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January 15, 2015

Mr. Jeffery Taylor
Chemical Control Division (7405M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001
(via *Federal eRulemaking Portal*: <http://www.regulations.gov>)

Re: Docket EPA-HQ-OPPT-2007-0490: Significant New Use Rule for Certain Nonylphenols and Nonylphenol Ethoxylates

Dear Mr. Taylor:

The American Cleaning Institute (ACI)¹ appreciates the opportunity to provide comments on the proposed significant new use rule (SNUR) for certain nonylphenols (NPs) and nonylphenol ethoxylates (NPEs) published in the Federal Register on October 1, 2014 (79 Fed. Reg. 59186).

Our members are concerned by the process used by the agency in developing this SNUR and the precedent it may set. In particular, the method by which the agency collected evidence to support the conclusion that these chemical substances are not currently being manufactured or otherwise used or distributed in commerce is inadequate and deeply flawed. Consequently, this proposed rule should be withdrawn and the agency should conduct a more rigorous evaluation of the ongoing uses of these substances in commerce before taking further action.

1. The method by which the agency evaluated whether these substances are used broadly within U.S. commerce is deeply flawed.

Use of NPs/NPEs within U.S. Commerce

The agency used three sources of information “in order to analyze use of NPs and NPEs broadly within U.S. commerce.” The agency accessed information from the EPA’s 2012 Chemical Data Reporting (CDR) rule database, the National Institute of Health’s Household Products Database and the Consumer Product Information Database. ACI has concerns with EPA relying solely on the use of these sources for the reasons set forth below.

¹ ACI is the trade association representing the \$30 billion U.S. cleaning products market. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI’s mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy.

Consumer Products Use

With respect to the Household Products Database and the related Consumer Product Information Database, the databases are limited in scope and the authors specifically state that “we cannot guarantee that the information in the database is 100% accurate, current or complete at a particular point in time.” So, while inclusion of a substance on those databases may indicate a chemical substance is in commerce, the fact that a chemical substance does not appear on the database does not necessarily demonstrate that it is no longer in commerce. When performing its use analysis, it does not appear that the agency considered the various synonyms that are used for the NPEs in chemical supply chains. Thus, we reviewed the databases, taking the use of NP and NPE synonyms commonly used in the supply chain, were able to find numerous products on these databases containing the chemicals of interest.

Nonylphenol ethoxylates appear in the International Cosmetic Ingredient Dictionary and Handbook (the “Dictionary”) under the International Nomenclature for Cosmetic Ingredients (INCI) name Nonoxynol-n where the “n” indicates the degree of ethoxylation (the number of OCH₂CH₂ ethoxylate units). In the Dictionary there are 26 Nonoxynols with the following suffixes: -1 through -15, -18, -20, -23, -30, -35, -40, -45, -50, -70, -100 and -120. Also, the Dictionary lists CAS Numbers that are associated with each of the Nonoxynols. The table below denotes which CAS numbers are associated with which Nonoxynol names found in the Dictionary.

CAS No.	Nonoxynol																									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	18	20	23	30	35	40	44	50	70	100	120
7311-27-5				X																						
9016-45-9		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
20427-84-3																										
26027-38-3	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X		X	X
26571-11-9								X	X																	
27176-93-8		X																								
27177-05-5								X																		
27177-08-8										X																
27986-36-3	X																									
37205-87-1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
51938-25-1																										

It is interesting to note that three of the CAS numbers above are “generic” in-nature, and are used to denote a broad range of ethoxylation levels (9016-45-9, 26027-38-3 and 37205-87-1).

In searching the Household Products Database and the Consumer Product Information Database, there are a number of products found using Nonoxynol-2, -4, -9, and -10. The Environmental Working Group’s Skin Deep Cosmetics Database² shows data on a number of products which contain Nonoxynol-2, -4, -9, -10, -12, -15, -20 and -30. The *Compilation of Ingredients Used in Cosmetics in the United States* from the Personal Care Products Council (October 2010), which is based on information from the U.S. Food and Drug Administration’s Voluntary Cosmetics Registration Program (VCRP),³ showed Nonoxynol-1, -2, -4, -5, -6, -9, -10, -12, -14, -15, -23

² <http://www.ewg.org/skindeep/>

³ <http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm>

and -30 were reported by companies as being used in cosmetic products. More recent data (2014) from the VCRP shows that these substances are still being utilized in cosmetic products with Nonoxynol-2, -4, -6, -9, -10 and -12 being used most frequently.

Other Consumer Uses

Nonoxynol-9 is listed in the U.S. Pharmacopeia and it is widely used in contraceptives for its spermicidal properties.

Several of the compounds are permitted for use under FDA regulations as indirect food additives in food contact polymers (9016-45-9, 25154-52-3), food contact adhesives and coatings (25154-52-3, 26027-38-3), and food contact paper and paperboard products (25154-52-3, 26027-38-3).

Agricultural Uses

At least four of the NPs/NPEs are known by EPA to be used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (40 CFR 180.910), applied to growing crops only (40 CFR 180.920) or applied to animals (40 CFR 180.930): 9016-45-9, 25154-52-3, 26027-38-3 and 37205-87-1.

The evidence is clear that a significant number of the chemical substances identified in the proposed SNUR likely are actively in use within U.S. commerce.

