



June 26, 2012

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Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460-0001

Attention: Docket ID Number EPA-HQ-OPPT-2010-0573  
*Submitted via Federal eRulemaking Portal:* <http://www.regulations.gov>

Re: Comments of the American Chemistry Council on EPA's Proposal to add nine Benzidine-Based chemical substances to the Significant New Use Rule (SNUR) on Benzidine-Based Chemical Substances; [77 FR 18752, 3/28/12] [EPA-HQ-OPPT-2010-0573; FRL-8865-2]

Dear Sir or Madam:

The American Chemistry Council (ACC)<sup>1</sup> appreciates the opportunity to submit comments on the above-referenced proposal in which EPA is proposing to add nine chemical substances to an existing SNUR at § 721.1660. That regulation includes as significant new uses “any use other than as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for Colour Index (C.I.) Direct Red 28 (Congo Red, CAS No. 573-58-0) as an indicator dye.” § 721.1660(a)(2). For the nine newly-proposed benzidine-based chemical substances, EPA is proposing to designate any use as a significant new use. To achieve its objective, EPA is also proposing to amend the SNUR at §721.1660 to make inapplicable the exemption at § 721.45(f) for persons that import or process benzidine-based chemical substances as part of an article.

To date, the Agency has been very select in removing the customary article exemption, having issued only three SNURs that rendered that exemption inapplicable as it is

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<sup>1</sup> 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 \$720 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in 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.



contained in §721.45(f)<sup>2</sup> of TSCA's general SNUR provisions. These include SNURs for elemental mercury in 2011, erionite fiber in 1991, and a chemical formerly covered by a SNUR that has since been revoked. The proposed SNUR could therefore be viewed as heralding a shift by the Agency toward greater regulation of chemicals in articles.

EPA has historically chosen to adopt administrative exemptions for many of TSCA's provisions for chemicals in articles, including general information-gathering rules, export notifications, import notifications, premanufacture notifications, SNURs, and restrictions on use of certain chemicals as regulated under section 6. EPA adopted the "article exemption" in a Federal Register Notice in 1983<sup>3</sup> largely due to concerns about the very practical difficulties importers would have in finding out what chemical substances are in the articles they import. EPA described its rationale in 1983 as follows: "because it would be enormously difficult for an importer to determine the identity and inventory status of each chemical substance in imported articles (e.g., automobiles), the rule does not require persons to submit notices on new substances imported as part of articles."<sup>4</sup>

In ACC's view, removing the article exemption should not become EPA's default approach in SNURs. It should be limited to exceptional circumstances on a chemical specific basis. It should be a decision that is based on sound criteria, including science based criteria such as potential health and environmental concerns regarding exposure to the chemical from specific articles, and feasibility criteria such as feasibility of compliance by the regulated community and enforcement by EPA, as well as evaluation of costs that may be incurred.

ACC recommends that EPA clarify the specific criteria that it has followed in this proposal as well as the criteria that the Agency will follow in its decision making process to revoke the article exemption in any future SNURs. EPA should define a clear policy framework including criteria for determining when TSCA regulation of articles is appropriate. In any proposed SNUR, the Agency should present a compelling basis for a decision to apply a SNUR to articles. The Agency should address questions such as the following:

- Can the risk posed by the chemical of concern be addressed through the standard regulation?
- Why is the standard approach for SNURs that exempts articles not sufficient?
- What conditions make direct regulation of articles necessary?
- What gaps in health and environment protection are likely to occur if a SNUR only regulates chemicals and mixtures?

EPA should define the scope of the SNUR and identify those specific articles likely to include the chemical of concern. The Agency should provide more specific information about how the chemical is released through the use of specific articles (direct exposure; release,

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<sup>2</sup> <http://www.gpo.gov/fdsys/pkg/CFR-2005-title40-vol30/pdf/CFR-2005-title40-vol30-sec721-45.pdf>

<sup>3</sup> Federal Register Volume 48. 21722, May 13, 1983

<sup>4</sup> Id., page 21726



metabolite, breakdown products) and how such uses and distribution contribute to potential exposures that are at a level that poses a risk to health and the environment.

Further, the Agency should provide an opportunity for public comment on the criteria that the Agency has considered whenever it proposes to eliminate the article exemption in SNURs.

ACC appreciates the opportunity to comment on the proposal. For any additional information regarding these comments, please contact me at 202-249-6425 or [Sylvia.Palmer@americanchemistry.com](mailto:Sylvia.Palmer@americanchemistry.com).

Sincerely,



Sylvia A. Palmer  
Director, Regulatory & Technical Affairs  
American Chemistry Council

