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By email to morris.jeff@epa.gov

August 31, 2016

Dr. Jeff Morris (7401M)
Environmental Protection Agency
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1200 Pennsylvania Avenue, N.W.
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Re: Impact of TSCA Reform on EPA Evaluation of MCCPs and LCCPs

Dear Jeff:

I have enclosed a memorandum on the process EPA should use going forward to evaluate mid- and long-chain chlorinated paraffins (MCCPs and LCCPs) under the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Chemical Safety Act (LCSA). This purpose of this memorandum is to follow up on our meeting on June 27 with you and other representatives from OPPT and OGC, and my June 30 letter addressed to Avi Garbow. The June 30 letter identified some ways in which the newly amended TSCA will affect EPA's review of MCCPs and LCCPs. The attached memorandum provides a more comprehensive explanation.

In summary, the memorandum discusses the following:

- The current draft risk assessments of MCCP and LCCP fail to meet the new scientific criteria in section 26(h) and (i). The current draft assessments must be revised to meet these new scientific standards and subjected to peer review. The new scientific requirements of the LCSA increase the importance of external peer review of the draft risk assessments.
- In light of the new language on statutory mixtures, section 8(b)(3)(A)(iii), EPA's historic reliance on two categorical entries for chlorinated paraffins on the TSCA Inventory means that each individual chemical substance covered by those categories is to be regarded as on the TSCA Inventory. It is not appropriate for EPA to continue to regard MCCPs and LCCPs as new chemical substances subject to section 5.
- The new provision on initial risk evaluations and subsequent designations of high- and low-priority substances, section 6(b)(2), directs EPA to address the chemical substances and categories listed on the 2014 update to the TSCA Work Plan chemicals under the



section 6 process. MCCPs and LCCPs are on that 2014 Work Plan list. Accordingly, EPA should address them under the new section 6.

- EPA must ensure that the MCCP and LCCP risk assessments meet all applicable requirements of section 6(b) and 26.

Please let me know if you would like to discuss the ACC positions reflected in this paper.

Sincerely,



Christina Franz
Senior Director, Regulatory & Technical Affairs

Enclosure

Cc: Maria Doa
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Impact of TSCA Reform on EPA Review of MCCPs and LCCPs

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EXECUTIVE SUMMARY

Enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act¹ has changed how EPA must evaluate mid- and long-chain chlorinated paraffins (MCCPs and LCCPs) under the Toxic Substances Control Act (TSCA). In particular:

- EPA must establish that the MCCP and LCCP risk assessments meet the new scientific standards in sections 26(h) and (i). The current draft risk assessments do not appear to meet the science standards and will need to be revised. The new standards also increase the importance external peer review of EPA's draft risk assessments on MCCPs and LCCPs.
- EPA has been relying on section 5 to address MCCPs and LCCPs, on the basis that it does not consider them to be on the TSCA Inventory. However, section 8(b)(2) and section 26(c)(1) authorize EPA to add categories of chemicals to the TSCA Inventory, which EPA did with two categorical CAS numbers, CAS No. 61788-76-9, Alkanes, chloro, and CAS No. 63449-39-8, Paraffin waxes and Hydrocarbon waxes, chloro. New section 8(b)(3)(A)(iii) clarifies that EPA must consider all members of such Inventory-listed categories to be on the TSCA Inventory. This clarification suggests that MCCPs and LCCPs are existing chemical substances properly listed on the Inventory, and should be addressed under section 6. Section 5 is not appropriate to address these chemical substances.
- New section 6(b)(2) provides strong direction to EPA to address chemical substances listed on the 2014 update to the list of TSCA Work Plan chemical substances and categories under section 6 (not section 5). MCCPs and LCCPs are included on the 2014 update of the Work Plan chemical list, so EPA should address them under section 6.
- The MCCP and LCCP risk assessments must meet all applicable requirements for risk evaluations set forth in new sections 6 and 26.

DISCUSSION

1. The New Science Standards Require EPA to Revise Its Draft Risk Assessments of MCCPs and LCCPs and Increase the Importance of External Peer Review

EPA must base its risk evaluations and regulatory decisions on information consistent with the best available science and on the weight of the scientific evidence, as prescribed in new sections 26(h) and (i). EPA's science-based decision under section 6 about whether or not to regulate MCCPs and LCCPs must be based on its risk evaluations, as required by section 6(b)(4)(A). Accordingly, the final versions of the draft risk assessments on MCCPs and LCCPs that were made available for public comment² must be consistent with the best available science outlined

¹ The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSEA), Public Law 114-182 (June 22, 2016). References to sections in this memorandum are to TSCA as amended by the LCSEA.

