



UPDATE

National Toxicology Program

U.S. Department of Health and Human Services

July 2010

Headquartered at the
National Institutes of Environmental
Health Sciences • NIH-HHS

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NTP Tackles Soy Infant Formula Safety

Article by Mamta Behl reprinted from eFACTOR, June 2010

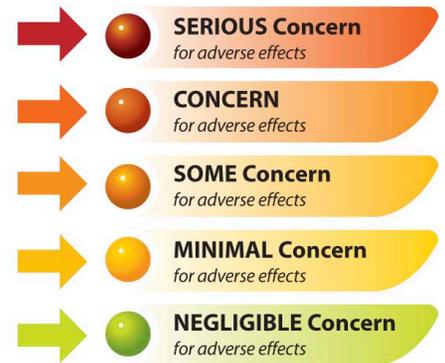


At its [May 10 meeting](#), the National Toxicology Program (NTP) [Board of Scientific Counselors \(BSC\)](#) took up the issue of whether use of soy infant formula (SIF) may cause adverse developmental effects in humans due to the presence of estrogenic isoflavones, also known as phytoestrogens. After nearly four hours of discussion, the BSC voted six to three to support the NTP Draft Brief on Soy Infant Formula conclusion of minimal concern for adverse effects on development in infants consuming SIF.

Kristina Thayer, Ph.D., acting director of the [NTP Center for the Evaluation of Risks to Human Reproduction \(CERHR\)](#), opened her presentation by describing the use of SIF. "Soy infant formula has been used for the past 60 years to replace or supplement use of breast milk or cow milk-based formula and now accounts for approximately 12% of U.S. infant formula sales," explained Thayer. She further emphasized that infants fed SIF are exposed to significantly higher levels of genistein, the main phytoestrogen present in SIF, compared to those fed breast milk or cow-milk formula.

Basis for NTP's conclusion of minimal concern level of concern

The NTP assigned a level "2" to SIF on the five-level scale of concern used by the CERHR, with levels of concern ranging from "1" for *negligible concern* to "5" for *serious concern*. The basis for this conclusion stemmed from a combination of insufficient information from studies in humans to reach a conclusion on potential adversity, coupled with findings from laboratory studies demonstrating clear adverse effects on the female reproductive system in rodents exposed to genistein. Extrapolation of these results to human infants is complicated because the animals were treated with only one component of SIF.



"Although infants fed SIF can have total genistein blood levels exceeding those measured in neonatal or weanling rodents treated with genistein, the effects of genistein or its glucoside genistin may be very different when administered in SIF, which is a complex mixture of other isoflavones and non-isoflavone ingredients," Thayer cautioned. Some of these mixture issues could be addressed through a series of animal studies being proposed by the NTP, presented to the BSC later in the day by Kembra Howdeshell, Ph.D., of CERHR.

Risk communication of the NTP Brief

One of the points of reservation expressed by members of the BSC and public spokespersons was the use of what some considered confusing language by the NTP. Some of the reviewers and public speakers, including Larry Williams, M.D., who represented the International Formula Council, pointed out that expressing "minimal concern" while also stating that SIF could "possibly affect human development" might create unnecessary anxiety for parents and confuse the general public. During the discussion, several members said that they felt the need for NTP to develop a more objective, precise, and consistent evaluation scale.

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Voting on the NTP Draft Brief on Soy Infant Formula

There was a lively discussion by the BSC on the extent to which the animal findings should be used to potentially raise concerns about the use of SIF, given its six decades of usage. Some panel members were reassured by the lack of reports of adverse effects in people who used soy formula during infancy. Others felt that the types of findings being observed in the animal studies had not been adequately assessed in humans.

The absence of reports of adverse effects does not necessarily mean they haven't or couldn't occur. Two prospective cohort studies of infants fed SIF are in early stages of development and will not generate results for several years — an NIEHS-funded Infant Feeding and Early Development Study (IFED) being conducted at the Children's Hospital of Philadelphia, and the USDA-funded Beginnings Study conducted by the Arkansas Children's Nutrition Center.

In the end, two-thirds of the members voted in favor of NTP classifying the risk level as *minimal concern* for adverse health effects from consumption of SIF by infants. Two members, Elaine Faustman, Ph.D., and Ruthann Rudel, said they felt the level of concern was too low, while the other opponent, James Sherley, M.D., Ph.D., said he considered the level of concern too high. ●

(Mamta Behl, Ph.D., is a research fellow in the NTP Toxicology Branch)

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NTP Hosts International Visitors

Article by Debbie McCarley reprinted from *eFACTOR*, July 2010

Rear Admiral William Stokes, D.V.M., director of the [NTP Interagency Center for the Evaluation of Alternative Toxicological Methods \(NICEATM\)](#), hosted a visit by representatives from the European Union and the Republic of Korea on June 16. The meetings fostered discussion of progress on international efforts to reduce the number of animals required for product safety testing and to develop internationally consistent regulations and guidelines for more human toxicological methods.

