ALTERNATIVE TEST MODELS

Ocular Safety Assays Accepted

In a significant step forward for alternative safety test methods designed to reduce, refine, or replace the use of live test animals, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) recently announced the regulatory acceptance of two new in vitro ocular safety assays by the U.S. Food and Drug Administration, Environmental Protection Agency, and Consumer Product Safety Commission. The acceptance was based on recommendations made by ICCVAM after an extensive evaluation of the methods.

The United States tallies an estimated 125,000 eye injuries in the home each year caused by accidental exposure to common household products such as bleach and oven cleaner, according to the American Academy of Ophthalmology. Proper identification and labeling of substances that can damage the eye is one way to combat such injuries. Several agencies require manufacturers to test new products for their potential to cause temporary or permanent blindness, irritation, or other eye injuries.

Working with the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), ICCVAM evaluated and recommended the bovine corneal opacity and permeability (BCOP) and the isolated chicken eye (ICE) test methods—the first nonanimal ocular safety test methods to be accepted by the regulators. In both cases, the animal eyes used for the tests are slaughterhouse waste, so no animals are euthanized specifically to obtain these tissues. The assays have been in development since the early 1990s.

Now that the BCOP and ICE assays have earned regulatory acceptance, they must be considered as the first option for ocular safety testing under the Animal Welfare Act, which requires the consideration of alternative methods before animals are used for procedures that may cause more than slight or momentary pain or distress. “If you get a positive result in either of these assays, you can use that as a positive for the purposes of classifying and labeling [a material] as a severe irritant,” says Marilyn Wind, chair of ICCVAM and a deputy associate executive director with the Consumer Product Safety Commission. “If it’s negative, then [manufacturers] have to go to the next step and test in animals. This eliminates the most corrosive and severe chemicals from having to be tested in animals, so there is a reduction in potential pain and distress.”

Although precise numbers are not available for the use of live animals in ocular testing, William Stokes, director of NICEATM and executive director of ICCVAM, estimates that based on the relative distribution of adverse effects, use of the two assays could reduce the use of live animals for eye safety testing by 10% or more. “The overall goal is to come up with an integrated testing strategy using several nonanimal tests that will accurately predict whether chemical products have the potential to damage the eye or not,” he says. ICCVAM and NICEATM are in the process of evaluating other in vitro methods for ocular safety, hoping to eventually eliminate altogether the need for in vivo testing in this realm.

In the near term, ICCVAM is working with its counterparts in Europe and Japan to expedite approval of the BCOP and ICE assays at the international level by the 30-member Organisation for Economic Co-operation and Development. This group includes the United States, Canada, Japan, and most of the European Union, where a ban on live animal testing of cosmetic ingredients takes effect in March 2009 and the newly implemented REACH (Registration, Evaluation, Authorisation and Restriction of Chemical Substances) legislation will require testing of thousands of chemicals by 2018.

—Ernie Hood

Skin Cancer Souvenir?

A population-based study of young, white British women published online 10 July 2008 ahead of print in the Journal of Investigative Dermatology suggests that vacationing—but not necessarily living—in hotter or higher-altitude locations than one’s home is associated with a greater whole-body number of nevi (benign moles) in women aged 18–29 who normally live in temperate climates. The association was particularly strong for nevi on the trunk and lower limbs, which typically are only intermittently exposed to the sun. The researchers believe this finding supports the hypothesis that intermittent sun exposure is a primary environmental risk factor for developing nevi, and thus for melanoma. Having a large number of nevi is the strongest known risk factor for melanoma in whites.

The Health Impact of Incense

In Asian countries where Buddhism and Taoism are the major religions, incense is burned daily in homes and temples. A review published 25 April 2008 in Clinical and Molecular Allergy and a study published 9 May 2008 in Chemico-Biological Interactions focus on the potential respiratory and carcinogenic effects of incense smoke, which can contain benzene, toluene, xylene, 1,3-butadiene, polycyclic aromatic hydrocarbons, and particulate matter. The first study found that exposure to incense smoke can cause airway dysfunction, elevated cord blood IgE levels, allergic contact dermatitis, and neoplasms, and advises people to reduce exposure when they worship and to ventilate homes during the burning of incense. The second found that temple workers in Thailand had significantly more DNA damage and reduced DNA repair capacity, and warns that exposure to incense smoke may increase the risk of cancer.

Potable Water a Priority in Hurricane Preparedness

In July 2008 the Harvard School of Public Health released survey results on hurricane preparedness of more than 5,000 participants from eight coastal states, plus a special sample of New Orleans residents. Three years after Hurricane Katrina, people affected by the storm named the need for fresh drinking water as a top priority in a storm’s aftermath, and 37% of participants reported keeping water purification supplies on hand. Some 34% of respondents affected by Katrina felt prepared if a major hurricane were to strike their communities within the next 6 months. The Atlantic Ocean hurricane season runs each year from June 1 to November 30.

Coast Guard workers distribute bottled water after Hurricane Katrina, 1 September 2005