existing terms at 40 CFR 711.6, this partial exemption will become inapplicable to a subject chemical substance in the event that the chemical substance later becomes the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of the Toxic Substances Control Act (TSCA); an enforceable consent agreement (ECA) developed under the procedures of 40 CFR part 790; an order issued under TSCA section 5(e) or 5(f); or relief that has been granted under a civil action under TSCA section 5 or 7.

In the January 27, 2015 **Federal Register** (80 FR 4482)(FRL-9921-56), EPA published a direct final rule to add these six chemical substances to the list of chemical substances that are partially exempt from reporting additional information under the CDR rule. EPA received one adverse comment that was pertinent to all six of the chemical substances that were the subject of that direct final rule. In accordance with the procedures described in the January 27, 2015 **Federal Register** document, EPA withdrew the direct final rule, and subsequently proposed to add the six chemical substances to the list of chemical substances that are partially exempt from reporting

additional information under the CDR rule in the July 22, 2015 **Federal Register** (80 FR 43383) (FRL- 9928–99). EPA received one comment on the proposed rule. Before taking final action, EPA considered both the comment it received in response to the direct final rule and the comment it received in response to the proposed rule. A full discussion of EPA's responses to these comments is included in Unit V. of this document.

B. What is the Agency's Authority for Taking this Action?

This action is finalized under the authority of TSCA, 15 U.S.C. 2600 *et seq.*, to carry out the provisions of section 8(a), 15 U.S.C. 2607(a). TSCA section 8(a) authorizes EPA to promulgate rules under which manufacturers of chemical substances and mixtures must submit such information as the Agency may reasonably require. The partial exemption list was established in 2003 (Ref. 1) and can be found in 40 CFR 711.6.

Consistent with section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, EPA is finalizing this action based on public notice and opportunity to comment afforded by the July 22, 2015 proposed rule. Under section 553(d)(1) of the APA, the Agency may make a rule immediately effective "which grants or recognizes an exemption or relieves a restriction." EPA has determined that this action "relieves a restriction" by creating a partial exemption from CDR reporting, without creating any new reporting or recordkeeping requirements, and that this action will be effective immediately upon publication in the **Federal Register**.

C. Why is the Agency Taking this Action?

This rule is in response to a petition EPA received for these chemical substances (Refs. 2 and 3) submitted under 40 CFR 711.6(b)(2)(iii)(A). EPA reviewed the information put forward in the petition and additional information against the

considerations listed at 40 CFR 711.6(b)(2)(ii). EPA's chemical substance-specific analysis is detailed in supplementary documents available in the docket under docket ID number EPA-HQ-OPPT-2014-0809 (Refs. 4, 5, 6, 7, 8, and 9). The Agency is adding these chemical substances to the partially exempt chemical substances list because it has concluded that, based on the totality of information available, the CDR processing and use information for these chemical substances is of low current interest.

D. What are the Impacts of this Action?

There are no costs associated with this action and the benefits provided would be related to avoiding potential costs. This partial exemption eliminates an existing reporting requirement without imposing any new requirements. See also the discussion in Unit VI.

III. Petition Process and “Low Current Interest” Partial Exemption

In 2003 (Ref. 1), EPA established a partial exemption for certain chemical substances for which EPA determined the processing and use information required in 40 CFR part 711 to be of “low current interest.” That provision establishes a particular procedure whereby the public may petition EPA to add or remove a chemical substance to or from the list of partially exempt chemical substances. In determining whether the partial exemption should apply to a particular chemical substance, EPA considers the totality of information available for the chemical substance in question, including but not limited to information associated with one or more of the considerations listed at 40 CFR 711.6(b)(2)(ii).

The addition of a chemical substance under this partial exemption will not necessarily be based on its potential risks. The addition is based on the Agency's current assessment of the need for collecting CDR processing and use information for that

chemical substance, based upon the totality of information available during the petition review process. Additionally, interest in a chemical substance or a chemical substance's processing and use information may increase in the future, at which time EPA will reconsider the applicability of a partial exemption for a chemical substance.

