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EPA

Chemical Right to Know
High Production Volume Challenge Program

Fact Sheet on Animal Welfare

The HPV Challenge Program

The goal of the HPV Challenge Program is to ensure that a baseline set of environmental and health effects data on approximately 2,800 high production volume (HPV) chemicals is made available to EPA and the public. EPA believes that the availability of this information is vitally important so that the public can better understand chemical hazards in their communities, homes, and workplaces, and so that EPA can make sound decisions about priorities for possible future regulation and take appropriate risk management actions if necessary.

Under the HPV Challenge Program, U.S. manufacturers and importers of HPV chemicals were invited to voluntarily provide basic human health and environmental effects data for their HPV chemicals; i.e., those manufactured or imported into the United States in volumes of 1 million pounds or more per year. The requested data comprise the HPV Screening Information Data Set (SIDS), developed by the Organization for Economic Cooperation and Development (OECD). EPA intends to consider specific chemicals which are not voluntarily sponsored as candidates for test rules under Section 4 of the Toxic Substances Control Act. Sponsorship entails the identification and initial assessment of the adequacy of existing information, the conduct of new testing only if adequate information does not exist, and making the new and existing test results available to the public.

The Role of Existing Test Data

EPA believes that it is important to achieve the goals of the HPV Challenge Program in a manner that takes into account animal welfare concerns. As a result, the HPV Challenge Program has been designed from the start to encourage companies to consider approaches that can reduce the amount of testing needed and that avoid duplicative testing. EPA encourages industry and others to search for relevant and scientifically valid existing data, and to share that information with EPA and the public. Companies have the opportunity to develop and submit plans for testing chemical categories, which involves collecting data on a subset of chemicals as representative of an entire class or group of chemicals. Other approaches can be used to help assess closely related chemicals in order to reduce the need for testing. Chemicals for which adequate SIDS data already exist will not be retested under the HPV Challenge Program or any associated test rule(s) that are limited to SIDS testing. In addition, all test plans submitted by sponsors under the HPV Challenge Program will be posted on the Internet for a 120-day review period prior to the start of testing. This will provide an opportunity for the identification of scientifically valid existing data which may not have been cited and for the recommendation of revisions to the test plans which could reduce the need for additional animal testing.

Efforts to Reduce Animal Testing

In implementing the HPV Challenge Program, EPA is committed to examining alternative test methods that reduce the number of animals needed for testing, that reduce pain and suffering of test animals, and whenever possible, that replace animals in testing with

validated *in vitro* (non-animal) test systems. EPA believes that reduction, replacement, and refinement are all important elements in the overall consideration of alternative testing methods. EPA has released guidance on this issue for companies participating in the HPV Challenge Program to follow. This guidance promotes the maximum use of existing data, and is designed to encourage companies to disclose existing data not previously made publicly available. The guidance states that sponsors of HPV chemicals are encouraged to defer certain animal tests, and to use certain *in vitro* tests to address endpoints for which adequate existing data are not available. EPA recommends delaying some necessary testing of individual chemicals until November 2001, and testing of closed system intermediates, which present less risk of exposure, until 2003. Federal funds have also been committed to the evaluation of alternative test methods.

EPA has taken a number of important steps to address animal welfare issues in the HPV Challenge Program. EPA recommends the use of an alternative to the standard LD50 test that reduces the number of rodents needed by 60 percent. EPA has reevaluated its preference for the rodent genetic toxicity test and encourages the use of non-animal alternatives. EPA also recommends the use of combined studies and specific actions to reduce pain and distress in test animals. Taken together, the measures which EPA has recommended would reduce animal usage by 68 to 80 percent. EPA has communicated these testing recommendations to sponsors of HPV chemicals.

For more information on the specific actions EPA is taking to reduce the use of animals in the HPV Challenge Program or general information about the Chemical Right-to-Know Initiative, please visit our web site at *http://www.epa.gov/chemrtk* or call (202) 260-3951. Interested stakeholders may join our automated updated notification service on the What s New page to receive email updates on the HPV Program. All documents posted on the website may be obtained in hard copy by contacting the TSCA Assistance Information Service at (202) 554-1404.

Types and Validity of Data to be Collected

The OECD HPV Screening Information Data Set (SIDS) represents an internationally agreed upon set of studies needed to screen HPV chemicals and identify potential hazards. These include studies for physical chemical properties (e.g., water solubility), environmental fate (e.g., biodegradation), environmental toxicity to fish and other aquatic species, and mammalian toxicity (acute toxicity, genetic toxicity, repeat dose toxicity, and reproductive and developmental toxicity). Any needed testing under the HPV Challenge Program is to be conducted using test guidelines which are recognized and accepted by governments and scientists worldwide as providing high quality, screening level test data.

Scientific Validation of Alternative Non-Animal Testing

Scientific validation is an essential step in determining the adequacy of new alternative test methods. Scientific peer review to determine the level of validation of alternative protocols is performed by various recognized authorities such as the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), of which EPA is a member. Following the recommendations of such organizations, federal agencies then decide whether to adopt alternative test methods for their regulatory purposes.

Until non-animal test methods are validated and achieve regulatory acceptance, these methods cannot be relied on as alternatives to established test guideline studies for purposes of the HPV Challenge Program or any associated test rule(s). EPA is working with other federal agencies to identify, validate, and peer review potential alternative protocols, and to ensure the scientific and regulatory acceptability of the tests. For example, ICCVAM recently initiated a process to investigate the potential for validation of various acute *in vitro* methods, including the Multicenter Evaluation of In Vitro Cytotoxicity (MEIC) battery of tests. These *in vitro* tests are being evaluated as possible alternatives to or supplements for animal tests for acute toxicity. An ICCVAM/EPA workshop is being planned for October 2000. If relevant alternative test methods become validated and achieve regulatory acceptance during the implementation of the HPV Challenge Program, EPA will consider their immediate implementation in the Program. To enhance the use of alternative testing methods, EPA will continue to involve animal welfare interest groups and other interested parties in a constructive dialogue to identify and develop such methods.