

Questions and Answers on the Extended HPV Program

1. What is the “Extended” HPV (EHPV) Program?

The EHPV program is a voluntary initiative that allows companies in the business of chemistry to continue to demonstrate that adequate screening data exist for organic HPV chemicals produced/imported in volumes greater than 1 million pounds/year.

2. How is this program different from the HPV Chemical Challenge Program?

There are three main differences. First, the HPV Challenge Program was based on chemicals that were produced in high volumes according to the 1990 Toxic Substances Control Act (TSCA) Inventory Update. The EHPV program is based on chemicals that were produced in high volumes according to the 2002 TSCA Inventory Update. Second, the Challenge Program sought primarily hazard information, but the EHPV program asks companies to also provide screening level use and exposure information. Finally, the original program was framed a challenge, whereas this program is initiated by industry.

3. How does the EHPV Program fit with other industry initiatives, such as Responsible Care[®] and the Global Chemicals Management Policy (GCMP)?

The EHPV Program will provide a solid foundation for implementation of the Global Chemicals Management Policy, and a structure for defining and attaining Product Stewardship metrics under Responsible Care[®].

4. Will there be a parallel “Extended” ICCA HPV Initiative?

The EHPV Program is designed to be consistent with other national, regional and international data gathering and assessment activities. However, it is not currently expected that there will be an extended ICCA HPV Initiative because that initiative is not yet complete. Nevertheless, the EHPV Program compliments the ICCA HPV Initiative through domestic efforts of companies to gather information that underpins OECD assessments. Thus, companies operating in a global market have a variety of options for conducting work on HPV chemicals in ways that take advantage of cost and other savings resulting from collaborative work.

5. How will the EHPV Program maximize opportunities to reduce the use of animals?

Volunteers are urged to: consider the likelihood of potential human and environmental exposures; make maximum use of appropriate chemical categories (including retro-fitting “new” HPV chemicals into existing categories); conduct comprehensive searches for existing data; coordinate closely with producers and programs in other regions; and use validated non-animal methods where accepted and appropriate. Moreover, by incorporating a use and exposure component, the EHPV Program will provide the type of information necessary for sponsors to justify claims for a reduced data set.

6. What specific activities will participants be asked to conduct?

Participants will be asked to make commitments to assemble and make public: (1) screening-level hazard information for “new” HPV chemicals; and (2) use and exposure information for both the new HPV chemicals, as well as for chemicals in the HPV Challenge Program that do not yet have such information.

7. What is a “new” HPV chemical?

For purposes of this program, a “new” HPV chemical is one for which publicly reported production/import volumes exceed 1 million lbs. under the 2002 IUR, but which was not eligible for sponsorship in the original HPV Challenge Program. In other words, a “new” HPV chemical is one that is on the market in high volumes now that wasn’t made at such volumes in 1990.

8. Should sponsors first work on the “new” HPV chemicals, or on the use and exposure component for previously-sponsored chemicals?

Participants may choose to begin with the “new” HPV chemicals, or with the exposure component for previously sponsored HPV chemicals. Pursuing work on these elements simultaneously and in connection with other voluntary and regulatory programs could produce certain efficiencies. However, the program is voluntary and decisions on when to begin work on which section are up to sponsors.

9. Why are sponsors not asked to gather use and exposure information for chemicals previously sponsored via the ICCA HPV Initiative?

By program definition, chemicals in the ICCA HPV Initiative already include a screening set of use and exposure information.

10. Will there be “start years” as in the prior program?

Yes. Participants will be asked to select a start year in which existing information and assessment plans for providing new information will be made public.

11. What kind of hazard information will be provided?

The aim is to provide appropriate screening-level hazard information, consistent with demonstrated use and exposure patterns, to support an initial hazard characterization on “new” HPV chemicals. In the majority of cases the data provided should match the OECD/SIDS data set. The use of categories is encouraged, including “retrofitting” existing Challenge Program and ICCA Initiative categories to include new HPV chemicals. Consistent with other initiatives, where existing data on “non-SIDS” endpoints (e.g., cancer, irritation, sensitization) are available, sponsors are encouraged to provide robust summaries of key studies that would be relevant to an initial assessment.

The existence of other studies can simply be noted. Where appropriate, QSAR information or models can be used to fulfill an endpoint.

