



September 17, 2018

By Federal eRulemaking Portal

Docket Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

**Re: Significant New Use Rules on Certain Chemical Substances,
Docket No. EPA-HQ-OPPT-2017-0414**

Dear Madam or Sir:

On behalf of a coalition of trade associations,¹ the American Chemistry Council (ACC)² submits these adverse comments on the following significant new use rules published as direct final rules at 83 Fed. Reg. 40986 (Aug. 17, 2018) and as proposed rules at 83 Fed. Reg. 41039 (Aug. 17, 2018):

- 40 C.F.R. § 721.11068, Alkanes, C₂₀₋₂₈, chloro (PMN P-12-277)
- 40 C.F.R. § 721.11069, Slack waxes (petroleum), chloro (PMN P-12-278)
- 40 C.F.R. § 721.11070, Hexacosane, chloro derivs. and octacosane, chloro derivs. (PMN P-12-280)
- 40 C.F.R. § 721.11071, Alkanes, C₂₀₋₂₄, chloro (PMN P-12-281)
- 40 C.F.R. § 721.11072, Alkanes, C₁₄₋₁₆, chloro (PMNs P-12-282 and P-14-684)
- 40 C.F.R. § 721.11073, Tetradecane, chloro derivs. (PMNs P-12-283 and P-14-683)

¹ The other coalition members include the Adhesive and Sealant Council, the American Wire Producers Association, the Center for the Polyurethanes Industry, the Independent Lubricant Manufacturers Association, and the Industrial Fasteners Institute.

² The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



- 40 C.F.R. § 721.11074, Octadecane, chloro derivs.
- 40 C.F.R. § 721.11075, Alkanes, C₁₈₋₂₀, chloro (PMN P-12-433)
- 40 C.F.R. § 721.11076, Alkanes, C₁₄₋₁₇, chloro (PMN P-12-453)
- 40 C.F.R. § 721.11707, Alkanes, C₂₂₋₃₀, chloro (PMN P-12-505)

ACC objects to the following statement in each of these SNURs:

It is a significant new use to manufacture the chemical substance for more than 5 years.

ACC believes that for each of these chemical substances (the SNUR substances), that current use is ongoing and cannot be listed as a significant “new” use.

These SNURs differ significantly from other SNURs in that the SNUR substances have been marketed commercially for many years, probably multiple decades. They were all the subject of PMNs: submitted in 2012: section 5(e) orders that became effective in 2017: and notices of commencement of manufacture (NOCs) submitted shortly after the respective orders became effective. That said, they have all been continuously on the market for many years notwithstanding these recent developments.

1. These SNUR Substances Had Been Manufactured for More Than Five Years Prior to 2012

As EPA is aware, chlorinated paraffins have been manufactured in the U.S. since before TSCA was enacted in 1976.³ The original 1979 TSCA Inventory included two categorical entries for chlorinated paraffins, having been included by EPA in the 1977 Candidate List:

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

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

EPA subsequently used those CAS numbers in multiple regulatory actions to refer to categories of chlorinated paraffins. See, e.g., 40 C.F.R. §§ 712.30(d) (listing CAS No. 61788-76-9 among the high production volume (HPV) chemicals subject to PAIR reporting); 716.120(c) (list of categories of chemical substances subject to section 8(d) reporting, including both CAS No. 61788-76-9 and CAS No. 63449-39-8).

These non-specific listings were for categories of chlorinated paraffins, not individual chlorinated paraffins. Section 8(b)(2) of TSCA authorizes EPA to list categories of chemical substances (as defined by section 26(c)) on the Inventory instead of individual substances. Following the 2016 amendments, section 8(b)(3)(iii) directs EPA to “treat the

³ See, e.g., Syracuse University Research Corporation, “Investigation of Selected Potential Environmental Contaminants: Chlorinated Paraffins, Prepared for Environmental Protection Agency” (Nov. 1975) at ix (“Approximately 74 million pounds of chlorinated paraffins were produced in the United States in 1973 and the market for these compounds continues to rise (>10% increase per year.”)

individual members of the categories of chemical substances identified by the Administrator ... as being included on the [TSCA Inventory].”