IV. Rationale for These Partial Exemptions

EPA is granting a partial exemption for: Fatty acids, C14-18 and C16-18 unsaturated, methyl esters (CASRN 67762-26-9); fatty acids, C16-18 and C-18 unsaturated, methyl esters (CASRN 67762-38-3); fatty acids, canola oil, methyl esters (CASRN 129828-16-6); fatty acids, corn oil, methyl esters (CASRN 515152-40-6); fatty acids, tallow, methyl esters (CASRN 61788-61-2); and soybean oil, methyl esters (CASRN 67784-80-9) because the Agency has concluded it has low current interest in the processing and use information for these chemical substances. EPA made these determinations based on its analysis of the totality of information available on the six chemical substances, including information about the chemical substances relevant to the considerations defined at 40 CFR 711.6(b)(2)(ii). EPA's chemical substance-specific analysis is detailed in supplementary documents available in the docket under docket ID number EPA-HQ-OPPT-2014-0809 (Refs. 4, 5, 6, 7, 8, and 9).

V. Response to Comment

The Agency reviewed and considered both comments received related to the direct final rule and the proposed rule.

Comment 1: The commenter states that methyl esters can degrade to methanol, and provides references to support this statement. The commenter questioned how the

possible existence of methanol from methyl esters can be ignored as “a hazard for human health and the environment.”

EPA Response: EPA is aware that some methanol may be formed when methyl esters degrade. However, under both aerobic and anaerobic conditions, such methanol is itself rapidly degraded (Ref. 10). Therefore, EPA does not expect exposure to methanol from use of the six biofuels included in this petition for partial exemption. Note also that the inclusion of a chemical substance under this partial exemption is not a determination on the potential risks of a chemical substance. Rather, it is a determination that there is a low current interest in CDR processing and use information for that substance. Hazard alone is not determinative of the level of interest in such information. Other pertinent factors include the information needs of various parties and the current availability of comparable processing and use information. The commenter did not assert that he had a particular need for additional CDR information about the processing and use of these chemical substances. Nor did he dispute EPA’s characterization of the currently available processing and use information. If the level of interest in the CDR processing and use information for any listed chemical substance were to change after final listing, EPA may reevaluate the listing decision and pursue amendment of the listing as appropriate.

Comment 2: The Biobased and Renewable Advocacy Group (BRAG), the group that submitted the petitions to EPA for these chemical substances, submitted a comment on the proposed rule in support of adding these chemical substances to the list at 40 CFR 711.6(b)(2)(iv). BRAG’s comment stated that these chemical substances should be treated similarly to the petroleum products included in 40 CFR 711.6(b)(1) due to the conditions of manufacture and the properties and uses of the substances. The commenter

also notes that based on the considerations listed at 40 CFR 711.6(b)(2)(ii) “a partial reporting exemption does not require that EPA determine that an affected substance poses neither hazard nor toxicity.”

EPA Response: This partial exemption decision is based on the considerations described under 40 CFR 711.6(b)(2)(ii). EPA has made no determination whether any of the six chemical substances should be, as the commenter BRAG suggested, treated similarly to the petroleum products included in 40 CFR 711.6(b)(1) due to the conditions of manufacture and the properties and uses of the substances. This latter issue is moot because equivalent partial exemptions are being granted under 40 CFR 711.6(b)(2)(ii).

EPA agrees that in this action it is not making a determination of the potential risks of the six chemical substances.

VI. Economic Impacts

EPA has evaluated the economic consequences associated with amending the CDR partially exempt chemical substances list. Since this final rule creates a partial exemption from CDR reporting, without creating any new reporting or recordkeeping requirements, this action does not impose any new burden. Based on the currently approved Information Collection Request (ICR), the burden estimates for reporting processing and use information total 65.63 hours with an associated cost of \$4,367 per submission. Based on 2012 CDR reporting, EPA estimates that 61 submissions with manufacture volumes of 25,000 pounds or greater will be received for these chemical substances in 2016 and subsequent reporting years.

Eliminating the requirement to report processing and use information for these submissions results in a total burden savings of approximately 4,003 hours and \$266,387 in future reporting cycles (Ref. 11).

VII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Inventory Update Rule Amendments; Final Rule. **Federal Register** (68 FR 848, January 7, 2003) (FRL-6767-4).
2. Letter from Biobased and Renewable Products Advocacy Group, to EPA, OPPT CDR Submission Coordinator, October 21, 2014. Docket ID number EPA-HQ-OPPT-2014-0809, regarding request for exemption of biodiesel products.
3. Letter from Biobased and Renewable Products Advocacy Group, to EPA, OPPT CDR Submission Coordinator, November 5, 2014. Docket ID number EPA-HQ-OPPT-2014-0809, supplement to request for exemption of biodiesel products.
4. EPA, OPPT. Fatty acids, C14-18 and C16-18 unsaturated, methyl esters (CASRN 67762-26-9) Partial Exemption Analysis. December 2014.
5. EPA, OPPT. Fatty acids, C16-18 and C-18 unsaturated, methyl esters (CASRN 67762-38-3) Partial Exemption Analysis. December 2014.

