

Session 3: Tiered Evaluation Strategies

Session Chairs: Jay Ansell (Yves Rocher North America, Inc.), Simon Webb (Procter & Gamble)

Tiered Evaluation Strategies: Experiences from HPV Programs, Larry Rampy (American Chemistry Council)

- Will attempt to emphasize what has been learned from the HPV program to minimize the amount of chemical testing needed.
- The HPV Challenge began in the late 1990's stimulated by the observation that there was insufficient information on many chemicals for risk evaluations or conclusions on toxicity to humans. Industry, environmentalists, and the EPA came up with the HPV Program to compile toxicity data on chemicals that were produced or imported in the US at more than one million pounds per year as of 1992. The program included greater than 95%, by volume, of chemicals in commercial use.
- The HPV Program adopted the OECD/SIDS screening set, was voluntary, had timeframes, and was transparent. When the program began in 1998 approximately 2,400 chemicals were identified as HPV and a commitment was received for approximately 2,222.
- The current "extended" EHPV covers new chemicals and includes an exposure/use information component for new submissions, and encourages addition of it to old submissions, to allow for better use-based derogation.
- HPV Program strategies to reduce animal use include: reliance on existing data, sharing of data and technology expertise, creation of chemical categories for data extrapolation, and opportunity for public comment.
- Challenges that came up were that categories were difficult to form (*i.e.* complex mixtures, changing mixture composition, etc.), categories were not always obvious to all stakeholders, government acceptance of categories was slow at first (has since been well-established), and the scientific community was unfamiliar with the approach at first. Now the use of categories is well established and useful in moving forward in risk assessment.
- Toxicity Testing Data and Information on HPV Chemicals
 - TSCA Inventory includes about 90,000 chemicals; however, it is not a list of chemicals in commerce. It includes many chemicals that were proposed for development and those that are not used any longer.
 - Only about 9,000 chemicals are produced at > 10,000 lbs/year
 - When data collection for the HPV Program and the ICCA HPV Program is finished, information on > 3,000 chemicals will be available to the public.
 - Of the 1,350 submissions received, data on many of these chemicals already existed in private company files, and much was used to extrapolate to similar compounds so that minimal new testing was needed.
- Lessons learned from the HPV Program development include: more data existed (mostly in private company databases) than predicted; creating categories is not complicated and decreased time, money, and the number of animal tests needed; public comment increased the quality of the program.

- The HPV Program data can be applied to other programs such as OECD/SIDS, REACH, and VCCEP (Tier 1)
- Q & A – Is the HPV database publicly available and searchable? Not yet. EPA is in the process of developing the database and hopes to have it available in early 2006.