Lack of Reporting to the CDR

In addition to the databases noted above, the agency relied heavily on the CDR rule database for its determinations concerning which of the 15 substance listed in the proposed rule are in commerce and their uses. Unfortunately, the CDR rule database does not provide a reliable mechanism for determining accurately and reliably whether certain substances are in commerce in the US. For example, at least four of the substances which are subject to the Proposal are not required to be reported for the CDR, even if there are in commercial production domestically or are imported to the US, because they are considered to be polymers and are listed on the Inventory with an "XU" regulatory flag indicating that they are exempt from reporting under the CDR rule: (9016-45-9, 26027-38-3, 37205-87-1, 51938-25-1). As such, it is not surprising that they were not reported.

At least one company (3M) has already submitted comments to this rule indicating that they import two substances (9016-45-9, 25154-52-3) in quantities below the reporting threshold for the 2012 CDR rule.

In addition to the exemption for polymers, there are other exemptions to the CDR rule that will limit the agency's ability to state accurately whether a substance is in commercial production or use in the US. Thus, substances which are not imported or manufactured during a reporting period in quantities greater than the 25,000 pound reporting threshold will not be reported for CDR purposes, and substance produced or imported solely for research and development (R&D) also will not be reported for the CDR.

It is well-established that the agency may not issue a SNUR for an on-going use of a chemical substance.⁴ Yet the EPA's reliance on limited information sources calls into question the efforts to which the agency has gone to meet its statutory obligation under Section 5(a)(2) to consider "all relevant factors".

2. The Statutory and Executive Order Reviews were deficient and should be revised.

Economic Analysis

The agency prepared a very limited economic analysis which led to the conclusion that the proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866. The analysis was limited to compliance costs associated with submitting a significant new use notification (SNUN) for those firms intending to engage what would be new uses of the subject chemicals and found that the total cost was well below that of a significant regulatory action (more than \$100 million).

Several companies (Boeing, Baker Petrolite) have already submitted comments to this Proposed Rule indicating that they do not manufacture or import the subject chemical substances but they do use them in their products, including imported products as well as those produced domestically. Consequently, the Proposed Rule could limit availability of the affected substances for their existing uses if the Agency does not modify or withdraw the proposal. Several of the substances clearly are used in high volume globally and the Proposed Rule could have significant negative supply chain implications that affect companies doing business in the United States. EPA should include an analysis of these economic impacts in its analysis and seek public comment on such a revised evaluation. Likewise, as was previously demonstrated above, there are wide spread ongoing uses within the U.S. in non-TSCA regulated industries (cosmetics, food packaging and pesticides) and the Proposed Rule could limit availability of these substances which impact those industries. Those impacts should be examined by the agency to determine whether the Proposed Rule is a significant regulatory action under section 3(f) of Executive Order 12866.

Small Business Impact

Similar to the situation describe above with respect to economic impact, the agency should analyze whether the Proposed Rule could limit availability of these substances and subsequently result in a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

Paperwork Reduction Act (PRA) Reporting

Because SNURs require reporting from both manufacturers (including importers) and processors of the affected substances, if it is not withdrawn or modified, the Proposed Rule effectively represents a reporting requirement for companies that have been legitimately using these substances in commerce on an on-going basis for years. Following only a cursory search of information regarding the use of these substances in commerce in the U.S., the agency is proposing to declare these substances "dead chemicals." Consequently, companies are effectively required to submit information to the agency regarding the uses and use volume of

⁴ See discussion in EPA's Federal Register notice of April 24, 1980 (55 Fed. Reg. 17376).

the substances in order to continue to do business. Several companies have already submitted such information and many more are likely to do so.

3. EPA Is Using the Incorrect Authority Under TSCA.

In light of the many comments and concerns received to-date by EPA regarding numerous ongoing uses of some of the listed substances EPA believed to be dormant, the agency clearly must recognize it erred by proposing a SNUR at this time. If the agency needs to determine the commercial status of any particular substance or class of substances, it is more appropriate in such circumstances to use EPA's information collection authorities under the statute, Sections 8(a) and (d)). Following collection of the needed information using its Section 8(a) and (d) authorities, the agency could then more effectively determine whether and in what manner it may wish to issue a SNUR, or other form of action under TSCA. Proper use of EPA's TSCA authorities allows EPA to collect needed information before taking regulatory actions which ultimately streamlines the regulatory process. By skipping the proper information collection processes under the Act and attempting to issue a "dead chemical" SNUR, the agency subverts and ultimately undermines its authority under TSCA.

4. Additional flaws have been identified by other commenters.

We are aware that other commenters have identified additional flaws with the proposed rule of which they will inform the agency. In particular, we note that the American Chemistry Council (ACC) is providing detailed commentary regarding the complicated nature of chemical nomenclature for NPs/NPEs. ACI fully supports the ACC comments and concurs that EPA should do more to publicize and clarify its nomenclature guidance on linear and branched alkyl chains and provide opportunities for entities to make corrections to Inventory listings before a final SNUR for the NPs and NPEs is issued.

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Due to the numerous analytical and procedural flaws associated with this proposed rule, ACI requests that the agency withdraw the proposal and conduct a more rigorous evaluation of the use of these substances in commerce before taking any further action.

We thank you once again for the opportunity to provide comment on the proposed significant new use rule for certain nonylphenols and nonylphenol ethoxylates. If you have any question regarding our submission, please feel free to contact Paul DeLeo by phone at 202-662-2516 or by e-mail at pdeleo@cleaninginstitute.org.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Paul C. DeLeo". The signature is written in dark ink and is positioned above the printed name and title.

Paul C. DeLeo, Ph.D.
Associate Vice President, Environmental Safety