² 80 Fed. Reg. 79886 (Dec. 23, 2015); 81 Fed. Reg. 8712 (Feb. 22, 2016).

in section 26(h)³ and based on the weight of the scientific evidence, as provided in new section 26(i).⁴

The American Chemistry Council (ACC) and a coalition of trade groups submitted detailed comments on the draft MCCP and LCCP risk assessments to the docket. In those comments, the coalition noted the various ways in which EPA had failed to use the best available science and apply a weight of the evidence approach. Summarizing those comments briefly here, had EPA used the best available science and applied a weight of the evidence approach, the available data provides an adequate basis for concluding the following:

- The physiochemical properties of MCCPs and LCCPs, such as very low ambient vapor pressure and very low water solubility, limit the potential for the release of significant quantities of these substances to the environment, particularly to surface water or air.
- Information from the manufacturers and downstream users of these substances indicates that there are not the release pathways to water for MCCPs and LCCPs that EPA assumed in the draft risk assessments.
- Use applications are well defined and controlled. Many of the uses are in applications that are water-sensitive and therefore do not present a likely release pathway to water.
- Exceedances of EPA's concentrations of concern in environmental surface water or sediment do not appear to be occurring in the U.S. An EPA-led binational effort on chemicals of interest in the Great Lakes has shown levels of chlorinated paraffins in the Great Lakes to be dropping over time in recent years.
- Conclusions regarding the PBT characteristics of MCCPs and LCCPs are overstated in the risk assessments and EPA failed to make a weight-of -the-evidence evaluation of the available data.

³ Section 26(h) provides, "In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models."

⁴ Section 26(i) provides, "The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence."

Indeed, our comments and those of others submitted on the draft risk assessments raised substantial questions about whether the risk assessments would meet the new scientific criteria under consideration at the time the docket was open to receive comments.

A number of the comments also requested EPA to provide for external peer review of the drafts. To ensure that the final risk evaluations meet the requirements of section 26(h) and (i), EPA itself should review the comments received; revise the assessments to ensure they rely on the best available science and scientific weight of the evidence; call on qualified external peer reviewers to provide an independent judgment about the scientific quality of the drafts; and revise the assessments as warranted to incorporate the comments of the peer reviewers.

2. The Statutory Mixtures Provision Requires EPA to Regard All MCCPs and LCCPs as Existing Chemicals, Making Section 5 Inapplicable

Section 8(b)(2) and section 26(c) had previously authorized EPA to establish categories on the Inventory. New section 8(b)(3)(A)(iii) directs EPA to treat all members of such categories as being on the Inventory. As previously discussed,⁵ EPA has established broad categories for chlorinated paraffins that cover MCCPs and LCCPs. The new language means that EPA must consider all MCCPs and LCCPs to be on the Inventory. Consequently, it is inappropriate for EPA to evaluate and regulate MCCPs and LCCPs under section 5.

a. EPA Added Chlorinated Paraffins to the Inventory as a Category

Section 8(b)(2) authorizes EPA to list categories on the Inventory:

To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

EPA has listed several categories on the Inventory, including the following, among others:

Cement, Portland, Chemicals, CAS No. 65997-15-1
Cement, Alumina, Chemicals, CAS No. 65997-16-2
Glass, Oxide, Chemicals, CAS No. 65997-17-3
Frits, Chemicals, CAS No. 65997-18-4
Steel Manufacture, Chemicals, CAS No. 65997-19-5
Ceramic Materials and Wares, Chemicals, CAS No. 66402-68-4

EPA explained why it listed those categories:

When the initial Inventory was being developed, both EPA and industry recognized that the individual substances comprising these mixtures are complex solids and would be very difficult to identify. Therefore, instead of requiring industry to identify and report every such substance for the Inventory, several special categories were created to include

⁵ See ACC's letter to Avi Garbow captioned "Status of Chlorinated Paraffins as a Category Under Sections 8(b)(2) and 26(c) of TSCA" (Feb. 25, 2016).

the various substances formed when cement, glass, frit or ceramic are produced. These categories were reported during the initial Inventory reporting period and are currently listed on the TSCA Inventory.⁶

For the same reasons, EPA added the following categories for chlorinated paraffins to the TSCA Inventory:

Alkanes, chloro, CAS No. 61788-76-9

Paraffin waxes and Hydrocarbon waxes, chloro, CAS No. 63449-39-8

These non-specific names make no attempt to describe an individual chemical substance. Instead, their broad coverage constitutes overlapping categories of chlorinated paraffins, including MCCPs and LCCPs.