Nevertheless, in 2009 EPA brought enforcement actions against the leading domestic manufacturer of chlorinated paraffins, Dover Chemical Corporation (Dover), and the leading importer of chlorinated paraffins, INEOS Chlor Americas, Inc. (now INOVYN Americas) (INOVYN). Each complaint alleged that the company “‘manufactured’ and continues to manufacture” chlorinated paraffins with chemical descriptions that did not appear on the TSCA Inventory and thus were new chemical substances. The chemical descriptions were largely based on the carbon-chain lengths or carbon-chain length ranges actually being manufactured. EPA took the position that the two categorical entries on the TSCA Inventory did not cover the individual chlorinated paraffins then being manufactured.⁴

These enforcement actions were resolved in 2012 through consent decrees entered by a federal district court. As a compromise, the parties agreed that the companies would not manufacture or distribute any short-chain chlorinated paraffins (SCCPs) (those with carbon chain lengths $< C_{14}$), for medium-chain chlorinated paraffins (MCCPs) (those with chain lengths of $C_{14} - C_{17}$), and for long-chain chlorinated paraffins (LCCPs) (those with chain lengths $> C_{17}$), the consent decrees contained a key paragraph. As provided in the Dover consent decree (the corresponding paragraph in the INOVYN consent decree is similar):

The Defendant’s manufacturing or distribution in commerce of any chemical substance composed of a MCCP, LCCP, or a combination of MCCPs or LCCPs, for which a Premanufacture Notice is submitted within 30 days of the Effective Date of this Consent Decree, during the period from the Date of Lodging this Consent Decree through the date of withdrawal of such Premanufacture Notice or publication of such chemical substance on the TSCA Inventory, shall not constitute a violation of this Consent Decree and stipulated penalties shall not accrue due to such manufacturing or distribution during that time period.

This paragraph allowed for the continued manufacture of individual chlorinated paraffins for which the companies submitted timely PMNs, even though EPA considered that those individual chlorinated paraffins were not on the Inventory, at least in part for the purpose of avoiding market disruption. The parties did not contemplate that that companies would quickly develop new chlorinated paraffins for which they would submit PMNs. Rather,

⁴ While the enforcement actions commenced in 2009 were ongoing, the Office of Pollution Prevention and Toxics continued to regulate on the basis of one of the chlorinated paraffin categories on the Inventory. In 2010, OPPT proposed to require testing of CAS No. 61788-76-9 under section 4 as an orphan HPV chemical. 75 Fed. Reg. 46174 (Feb. 25, 2010). It was not until nearly two years after initiation of the enforcement actions that OPPT said it would “defer” reliance on that CAS number. 76 Fed. Reg. 65385, 35399 (Oct. 21, 2011) (“There is currently an unresolved issue regarding whether all the production previously reported to the Agency under CASRN 61788-76-9 should in fact be covered by that listing. Pending resolution of this issue, EPA will defer making a final decision regarding test rule requirements for CASRN 61788-76-9, and will reevaluate the testing needs for CASRN 61788-76-9 based on future CDR reports.”).

they expected that during the PMN review period the companies would continue to manufacture and distribute those chlorinated paraffins already on the market, on which downstream businesses were dependent.

Dover and INOVYN subsequently submitted in a timely manner the FY 2012 PMNs that are the basis of the cited SNURs.⁵ (The FY 2014 PMNs were submitted by another company.) ACC understands that the PMNs were all for MCCPs and LCCPs that the companies had been manufacturing for more than five years.

This history means that the SNUR substances had already been manufactured for more than five years at the time of the submission of the PMNs. Indeed, EPA had repeatedly regulated or proposed to regulate them as high production volume chemicals. Thus, manufacture of those SNUR substances for more than five years is an ongoing use and cannot be a significant “new” use.

2. The SNUR Substances Have Been Manufactured for More Than Five Years Since 2012

Dover and INOVYN have been manufacturing their respective SNUR substances since 2012 as well, a period of some six years.

About five years after the consent decrees were entered and the PMNs were submitted, EPA issued section 5(e) orders for the SNUR substances.⁶ Each contained a five-year manufacturing limit contingent on submission and evaluation of studies:

Beginning five years following the date of submission of a Notice of Commencement of Manufacture (“NOC”), the Company is prohibited from manufacturing (which under TSCA includes importing), processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purposes, unless the Company conducts the following studies on the PMN substances and submits all final reports and underlying data in accordance with the conditions specified in this Testing section. This information is necessary for a reasoned evaluation of the environmental effects of the substances. After that period, the activities described in this paragraph may not resume until EPA has completed review of, and taken any regulatory action deemed appropriate by EPA based on that information, except in accordance with the conditions described in this Order.

⁵ Dover submitted PMNs P-12-277 through -0284. It originally claimed its identity as confidential, but later waived that confidentiality claim. See 77 Fed. Reg. 24705, 24707 (Apr. 25, 2012). INOVYN submitted PMNs P-12-0433, -0453, and -0505 under its own name. See 77 Fed. Reg. 48514, 48518 (Aug. 14, 2012); 77 Fed. Reg. 48976, 48978 (Aug. 15, 2012); 77 Fed. Reg. 56639, 56641 (Sept. 13, 2012).

⁶ The effective date of the section 5(e) orders for both the Dover and the INOVYN PMNs was June 5, 2017. 83 Fed. Reg. 40886, 40988-89 (Aug. 17, 2018).

