

# Legal Lookout: HPV Challenge Program: EPA Goes After Orphan Chemicals

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EPA recently posted on its Chemical Right-to-Know website a new policy, entitled Policy Regarding Acceptance of New Commitments to the High Production Volume (HPV) Challenge Program, available at [www.epa.gov/chemrtk/hvpolicy.pdf](http://www.epa.gov/chemrtk/hvpolicy.pdf). The policy outlines how companies can commit to sponsor any of the remaining so-called "orphan chemicals," which include the 300 chemicals that are currently unsponsored under the HPV Chemical Challenge Program. EPA's website also has a list of the HPV chemicals unsponsored as of July 5, 2005.<sup>[1]</sup> This column briefly describes the new policy and its implications.

## Background

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HPV chemicals are those that are manufactured in or imported into the United States in amounts equal to or greater than one million pounds. The HPV Chemical Challenge Program was initiated in 1998. EPA developed a list of 2,800 chemicals based on the 1988 Toxic Substances Control Act (TSCA) Inventory which, at the time, was the most comprehensive list of chemicals believed to be in commerce. Under the program, companies were invited to sponsor HPV chemicals, which essentially meant that a sponsor agreed to submit or generate Screening Information Data Set (SIDS) data for the sponsored chemical.

Over 400 chemical manufacturers volunteered to sponsor 2,200 HPV chemicals, representing 90 percent of the U.S. market by volume. Several hundred unsponsored chemicals were eventually identified as no longer produced in HPV quantities, or were otherwise determined to be ineligible under the program. Approximately 300 chemicals were unsponsored, which are the orphan chemicals under the new policy.

## The new policy

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After describing the genesis and background of the HPV Challenge Program ("Chemical" was later removed from the title), EPA explains in the policy that it "continues to encourage" sponsorship commitments from U.S. manufacturers and importers of orphan chemicals, and reiterates that it "is currently developing" direct final rules under TSCA Section 8(a) and 8(d) that are intended to gather data on those chemicals. Under these provisions, the agency is authorized to compel the submission of product manufacture, use, and other preliminary assessment information (Section 8(a)) and unpublished product health and safety studies (Section 8(d)). According to the policy, EPA expects to issue direct final TSCA Section 8(a) and 8(d) rules this summer.

EPA states in the policy that it "will accept new commitments to sponsor chemicals under the HPV Challenge Program within 14 days following publication of [the] 'direct final' rules in the Federal Register." Orphan chemicals, for which such timely new commitments were made, will be removed from the Section 8(a) and 8(d) rules prior to its effective date, which EPA indicates will be 30 days from the date of the Federal Register publication. New commitments made in a timely manner will be treated by EPA as "viable commitments," but

unlike “viable commitments” made after Dec. 26, 2000, EPA “will not expect companies to provide full copies of studies unless requested.” This is intended to create an incentive for companies to sponsor chemicals at this late stage – in addition to exclusion from the TSCA Section 8(a) and 8(e) rules, full copies of unpublished studies and newly conducted studies will be required only upon request. Importantly, chemicals subject to TSCA Section 8(a) and/or 8(e) rules are subject to TSCA Section 12(b) export notification, which has long been regarded as a considerable paperwork burden.

To make a viable commitment under the policy, a company must send EPA a letter announcing the company’s commitment to participate in the program and specifying the name and Chemical Abstract Service number of the orphan chemical(s) that the company will sponsor, as well as the name and contact details for a technical person within the company. In addition, companies will have to submit, as soon as possible but not later than Dec. 31, 2005, the following information:

- Robust summaries of existing studies;
- Full citations of published studies;
- Full copies of unpublished studies when, as noted above, requested by EPA; and
- A test plan for filling information needs.

New testing must be completed and robust summaries of those studies must be submitted as soon as possible, but no later than 24 months from the effective date of the forthcoming TSCA rules. Full copies of the new studies would have to be submitted when requested by EPA.

In addition to the above submission requirements, companies that make a sponsorship commitment more than 14 days after publication of the TSCA rules will have to provide EPA with robust summaries “for all relevant health and safety studies submitted to EPA by all respondents to the TSCA section 8(d) . . . rule.” Moreover, for new testing, robust summaries and also full copies of the studies must be submitted. Thus, unlike viable commitments made within the 14-day window, the submission of full copies of new studies is not conditioned on an EPA request.

Finally, EPA indicates in the policy that it intends to issue, by the end of this year, the final TSCA Section 4 test rule that was proposed in December 2000 for various other orphan chemicals that were not sponsored under the program.

## Implications

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For manufacturers of orphan chemicals, the failure to sponsor such materials will result in the issuance of final and effective TSCA Section 8(a) and 8(d) rules. Failure to submit the data required under these rules could result in EPA enforcement action. Once submitted and reviewed, the agency is authorized under appropriate circumstances to take additional steps to regulate a chemical if EPA’s review suggests that additional regulation is needed to abate risks. Such steps include, for example, consideration of the need to propose a TSCA Section 4 test rule. Test rules seek data that are often extensive and costly to produce. If manufacturers are unwilling to produce the data, and no downstream users step up to fulfill the data requirements, EPA is authorized to demand that production and import activities with respect to such chemicals stop.

**Pollution Engineering** readers should watch for issuance of these TSCA rules, determine if chemicals important to them are listed, and take appropriate action in response. Additionally, readers should monitor the actions EPA may take on one or more of these orphan chemicals, as further EPA action could impact the regulatory and toxicological profile of any such chemical, and thus inspire commercial issues of which readers should be aware.

#### REFERENCES

1) See Un-sponsored Chemicals as of 7/05/05, available at [www.epa.gov/chemrtk/hpvunspn.pdf](http://www.epa.gov/chemrtk/hpvunspn.pdf).

#### ADDITIONAL INFORMATION

Lynn L. Bergeson is a Managing Director of Bergeson & Campbell, P.C., a Washington, D.C. law firm focusing on chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues.