Subject: FR Notice Comments - 72FR23832: Draft Five-Year Plan
Date: Thursday, June 7, 2007 5:26 PM

Below is the result of your feedback form. It was submitted by
() on Thursday, June 7, 2007 at 17:26:15

Comment_date: June 7, 2007

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Comments: NAVS Comments on ICCVAM Draft Five-Year Plan

The priorities enumerated in the draft five-year plan are admirable, with those areas of research relying on the most numbers and severity of animal use singled out for the most attention. The specifics are also clearly stated and provide an excellent framework for the future of ICCVAMâ•¯s next five years of activity.

Our comments are therefore confined to several specific concerns in this plan:

1. Escalation of a procedure to incorporate alternatives already validated by ECVAM

2. Substituting roundworms, fish and amphibian for mammalian animal models

3. Clarification of the gathering of in vivo data for inclusion in development of toxicology databases

1. Escalation of a procedure to incorporate alternatives already validated by ECVAM

A review of the developments by the European Centre for the Validation of Alternative Methods (ECVAM) calls into question the failure of ICCVAM to adopt these methods in a timely fashion, instead requiring a repetition of the entire validation process and a delay of several years before implementation. While it is noteworthy that ICCVAM has stated its intention to continue its cooperative work with ECVAM and the Japanese Center for the Validation of Alternative Methods (JaCVAM), especially in the area of design and evaluation of international independent validation studies, the adoption of internationally validated alternatives is even more essential. ICCVAM should be making a strong commitment to speeding the incorporation of validated alternatives from Europe and Japan into the list of alternatives accepted by ICCVAM.

Specific tests used for biologics/vaccine testing, that are set as priorities under the current five-year plan, have already been validated by ECVAM, included batch potency tests for tetanus (2003) and erysipelas (2004) vaccines. In addition, five in vitro tests for pyrogen testing were validated by ECVAM in 2006, while these tests are listed as proposed tests under review by ICCVAM in the current 5-year plan.

This process of reevaluating and revalidating test methods that have gone through a review process by a similar organization should be thoroughly overhauled to streamline the process of adopting and recommending these test methods for use in the U.S. Protocols should be developed to ensure that U.S. evaluation mandates are met while avoiding duplication and delay in the process.

2. Substituting roundworms, fish and amphibian for mammalian animal models

A decision to evaluate the use of the roundworm for use in determining adverse human health effects of chemicals is somewhat puzzling. Embracing an evolutionarily lower animal model for adverse human health effects is counterintuitive, especially by an organization that is charged with developing alternatives to the use of all types of animals. The fact that an animal is inexpensive to work with and has a rapid growth cycle does NOT make it an appropriate model for evaluation of human health issues. If monetary resources are going to be invested in the development of alternatives, it makes much more sense in every way to investigate a better in vitro model instead of determining how to fit the limitations of a different species of animal into a meaningful model for advanced research.

The EPAâ•˙s development of assays to evaluate various toxicity endpoints in fish and amphibians, including an assay to evaluate the growth and development of amphibians after they hatch, is unclear as to its purpose. Are these assays being used in order to benefit fish and amphibians which are being harmed by toxins released in the air and water, or are they being developed as a model for human responses to an exposure to toxins? If the former, then it is imperative that ICCVAM work to encourage the development of an assay that uses the fewest number of animals in reaching that endpoint, with the least pain inflicted on the animals. If it is for the latter purpose, than it calls into question the use of these animals and we strongly urge ICCVAM to assist the EPA in developing an assay that focuses more appropriately on the human health endpoint that they are trying to achieve.

At this point in time ECVAM is working to reduce the use of fish in its testing assays. It is hoped that ICCVAM is not spending its time and resources in developing new ways to use fishâ•‰and worms and amphibiansâ•‰instead of relying on the many new technologies that are also available in this field.

3. Clarification of the gathering of in vivo data for inclusion in development of toxicology databases

The greater use of searchable toxicological databases and access to these databases by the general public is an excellent investment of resources. In 1999, the EPA,

environmental, health, and animal protection groups reached an agreement delineating principles for minimizing irrelevant and repetitive tests including the incorporation of information from databases other than GRAS in developing its testing protocols for high volume production testing programs. An expansion of the information available in databases will certainly help reduce the number of animals used for testsâ•‰provided federal agencies and private researchers have the information necessary to use them.

However in the section on the establishment of a database for use in expanding the development and applicability of new alternative ocular test methods, there is a reference to the incorporation of submissions on in vivo reference data as well as data on alternatives. Is this new research being conducted in vivo or is this data culled from existing sources and incorporated in the database? If it is the former, we strongly urge that no new in vivo tests be conducted because such information is already available through decades of prior research on in vivo ocular responses.

NAVS applauds the five-year planâ•¯s inclusion of developing new technologies, as well as its commitment to sponsoring research and development of workshops to educate government scientists in the use of alternatives.

While the development of alternatives to animals is moving along, we hope to see an escalation in the pace of development, review and validation. Acceptance of alternatives validated by ECVAM is a start in this process, but we hope to see better leadership from ICCVAM in urging individual agencies to move forward with their development of in vitro testing.