EPA presumably designated manufacture of a SNUR substance as a significant new use so as to reflect this provision of the section 5(e) orders in the SNURs. Any person subject to one of these SNURs once effective would be limited to a five-year period of manufacture unless it were to submit a significant new use notice (SNUN) asking EPA to consider the conditions, if any, under which the person could manufacture the SNUR substance for more than five years. EPA presumably intends to review any SNUN in light of the studies submitted under the section 5(e) orders.

NOCs for the SNUR substances were submitted in July 2017, about 30 days after the effective date of the section 5(e) orders.⁷ Thus, the PMN submitters are more than a year into their five-year period of manufacture during which they must conduct and submit the specified testing. Unlike with most PMN substances, however, those NOCs do not signal the first non-exempt commercial manufacture of the PMN substances. The PMN submitters have apparently been manufacturing the SNUR substances since 2012, as well as before then. The period of manufacture since 2012 alone has exceeded five years.

3. EPA May Not Adopt a SNUR for an Ongoing Use

As EPA acknowledged in the preamble to the direct final SNURs, EPA cannot designate an ongoing use as a significant “new” use:

To establish a significant new use, EPA must determine that the use is not ongoing.

However, EPA proceeded to determine that all of the significant new uses in those direct final SNURs were not ongoing. First, it explained:

The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

Even for PMN substances for which EPA has received a NOC (as in the case of these SNUR chemicals), EPA concluded that:

the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.⁸

EPA provided no acknowledgement of the regulatory history of the SNUR substances that made the foregoing conclusions inappropriate for them. EPA then designated:

⁷ Dover submitted NOCs for its PMN substances on July 5, 2017. INOVYN submitted NOCs for its PMN substances on July 7, 2017. 82 Fed. Reg. 45019, 45022 (Sept. 27, 2017).

⁸ 83 Fed. Reg. 40986, 40995 (Aug. 17, 2018).

August 17, 2018 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the direct final rule.⁹

However, by its own actions, EPA authorized the manufacture of each of the SNUR substance for more than five years prior to that date. Thus, manufacture of a SNUR substance for more than five years is an ongoing use which EPA may not establish as a significant "new" use.

4. EPA May Address Manufacture Beyond Five Years Through Section 6

EPA is not without remedy in this case. It has simply proceeded using the wrong provision of TSCA. Under section 6, EPA may designate these particular chlorinated paraffins, or MCCPs and LCCPs more generally, as high-priority substances, then conduct risk evaluations of them.¹⁰ Thereafter, it may determine whether manufacture for more than five years (or any particular period) presents an unreasonable risk. If it needs additional testing to make that risk determination (beyond the testing it expects to receive under the section 5(e) orders), it may exercise its authority under section 4.

EPA included MCCPs (defined as those having carbon chain lengths of C₁₄₋₁₇) and LCCPs (defined as those having chain lengths of C₁₈₋₂₀) in the 2014 update to the TSCA Work Plan.¹¹ Some of the SNUR substances are MCCPs or LCCPs under those definitions. Under section 6(b)(2)(D), in designating high-priority substances, EPA "shall give preference to" those substances and categories on the 2014 update to the TSCA Work Plan which are listed therein "as having a Persistence and Bioaccumulation Score of 3." Both MCCPs and LCCPs are listed as having a Persistence and Bioaccumulation Score of 3. Thus, section 6 itself encourages EPA to address MCCPs and LCCPs under section 6.

What EPA may not do is treat the SNUR chemicals as typical PMN chemicals. They were not manufactured for non-exempt commercial purposes for the first time after the end of the PMN review periods. EPA based its two enforcement actions and its demands in the consent decrees on the understanding that Dover and INOVYN for many years had been, and were continuing to, manufacture these SNUR chemicals. The consent decrees expressly allowed manufacture to continue for what proved to be a period of five years. The section 5(e) orders have allowed manufacture to continue for the additional past year.

⁹ 83 Fed. Reg. at 40996 (italics in original).

¹⁰ EPA has already prepared draft risk assessments on the SNUR chemicals. See 80 Fed. Reg. 79886 (Dec. 23, 2015).

¹¹ Available at https://www.epa.gov/sites/production/files/2015-01/documents/tsc_a_work_plan_chemicals_2014_update-final.pdf. MCCPs and LCCPs were included in the original 2012 TSCA Work Plan as well.

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Thus, cumulatively, EPA has allowed manufacture to continue for considerably more than five years. It may not now assert that manufacture for more than five years is a significant “new” use.

Sincerely,

A handwritten signature in cursive script that reads "Christina Franz".

Christina Franz

Senior Director, Regulatory & Technical Affairs