12. Which chemicals are addressed in the EHPV Program?

The associations participating in this initiative will encourage their members to voluntarily commit to sponsor HPV organic chemicals that are produced/imported at 1 million lbs./year, according to the 2002 IUR, but were not within the scope of the US HPV Challenge Program. The following chemicals will be considered outside the scope of the EHPV Program: un-sponsored chemicals from the HPV Challenge Program; polymers and inorganics; chemicals which are also FIFRA-registered active ingredients; chemicals which already have been or will be evaluated (under the US HPV Challenge, OECD/SIDS, ICCA Initiative, EU Risk Assessment, or other similar program); chemicals which EPA or OECD may designate as a “low priority;” and any chemical which already has a full publicly available data set. It is initially estimated that approximately 500 chemicals are within the scope of the EHPV Program.

13. When does the EHPV program actually begin?

The EHPV Program is now underway. The remainder of 2005 will be devoted to organization, during which time companies will be asked to consider making commitments to sponsor chemicals. Sponsors will be asked to select one of four “start years,” ranging from 2006 to 2009. During the selected start year sponsors will submit an assessment plan, robust summaries of existing data, and a data matrix showing the test results by endpoint.

15. When is the EHPV program expected to end?

The goal is for all data to be public by the end of 2010, regardless of the start year. Volunteers will be encouraged to begin work as quickly as possible, spread multiple commitments evenly over all start years, and take other steps to avoid “back end loading.”

16. What guidance will be available to assist sponsors?

A significant number of tools and guidance documents developed during the HPV Chemical Challenge Program (and posted on EPA’s web site at <http://www.epa.gov/chemrtk/guidocs.htm>) are available to sponsors in the EHPV Program. Further, guidance on assessing HPV chemicals in the OECD SIDS Program, including data development and preparation of initial assessment documents, is available on the OECD web site (<http://webdomino1.oecd.org/comnet/env/tf-ec.nsf>).

17. Why does the EHPV program include use and exposure information?

The original HPV Challenge Program did not require use and exposure information, although several sponsors voluntarily provided varying amounts of such information in

their submissions. In the ICCA HPV Initiative certain use/exposure information is required, together with readily available, relevant information. Including a use/exposure component in the EHPV program will further harmonize the type and amount of screening level information available on HPV chemicals, and support the use of risk-based approaches in chemical risk management.

18. What kind of use and exposure information will EHPV Program sponsors be asked to provide?

Volunteers are asked to provide, at a minimum, the same “screening level” use and exposure information provided in the OECD/ICCA HPV programs, including: (a) production volume, (b) use functions and categories, (c) a qualitative description of likely sources of potential exposures, (d) the physical form of the marketed product (i.e., powder, liquid, gas), and (e) other readily available information relevant to a screening level assessment. (Providing this information in a manner consistent with OECD requirements would promote consistency and make the information useful in a SIAR context.) Beyond that, volunteers could provide as much information as possible and appropriate, depending on the chemical. For example, for chemicals with high hazard profiles, known occupational, environmental or consumer exposures, or wide dispersive uses, additional information could be appropriate. Such information could include measured values, modeled estimates, or regulatory limits. A mix of qualitative and quantitative information is envisioned, and volunteers would be encouraged to be clear and transparent as to the volumes covered by information provided.

19. Are there particular formats available for providing use and exposure information?

A variety of templates, formats and approaches are available for gathering and providing use and exposure information. Much of this information, and most of the tools, can be found on the Alliance for Chemical Awareness web site (www.chemicalawareness.org). In addition, a set of exposure reporting “formats” has recently been developed at the OECD which allow for similar information to be recorded in similar formats. The EHPV program does not mandate or endorse a particular tool or approach, since different tools will make sense for different circumstances.

20. How can the public find information on company commitments?

At this time the details on how sponsor commitments will be made public have not been finalized. Ideally, the EHPV program would utilize EPA’s HPV Challenge web site, but that option has not been fully explored with EPA.

21. How can the public find the hazard, use and exposure information provided by sponsors?

At this time, those details have not been finalized. However, to make maximum use of existing tools and processes, one option would be to utilize EPA’s HPV Challenge web site, and ultimately the HPV Information System for sponsors to post the results of their

work (including assessment plans, SIARs, robust study summaries, as well as chemical use/exposure information). To facilitate the transmission and exchange of information, sponsors will be urged to use IUCLID software.

22. How could the Extended HPV program impact the ICCA HPV Initiative?

At this time the EHPV Program does not envision creating a separate “path” to completing the work via sponsorship in a new ICCA HPV Initiative. However, under a process recently agreed by the OECD, companies volunteering under the EHPV Program who wish to have their chemicals assessed in the OECD may prepare draft SIDS Initial Assessment Profiles (SIAPs), SIDS Initial Assessment Reports (SIARs), and dossiers with robust study summaries, and post those documents on a “Committee Discussion Group” for OECD member countries to view. A chemical for which completed results are posted on the OECD web site could then count toward the current ICCA Initiative goal of 1,000 chemicals.

23. Who can I contact for more information?

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