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**Procedures for Removing Chemicals that are No Longer HPV  
and are not Likely to Become HPV Again  
from the HPV List**

The Framework Document which defines the design of the HPV Challenge includes the following language:

*“Substances that sponsors verify are no longer “HPV” and are not likely to become HPV again will not require testing and will be removed from the list. (Substances which are either only slightly, or temporarily, below the HPV threshold will remain on the list.)”*

EPA believes that for a chemical to be verified as no longer HPV, **all** manufacturers and importers that reported to the **1990 TSCA Inventory Update Rule (IUR)**<sup>1</sup> must provide support for the claim that the chemical is no longer HPV and is not likely to become HPV again. In addition, **all** manufacturers and importers of the chemical that reported to the **1994 and 1998 IUR**<sup>2</sup>, that did not report to the 1990 IUR must also verify the chemical is “no longer HPV” and is not likely to become HPV again. One factor arguing for the need to go beyond the 1990 reports is the dated nature of the 1990 data. However, beyond this, verification from 1994 and 1998 IUR submitters is important because IUR is a relatively volatile database. For example, 466 chemicals with cumulative production volumes greater than one million pounds per year were reported to the 1994 IUR and not reported to the 1990 IUR. This is a significant fraction (17%) of the approximately 2,800 chemicals included in the HPV Challenge. A similar fraction of HPVs reported to IUR in 1990 were not reported in 1994. Because so many chemicals periodically fall above or below the one million pounds per year HPV threshold, EPA believes that there should be strong evidence that such chemicals which are removed from the HPV program will not likely resume HPV status. Moreover, the absence of information concerning production status during the years between the quadrennial IUR reporting years (1991-1993 for the 1994 report and 1995-1997 for the 1998 report), argues for adequate documentation from reporters of record to establish “no longer HPV” status with some confidence.

Chemicals for which it can be established that they meet the test for “no longer HPV” will be removed from the HPV Challenge via an appropriate annotation on the HPV chemical list (i.e., they will not be removed from the list as such, however, their changed status will be clearly communicated).

**Procedures for Manufacturers and Importers to Verify “No Longer HPV” Claims**

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<sup>1</sup>For a description of IUR reporting requirements see 40 CFR 710.

<sup>2</sup>Note that only the 1990 IUR was used to establish the list of chemicals included in the HPV Challenge. EPA sent letters soliciting participation in the HPV Challenge to all manufacturers and importers of listed HPV Challenge chemicals reporting to both the 1990 and 1994 IUR's.

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One approach is to develop and implement a process whereby manufacturers and importers would provide written substantiation of “no longer HPV” claims to the HPV Challenge. This could be done via ad hoc responses to the Challenge from individual companies (or by groups of companies) identified as manufacturers or importers in the 1990, 1994, and 1998 reporting cycles. If responses substantiating an ongoing and significant decline in production are received from all manufacturers and importers of record, then the chemical could be identified as “no longer HPV.”

Alternatively all manufacturers and importers which reported to the 1990, 1994 and 1998 IUR could agree to jointly sponsor the chemical in the HPV Challenge and submit a Test Plan showing no testing and providing substantiation of the chemical’s HPV status. EPA will work to make publicly available non-confidential data from past IUR reporting cycles that would aid a chemical manufacturer or importer in identifying other chemical manufacturers and importers of a specific chemical that would need to support a “no longer HPV” claim.

In any event, “no longer HPV” chemicals would be identified in the course of proposing and promulgating Test Rules that cover chemicals not sponsored in the HPV Challenge.

#### **EPA Follow-up to “No Longer HPV” Claims**

Given the volatility of HPV status as shown in analyses of IUR reporting, it is important that some means for ongoing follow-up be implemented. At a minimum, EPA will monitor future IUR reports for changes in the status of “no longer HPV” chemicals and will move to obtain SIDS testing if production volumes warrant.

To ensure “no longer HPV” claims withstand the test of time EPA may also implement TSCA Section 8(a) or other reporting rules which would alert EPA to any change in status of a chemical removed from the HPV list. These rules would likely be designed so that reporting is triggered when certain production volumes are reached. This could involve annual reporting to deal with significant production occurring between IUR reporting cycles.

#### **Final Note -- Corrections to the 1990 IUR**

As described in the HPV Challenge Framework Document, EPA has endeavored to remove all polymers and inorganic chemicals reported to the 1990 IUR from the HPV List. EPA will continue its efforts to remove polymers and inorganics from the HPV list as they are brought to the Agency’s attention. Beyond these efforts, EPA does not plan to devote substantial resources to processing corrections to the 1990 IUR submitted by manufacturers and importers so that chemicals can be removed from the HPV List. Examples of recent 1990 IUR corrections also soliciting removal from the HPV list which EPA has received include:

improperly reported impurities,  
improperly reported byproducts,

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improperly reported naturally occurring substances; and  
improperly reported wastes.

As noted, this reporting is over 8 years old. Rather, EPA plans to focus its attention on implementing a process to identify chemicals that meet the terms of “no longer HPV.” EPA may, however, consider annotating the HPV List with comments that describe IUR corrections offered by manufacturers and importers since the launch of the HPV Challenge. Alternatively, EPA may consider simply posting letters that describe IUR corrections offered by manufacturers and importers on its HPV Challenge web site.