EPA has repeatedly referred to “chlorinated paraffins” or to one or both of those CAS numbers as a category for TSCA purposes. Examples include the following:

- 1977: The Interagency Testing Committee’s Initial Report to EPA recommended testing of “chlorinated paraffins,” 42 Fed. Reg. 55026 (Oct. 12, 1977). The description stated, “This category is comprised of mixtures of chlorination products of materials known commercially as paraffin oils or paraffin waxes; those having a chlorine content of 35% through 64% by weight are included.”
- 1978: EPA included “chlorinated paraffins” in a proposed section 8(d) rule, 43 Fed. Reg. 4073 (Jan. 31, 1978), and a final section 8(d) rule, 43 Fed. Reg. 30984 (July 18, 1978). The preamble to the proposed rule recognized that the ITC had recommended the “category” of chlorinated paraffins.
- 1979: EPA included “chlorinated paraffins” in a proposed section 8(d) rule, 44 Fed. Reg. 77470 (Dec. 31, 1979).
- 1982: EPA included both CAS numbers in a final section 8(d) rule, 47 Fed. Reg. 38780 (Sept. 2, 1982).
- 1985: EPA included both CAS numbers in a proposed section 8(d) rule, 50 Fed. Reg. 39715 (Sept. 30, 1985). The listing was in the “category” section of the rule, rather than in the “substance” section of the rule.
- 1986: EPA included both CAS numbers in a final section 8(d) rule, 51 Fed. Reg. 32720 (Sept. 15, 1986). The listing was in the “category” section of the rule, rather than in the “substance” section of the rule.

⁶ EPA, “Products Containing Two or More Substances, Formulated and Statutory Mixtures on the TSCA Inventory” (1995), <https://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf>.

- 2005: The Interagency Testing Committee’s 55th Report recommended testing of CAS No. 61788-76-9 under section 4, 70 Fed. Reg. 7364 (Feb. 11, 2005). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.
- 2006: EPA added CAS No. 61788-76-9 to the section 8(a) PAIR rule, 71 Fed. Reg. 47122 (Aug. 16, 2006). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.
- 2006: EPA added CAS No. 61788-76-9 to the section 8(d) rule, 71 Fed. Reg. 47130 (Aug. 16, 2006). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.
- 2010: EPA proposed to require testing of CAS No. 61788-76-9 under section 4, 75 Fed. Reg. 857502 (Feb. 25, 2010). The action reflected classification of Alkanes, chloro as an orphan HPV chemical.

For these reasons and others addressed in our February 25, 2016, letter to Avi Garbow, EPA did add those CAS numbers to the TSCA Inventory as categories, rather than as entries for ambiguously-defined individual chlorinated paraffins.

b. Individual Members of Inventory-Listed Chemicals Are on the Inventory by Virtue of the Category Listing

Section 26(c)(1)⁷ provides that actions taken with respect to categories (such as listing them on the Inventory) apply to all members of those categories:

Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

Since EPA listed several categories on the Inventory, under this provision all members of those categories should be regarded as being on the Inventory. EPA formerly took the same position.⁸

⁷ Section 26(c)(1) was not amended by the LCSA.

⁸ See, e.g., EPA, Toxic Substances Control Act (TSCA) PL 94-469 Candidate List of Chemical Substances Addendum III, Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (1978), <http://nepis.epa.gov/Exe/ZyNET.exe/20015VKF.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1976+Thru+1980&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C76thru80%5CTxt%5C00000009%5C20015VKF.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7C&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL#>, at 1 (“this addendum defines certain categories which encompass the individual chemical substances manufactured in the production of these mixtures.”).

Nevertheless, in 2007 EPA took the position that individual members of Inventory-listed categories are not themselves to be regarded as being on the Inventory:

EPA did not intend for these six chemical descriptions and CASRNs, which the Agency sometimes refers to as “statutory mixtures”, to be used to establish chemical nomenclature and determine Inventory status for actual chemical substances manufactured or imported for commercial purposes that may in a generic sense be thought of or described as either Portland cement, alumina cement, glass, frits, steel, or ceramics. The CASRNs for these “statutory mixtures” were included in the Initial Inventory for the purpose of defining the scope of these very broad categories of substances, with the expectation that particular substances or mixture components that fall within one of these categories of materials and that are intended to be commercially manufactured would be subject to TSCA reporting if they were not already explicitly listed in the Inventory.⁹

EPA announced plans to publish a “clarification” of its past, inconsistent guidance in which:

EPA will clarify which chemical substances comprise complex reaction products that fall under the “category listings” and which chemical substances (not currently on the TSCA Inventory) would be considered to be “new” chemical substances under TSCA and thus be subject to new chemical notification under TSCA Section 5.¹⁰

Since at least 2011, however, EPA has made no public statement to the effect that individual members of Inventory-listed categories are not considered to be on the Inventory.

Nevertheless, Congress felt strongly enough about this issue to add specific language to the LCSEA to nail down that individual members of Inventory-listed categories are to be considered on the Inventory themselves. New section 8(b)(3)(A)(iii) provides that, in carrying out section 8(b)(1) (i.e., the TSCA Inventory), EPA shall:

treat the individual members of the categories of chemical substances identified by the Administrator as statutory mixtures, as defined in Inventory descriptions established by the Administrator, as being included on the list established under paragraph (1).

