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October 21, 2014

Via Federal Express

OPPT CDR Submission Coordinator
Mailcode: 7407M
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Petition for Partial Exemption of Biodiesel Products

Dear Sir or Madam:

The Biobased and Renewable Products Advocacy Group (BRAG[®])¹ submits this petition to amend the Chemical Data Reporting (CDR) partially exempted chemical list at 40 C.F.R. Section 711.6(b)(2)(iv). Specifically, BRAG petitions to add “biodiesel” as a chemical category for partial exemption with the following chemicals and associated Chemical Abstracts Service Registry Numbers (CASRN) included:

- Tallow, Methyl Ester: CASRN 61788-61-2;
- Soy Oil, Methyl Ester: CASRN 67784-80-9;
- Fatty acids, corn-oil, Me esters: CASRN 515152-40-6;
- Fatty acids, C16-18 and C18-unsaturated, Me esters: CASRN 67762-38-3; and
- Fatty acids, C14-18 and C16-18-unsaturated, Me esters, CASRN 67762-26-9.

¹ BRAG provides a platform for organizations engaged in biobased chemistries to identify regulatory barriers for their unique products and to work collectively to address them. BRAG tackles regulatory hindrances related to commercialization of biobased products and works to improve public awareness of the benefits of these products.

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Background

The U.S. Environmental Protection Agency (EPA) maintains two lists of partially exempted chemicals for which manufacturers are exempt from reporting the processing and use information required by 40 C.F.R. Section 711.15(b)(4).

One list of partially exempted chemicals is found at 40 C.F.R. Section 711.6(b)(2)(iv), hereafter referred to as the (b)(2) List. EPA has stated that CDR processing and use information for chemicals on this list is of “low current interest.” EPA has established a formal petition process for amending the (b)(2) List in which EPA will issue a written response to the petition within 120 days of receipt. The petition process enables stakeholders to add chemicals to the (b)(2) List, but only after EPA has reviewed relevant information, including potential toxicity data, and determined there is low current interest in the processing and use information for that substance.

The other list, found at 40 C.F.R. Section 711.6(b)(1), referred to as the (b)(1) List, consists primarily of petroleum process streams that were exempted via a rulemaking process based on proposals submitted by the American Petroleum Institute (API). In the final rule adding the petroleum process exemption, EPA stated the following:

The basis for this exemption is not because these streams are of known low toxicity. EPA believes that the chemicals termed “petroleum process streams” for purposes of IURA are often toxicologically active. However, these chemicals are frequently processed at the site where they are produced in vessels which are designed to minimize losses and, coincidentally, the potential for releases and exposure. In many cases, the flammable nature of these products requires that they also be transported, processed, and stored in well controlled vessels. For these reasons, EPA believes worker exposure to the chemicals termed “petroleum process streams” for purposes of IURA is diminished and thus full IURA exposure-related reporting is not warranted at this time.²

There is no specified petition process to amend the (b)(1) List.

² 68 Fed. Reg. 848 (Jan. 7, 2003).



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Biodiesel is used in conjunction with or as a replacement for petroleum-derived diesel fuel (CASRN 68334-30-5) and diesel fuel number 2 (CASRN 68334-30-5), both of which are included on the (b)(1) List. Similar to currently exempted products included in the (b)(1) List, the biodiesel products in this petition are not of known low toxicity and can be toxicologically active. Notwithstanding, biodiesel products are a specific group of substances that are treated similarly to the petroleum products included in the (b)(1) List due to the conditions of manufacture and the properties and uses of the substances. Just like petroleum products, the biodiesel products included in this petition are transported, processed, and maintained in vessels to minimize losses that result in a low potential for release and exposure. Similar to the conclusions reached by EPA for the currently exempt petroleum products on the (b)(1) List, worker exposure to the listed biodiesel products for purposes of CDR is diminished and full CDR reporting is not warranted.

BRAG believes that adding biodiesels to the (b)(1) List is necessary to ensure equitable regulatory treatment of chemical substances of comparable release and exposure potential, and to avoid EPA providing regulatory relief to one subset of diesel products over another -- even though both meet the decision conditions identified by EPA in its final rulemaking to amend the (b)(1) List. Indeed, given EPA's stated objectives and interest in sustainable technologies in general, and ongoing programs that engage biodiesel producers in particular, the actions outlined in this petition are appropriate.

For the reasons listed above, BRAG believes it would be more appropriate to petition for biodiesel to be added to the (b)(1) List. As noted, however, there is no petition process to amend the (b)(1) List. While BRAG is proceeding with a request for a rulemaking to add biodiesel to the (b)(1) List via a Section 21 citizen's petition, the reality is that final EPA response under this approach could take many months, if not years, to proceed to completion.

Because timing is critical, BRAG is also submitting this petition to amend the (b)(2) List, recognizing that EPA is required to respond to the petition request within 120 days.



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Petition Elements

As identified in 40 C.F.R. Section 711.6(b)(2)(ii), EPA is required to consider the following information in determining whether a partial exemption should apply:

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

Information on each of these considerations is provided below.



