

The following BNA Article on ICCVAM Authorization Act of 2000 was published on December 18, 2000 (Note: The ICCVAM Authorization Act of 2000 was signed by President Clinton on Wednesday, December 19, 2000, and became Pubic Law No.: 106-545.):

NEWS

Chemical Safety

Alternative Test Methods Legislation Clears Senate, Ready for Clinton Signature

A bill to promote regulatory acceptance of new and revised toxicological test methods is expected to be signed soon by President Clinton, officials close to the legislation told BNA on Dec. 15.

The Senate gave unanimous approval Dec. 6 to the House-approved version of the bill (H.R. 4281) known as the ICCVAM Authorization Act of 2000. The bill, which would make permanent the Interagency Coordinating Committee on the Validation of Alternative Methods, was sent to the president Dec. 8 for signature.

Sen. Mike DeWine (R-Ohio), lead sponsor of the Senate version of the bill (S. 1495), said approving the House measure "would give companies and federal agencies a sense of certainty and would encourage them to make the long-term research investments necessary to develop new, revised, and alternative toxicology test methods for ICCVAM to review."

"This would decrease and ultimately could lead to the end of animal use in testing shampoos, pesticides, and other products, while ensuring that human safety and product effectiveness remain protected," DeWine said.

Support for Bill. The bill is supported by a large group of animal protection advocates and chemical makers, DeWine said. Supporters listed by DeWine include the Doris Day Animal League, Procter & Gamble, Colgate-Palmolive Co., Humane Society, American Humane Association, Massachusetts Society for the Prevention of Cruelty to Animals, Gillette Co., Chemical Specialties Manufacturers Association, American Chemistry Council, Soap and Detergent Association, Synthetic Organic Chemical Manufacturers Association, and American Crop Protection Association.

ICCVAM was created in response to a mandate by the 1993 National Institutes of Health Revitalization Act that the National Institute of Environmental Health Sciences recommend new processes for federal agencies' acceptance of new, revised, or alternative toxicology test methods.

ICCVAM is composed of representatives of various federal agencies that use or regulate the use of animals in toxicity testing, including the Environmental Protection Agency and the Food and Drug Administration.

Reaction. Sara Amundson, deputy director of the Doris Day Animal League, told BNA Dec. 15 that Clinton was expected to sign the bill Dec. 16 or 17.

This legislation "has demonstrated that in a bipartisan fashion when the issue is right, industry and animal groups can step up to the plate and move toxicology forward into the 21st century," Amundson said.

With this legislation, ICCVAM would operate on a permanent statutory basis, Amundson said, adding she also hoped it would have strong standing to obtain adequate funding. Funding for ICCVAM would continue to be done on a fiscal year by fiscal year basis, she said. Since the committee no longer would be a discretionary entity with the National Toxicology Program, it should be easier to secure and maintain funding, she predicted.

The legislation would not change ICCVAM's function, she said. "ICCVAM will not be in business of issuing policy, but instead focused on the quality of science and whether or not an assessed test method is validated for the stated purpose," she said. ICCVAM "can't trump the individual responsibility of regulatory agencies. It will facilitate identifying where a new test method will be appropriate," she said.

Amundson said the bill was able to move through the Senate because of the strong statement of support from the White House and because of a colloquy involving three senators that addressed any remaining concerns. "While there is no significant challenge to the intent or content of the bill in the colloquy, we are certainly hopeful it addressed the concerns" of the senators, she said.

Guidelines, Regulations. The bill would require the establishment of guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness, according to a summary of the bill.

The legislation states that ICCVAM will be a permanent standing committee administered by NIEHS under the National Toxicology Program's Interagency Center for the Evaluation of Alternative Toxicological Methods.

In late October, the bill appeared to have hit a snag when Sen. Barbara Boxer (D-Calif.) placed a "hold" on the bill to block a vote by the full Senate. Boxer, who has long supported the legislation, had been contacted by environmental and children's health advocates in California, who expressed concerns that they were left out of the final negotiations when the bill was moving through the House (210 DEN A-2, 10/30/00).

Existing Mandates Unaffected. The environmental advocates raised concern that the measure would interfere with EPA's endocrine disruption screening and testing program and the children's health testing program.

In addition, Sen. Max Baucus (D-Mont.) said during the Senate colloquy on Dec. 6 that he was "concerned that this legislation could be used to delay EPA's chemical testing programs including the proposed Endocrine Disruptor Screening Program, the agency's children's health testing initiatives, and EPA's pesticide registration/re-registration process."

Baucus asked DeWine to "assure me that nothing in this bill is intended to prevent or slow the implementation of existing statutory mandates under the Food Quality Protection Act and the Safe Drinking Water Act for these important programs."

"Nothing in this legislation challenges a federal agency's authority to choose which screens and tests to send to ICCVAM for review," DeWine said.

DeWine also said nothing in the legislation is intended to prevent or slow the implementation of existing statutory mandates under FQPA and SDWA. The bill would not have an effect on existing animal tests in existing federal regulatory programs, he said. Its goal is to facilitate the appropriate validation of new, revised, and alternative test methods for future use.

Earlier in October, the House approved the legislation by voice vote and sent it to the Senate (203 DEN A-10, 10/19/00).

By Sara Thurin Rollin