6. EPA, OPPT. Fatty acids, canola oil, methyl esters (CASRN 129828-16-6) Partial Exemption Analysis. December 2014.
7. EPA, OPPT. Fatty acids, corn oil, methyl esters (CASRN 515152-40-6) Partial Exemption Analysis. December 2014.
8. EPA, OPPT. Fatty acids, tallow, methyl esters (CASRN 61788-61-2) Partial Exemption Analysis. December 2014.
9. EPA, OPPT. Soybean oil, methyl esters (CASRN 67784-80-9) Partial Exemption Analysis. December 2014.
10. OECD (Organization for Economic Co-operation and Development). 2004. SIDS (Screening Information Data Set) Initial Assessment Report: Methanol. SIAM 19. Berlin, Germany, 18-20 October, 2004.
11. EPA, OPPT. Cost Savings Estimate of Adding Six Chemicals to the 40 CFR 711.6(b)(2)(iv) List of Chemical Substances. December 2015.

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866, October 4, 1993 (58 FR 51735) and 13563, January 21, 2011 (76 FR 3821).

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection requirements that would require additional review or approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.*

The information collection requirements related to CDR have already been approved by OMB pursuant to the PRA under OMB control number 2070-0162 (EPA ICR No. 1884.08). Since this action creates a partial exemption from that reporting, without creating any new reporting or recordkeeping requirements, this action does not impose any new burdens that require additional OMB approval.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C § 601 *et seq.* In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden effect or otherwise has a positive economic effect on the small entities subject to the rule.

As indicated previously, EPA is eliminating an existing reporting requirement for the chemical identified in this document. In granting a partial exemption from existing reporting, this final rule does not have a significant economic impact on any affected entities, regardless of their size.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. In granting a partial exemption from existing reporting, this action

imposes no new enforceable duty on any State, local or tribal governments, or on the private sector. In addition, based on EPA's experience with chemical data reporting under TSCA, State, local, and Tribal governments are not engaged in the activities that would require them to report chemical data under 40 CFR part 711. Accordingly, this action is not subject to the requirements of UMRA, 2 U.S.C. 1501 *et seq.*

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132, August 10, 1999 (64 FR 43255). It will not have substantial direct effects on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175, November 9, 2000 (65 FR 67249). This action will not have any effect on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Thus Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045, April 23, 1997 (62 FR 19885) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of

“covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, May 22, 2001 (66 FR 28355), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act (NTTAA)

This action does not involve any technical standards that would require the consideration of voluntary consensus standards pursuant to NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not involve special considerations of environmental justice related issues as specified in Executive Order 12898, February 16, 1994 (59 FR 7629). This action does not address human health or environmental risks or otherwise have any disproportionate high and adverse human health or environmental effects on minority or low-income or indigenous populations.

IX. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major” rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 711

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: MAR 22 2016

A handwritten signature in black ink, reading "Wendy C. Hamnett", written over a horizontal line.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR chapter I is amended as follows:

PART 711--[AMENDED]

1. The authority citation for part 711 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

2. In § 711.6, add in numerical order by CASRN number the following entries to Table 2 in paragraph (b)(2)(iv).

§ 711.6 Chemical substances for which information is not required.

	*	*	*	*	*
(b)		*	*	*	
(2)		*	*	*	
(iv)		*	*	*	

Table 2. -- CASRN of Partially Exempt Chemical Substances

CASRN	Chemical
* * *	* * * *
61788-61-2	Fatty acids, tallow, methyl esters
* * *	* * * *
67762-26-9	Fatty acids, C14-18 and C16-18 unsaturated, methyl esters
67762-38-3	Fatty acids, C16-18 and C-18 unsaturated, methyl esters
67784-80-9	Soybean oil, methyl esters
* * *	* * * *
129828-16-6	Fatty acids, canola oil, methyl esters
515152-40-6	Fatty acids, corn oil, methyl esters