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Qualification for Previous CDR Reporting

Based on information derived from the EPA Chemical Data Access Tool (CDAT, available at http://java.epa.gov/oppt_chemical_search/), all of the chemicals in this petition qualified for reporting under the 2012 CDR. Public information on national production volumes and number of reporting entities is as follows:

- Tallow, Methyl Ester: CASRN 61788-61-2
National Production Volume: 418,370,092 pounds, with nine companies reporting
- Soy Oil, Methyl Ester: CASRN 67784-80-9
National Production Volume: 3,094,877,961 pounds, with 23 companies reporting
- Fatty acids, corn-oil, Me esters: CASRN 515152-40-6
National Production Volume: WITHHELD, with one company reporting
- Fatty acids, C16-18 and C18-unsaturated, Me esters: CASRN 67762-38-3
National Production Volume: 602,936,770 pounds, with 15 companies reporting
- Fatty acids, C14-18 and C16-18-unsaturated, Me esters: CASRN 67762-26-9
National Production Volume: 1,000,000,000 - 5,000,000,000 pounds, with 11 companies reporting.

Physical/Chemical Properties and Health/Environmental Effects

Petitioners are not advocating that the subject chemicals are non-hazardous or non-toxic. Because of the nature of the chemicals and potential toxicity concerns, specific exposure controls and worker protections are in place to minimize potential releases. Because similar exposure controls and worker protection approaches were sufficient for EPA to determine petroleum process streams in the (b)(1) List should receive partial reporting exemptions, the same rationale for partial reporting exemption should be applied to the chemicals listed in this petition.

A compilation of available information related to the physical and chemical properties and health and environmental effects derived from registration dossiers for the



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European Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program and other publicly available sources is provided in Appendix 1. The petitioners note that EPA has additional information for health and safety of biodiesel on its website (Biofuels Compendium -- Biodiesel -- Handling, *see* <http://www.epa.gov/oust/altfuels/biohdl.htm>), as well as a presentation “Biofuels in the Environment: A Review of Behaviors, Fates and Effects & Remediation Techniques,” on its Office of Solid Waste and Emergency Response website (*see* <http://www.epa.gov/osweroe1/docs/oil/fss/fss09/hollebonebiofuels.pdf>). A summary of data for Soy Oil, Methyl Ester (CASRN 67784-80-9) was prepared for the National Toxicology Program (*see* http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/methylsoyate_508.pdf). Petitioners further note that a category related to the substances in this petition was the subject of international review under the Organization for Economic Cooperation and Development (OECD) Cooperative Chemicals Assessment Meeting (CoCAM) in October 2014.

Information Needs of EPA, Other Agencies, and Public

With the ongoing government dialogue concerning biofuels, including biodiesel, there is and will continue to be significant interest in biodiesel substances and this level of interest will result in identification of information needs. Nonetheless, the screening level process and use information collected under CDR will likely be of little use within this debate. Moreover, information can and is being collected under other programs. (*See Availability of Comparable Processing and Use Information below.*)

Availability of Complementary Risk Screening Information

EPA has access to risk screening information for the subject chemicals as follows:

- Tallow, Methyl Ester: CASRN 61788-61-2 -- Screened under the categorization of the Canadian Domestic Substances List (DSL)
- Soy Oil, Methyl Ester: CASRN 67784-80-9 -- Risk screening conducted as part of the Design for the Environment (DfE) program under Safer Chemical Ingredients for Use in DfE-Labeled products
- Fatty acids, corn-oil, Me esters: CASRN 515152-40-6 -- Risk screening conducted under Section 5 new chemical review
- Fatty acids, C16-18 and C18-unsaturated, Me esters: CASRN 67762-38-3 -- Risk screening conducted under Safer Chemical Ingredients for Use in DfE-Labeled Products



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- Fatty acids, C14-18 and C16-18-unsaturated, Me esters: CASRN 67762-26-9

Availability of Comparable Processing and Use Information

The collection of information on processing and use of biodiesel under CDR is not necessary for EPA, other agencies, or the general public, as relevant information collection and reporting already occurs under other federal programs. Information on the production and use of biodiesel is currently collected, maintained, and publicly reported by the U.S. Energy Information Administration (EIA). EIA issues a monthly biodiesel production report that provides data on the U.S. biodiesel industry, including plant locations, production volumes, and sales of biodiesel to end-users. There are also other reports on biofuels, including biodiesel, generated by EPA and the U.S. Department of Agriculture (USDA).

Management of Potential Risks

The manufacture and processing of these substances uses continuous closed systems, and regulations require transport and storage to occur in well-controlled vessels. These process controls to reduce potential for releases and exposures are similar to those implemented for the petroleum process streams listed at (b)(1), for which EPA determined full CDR reporting was not warranted.

BRAG members look forward to the opportunity to respond to any questions that EPA may have regarding this petition and to EPA's response to the petition request. Please call me at 443-964-4653 or e-mail me at kroberts@bc-cm.com for further information or to schedule a meeting.

Sincerely,

A handwritten signature in black ink that reads "Kathleen M. Roberts". The signature is written in a cursive, flowing style.

Kathleen M. Roberts
BRAG Executive Director

Attachment