This new statutory provision overrides any policy position EPA may have or had about whether individual members of Inventory-listed categories should be considered to be on the Inventory. Congress has spoken on the issue. Now, EPA must regard all members of Inventory-listed categories as being on the Inventory. This means that all members of the Inventory-listed categories of Alkanes, chloro and Paraffin waxes and Hydrocarbon waxes, chloro are on the TSCA Inventory. Those categories encompass all MCCPs and LCCPs. Therefore, EPA must regard MCCPs and LCCPs as existing chemical substances going forward. It is not appropriate for EPA to continue to address MCCPs and LCCPs as new chemical substances under section 5.

⁹ Letter from Tracy C. Williamson, Chief, Industrial Chemistry Branch, OPPT, to Greg McCarney, 3M Toxicology and Regulatory Services (Sept. 18, 2007) (IC-6506). See also a similar letter to Michael P. Walls, American Chemistry Council (May 28, 2008) (IC-6620).

¹⁰ Unified Agenda, RIN: 2070-AJ68 (editions of April 26, 2010; December 20, 2010; and July 7, 2011).

3. New Section 6(b) Directs EPA to Address TSCA Work Plan Chemicals and Categories, Including MCCPs and LCCPs, Under Section 6

MCCPs and LCCPs are listed in the 2014 update to the TSCA Work Plan.¹¹ Congress has provided strong direction to EPA these and the other chemical substances listed in the 2014 Update are priorities for review under the new section 6 process. As a consequence, EPA should address MCCPs and LCCPs under section 6.

Several provisions require EPA to address chemical substances and categories in the 2014 Update under section 6, including the following:

- Section 6(b)(2)(A) – By six months after enactment, EPA must be conducting risk evaluations on ten of the 2014 Update chemical substances and categories.¹²
- Section 6(b)(2)(B) – At three years and six months after enactment, at least 50% of the risk evaluations must be on 2014 Update chemical substances and categories.¹³

With this clear direction from Congress to address 2014 Update chemical substances and categories under the new section 6, EPA should announce that it will review MCCPs and LCCPs under that provision and not under section 5.

4. Congress Directed EPA to Ensure That the MCCP and LCCP Risk Assessments Meet the New Section 6(b) and 26 Requirements

EPA must ensure that the final risk assessments for MCCPs and LCCPs meet all the applicable section 6 and 26 science requirements for risk evaluations. There is no interpretation of TSCA as amended by LCSA that would permit EPA to avoid the requirements of these sections.

Among the section 6 requirements that EPA must ensure are met with respect to the risk assessments for MCCPs and LCCPs are the following:

¹¹ EPA, TSCA Work Plan for Chemical Assessments: 2014 Update (Oct. 2014) (the 2014 Update), https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf, at 16-17 (items 60 and 61). The 2014 Update lists both individual substances, such as acetaldehyde (item 1), and categories of chemical substances, such as antimony and antimony compounds (item 5).

¹² Section 6(b)(2)(A) provides, “Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.”

¹³ Section 6(b)(2)(B) provides, “Not later than three and one half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.”

- Section 6(b)(4)(D)¹⁴ – EPA must publish the scope of the risk evaluation.
- Section 6(b)(4)(F)¹⁵ – EPA must assess available information, describe whether aggregate or sentinel exposures were considered and the basis for that consideration, and describe the weight of the evidence.
- Section 6(b)(4)(A)¹⁶ – EPA must decide whether or not MCCPs and LCCPs present or do not present an unreasonable risk to health or the environment under the conditions of use.
- Section 6(b)(4)(H)¹⁷ – EPA must provide notice and opportunity for comment on draft risk evaluations before finalizing them. This should include opportunity for comment on revisions that EPA makes since the enactment the LCSA amendments.

Accordingly, before finalizing the risk assessments for MCCPs and LCCPs, EPA must ensure that it has met all of the applicable section 6 and 26 requirements.

CONCLUSION

Enactment of the LCSA altered the statutory framework for EPA’s assessment of MCCPs and LCCPs. With these statutory changes, EPA should change its approach to MCCPs and LCCPs and proceed under section 6.

¹⁴ Section 6(b)(4)(D) provides, “The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.”

¹⁵ Section 6(b)(4)(F) provides, “In conducting a risk evaluation under this subsection, the Administrator shall—
 (i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;
 (ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;
 (iii) not consider costs or other nonrisk factors;
 (iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
 (v) describe the weight of the scientific evidence for the identified hazard and exposure.”

¹⁶ Section 6(b)(4)(A) provides, “The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.”

¹⁷ Section 6(b)(4)(H) provides, “The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.”