U.S. Environmental Protection Agency  
High Production Volume Chemicals Challenge Program:  
Accounting for the Animals  
Joseph Manucci, M.S., Research Associate  
Kate Wiltett, Ph.D., Science Policy Advisor  
Jessica Sandler, Director  
Regulatory Testing Division • People for the Ethical Treatment of Animals

Introduction

Announced in October 1999, the U.S. Environmental Protection Agency’s (EPA’s) High Production Volume (HPV) Chemicals Challenge Program (challenged) industry to make baseline health and environmental effects data publicly available on nearly 2,000 HPV chemicals. This data required were based in the Organization for Economic Co-operation and Development's (OECD) HPV Screening Information Data Set (SID) Program. Program participants sponsored HPV chemicals they were required to have an impact, and were required to provide the data to EPA. Participants provided test plans that include many of the same toxicology measures as those used in the chronic toxicity tests being conducted by the National Academy of Sciences’vae in 2007 and in the 2009 EPA Strategic Plan.

Existing Data

Existing data – including genotoxicity, OECD TG 471 and 473, for bacterial reverse mutations and endocrine disruption by other thoughtful toxicology measures. EPA also strongly recommended the use of combined protocols, OECD TG 421 and 422 test instead of both repeat dose tests in the toxicology endpoints. Furthermore, EPA also directed program participants to “maximize the use of scientifically appropriate categories of related chemicals and major constituents of complex mixtures.”

Other toxicology measures

EPA “strongly recommended” the use of combined protocols, OECD TG 421 and 422 for repeat dose, developmental and reproduction toxicity tests, OECD TG 414 and 415 (Table 1). Conducting an OECD TG 421 or 422 test in place of both repeat dose tests in the toxicology endpoints allowed a developmental study. We also estimate the number of additional chemicals that may have been tested.

Conclusions

The original and revised test plans and EPA comments considered there approximately 1,400 chemicals. If a full battery of tests were conducted for each of these chemicals, 1,384,893 animals would be used. Indeed, we estimate that 158,380 animals were used for tests proposed in the test plans revisions with a maximum of 7,595 animals already tested in tests conducted to date. EPA estimated that 108,000 animals are required for acute toxicity tests. The number of animals required for genotoxicity tests was 26,000. The number of animals required for acute toxicity tests was 26,000. The number of animals required for combined protocols rose to 38%.

Animal Use

The original and revised test plans and EPA comments considered there approximately 1,400 chemicals. If a full battery of tests were conducted for each of these chemicals, 1,384,893 animals would be used. Indeed, we estimate that 158,380 animals were used for tests proposed in the test plans revisions with a maximum of 7,595 animals already tested in tests conducted to date. EPA estimated that 108,000 animals are required for acute toxicity tests. The number of animals required for genotoxicity tests was 26,000. The number of animals required for acute toxicity tests was 26,000. The number of animals required for combined protocols rose to 38%.

Reducing Animal Use

In an October 1999 letter, EPA directed program participants to “conduct a thoughtful, qualitative analysis rather than use a rule of thumb approach,” that they “may consider that sufficient data is given, the toxicity of which is unknown about a chemical, including whether or not that certain endpoints need to be tested.”

References

OECD Test Guidelines available at: http://www.epa.gov/opppt setbacks proposed, so additional animals in delayed test plans revisions.

Table 1: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.

Table 1: Numbers of animals required for currently proposed tests.

Table 2: list the animal tests most commonly proposed in the HPV Challenge Program. Approximately numbers of animals used are calculated based on published OECD test guidelines (TG). At a minimum, data from OECD TG 425, 426 and 427 were required for repeat dose endpoints.

Figure 1: numbers of animals killed throughout the program.

Figure 3: Numbers of animals saved throughout the program.

Figure 4: Numbers of animals used for combined and reproduction tests.

Figure 5: numbers of animals killed in proportion to the total number proportionately reduced.