The meeting provided an opportunity for the participants to review the progress of ongoing international validation studies evaluating new non-animal test methods to identify potential hazards. In addition to discussing the progress of ongoing validation studies, the international visitors attended the annual meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) at the U.S. Environmental Protection Agency Research Triangle Park campus June 17 and 18.

Joachim Kreysa, Ph.D., head of the European Centre for the Validation of Alternative Methods (ECVAM), attended the international meeting. ECVAM is a unit of the Joint Research Centre within the European Commission's Institute for Health and Consumer Protection.



The international collaborators from left to right, are Soon Young Han, Birnbaum, Stokes, Joachim Kreysa, and ICCVAM Vice-Chair Jodie Kulpa-Eddy, D.V.M., of the U.S. Department of Agriculture.

(Photo courtesy of Steve McCaw)

Upcoming Events

September 14-16, 2010

International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing

Sponsor: NICEATM-ICCVAM
NIH Natcher Conference Center
Bethesda, MD

October 12-13, 2010

NTP Board of Scientific Counselors
Technical Reports Review
Subcommittee

NIEHS
111 TW Alexander Drive
Research Triangle Park, NC

December 6-7, 2010

NTP Board of Scientific Counselors

NIEHS
111 TW Alexander Drive
Research Triangle Park, NC

January 11-13, 2011

Role of Environmental Chemicals
in the Development of Diabetes
and Obesity Workshop

Raleigh Marriott Crabtree Valley
4500 Marriott Drive
Raleigh, NC

January 25-26, 2011

NTP Board of Scientific Counselors
Technical Reports Review
Subcommittee

NIEHS
111 TW Alexander Drive
Research Triangle Park, NC

<http://ntp.niehs.nih.gov/go/calendar>

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Two representatives of the Korean Center for the Validation of Alternative Methods (KoCVAM) also attended — Soon Young Han, Ph.D., director of KoCVAM, and Chea-Hyung Lim, D.V.M., KoCVAM is part of the National Institute of Food and Drug Safety in the Korean Food and Drug Administration. Han and Lim also met with NTP Associate Director John Bucher, Ph.D., and other NIEHS scientists.

Stokes was a featured speaker at the symposium celebrating establishment of KoCVAM last year. Hajime Kojima, Ph.D., director of the Japanese Center for the Evaluation of Alternative Methods (JaCVAM) provided a written update on Japanese activities that was presented at the meeting.

ECVAM and JaCVAM are participants in the International Cooperation on Alternative Test Methods (ICATM), through which the ongoing validation studies are being coordinated. ICATM was established last year as the result of efforts initiated by NICEATM and the [Interagency Coordinating Committee on the Validation of Alternative Methods \(ICCVAM\)](#), an interagency committee of the U.S. federal government administered by NICEATM.

The ICATM agreement provides a framework through which NICEATM and ICCVAM can cooperate with other international validation organizations to speed the international acceptance of scientifically valid test methods that may reduce, refine, or replace animal use while continuing to protect people, animals, and the environment. Representatives of NICEATM and ICCVAM, ECVAM, JaCVAM, and Health Canada signed the ICATM agreement. KoCVAM has expressed interest in joining ICATM.

The ICATM agreement facilitates activities such as the ongoing validation studies led by NICEATM. These studies are evaluating test methods to identify potential endocrine disruptors and were designed by NICEATM in consultation with ICATM participants. Laboratories in Japan and Korea, sponsored by JaCVAM and KoCVAM, are participating in the studies to ensure the test methods yield consistent results when conducted by different laboratories.

ECVAM, JaCVAM, Health Canada, and KoCVAM will have an opportunity to nominate experts to participate on a NICEATM-ICCVAM-sponsored peer review panel that will be convened in 2011 to review the data from the validation studies and the draft ICCVAM recommendations on the use of the test methods. Following the peer review, ICCVAM will develop final recommendations for U.S. federal agencies. These recommendations will consider the results of the peer review and public comments, as well as comments from the advisory committee and from other ICATM participants.

Active participation of ICATM members throughout the validation study, peer review, and development of final recommendations increases the likelihood that the ICCVAM recommendations will be used to develop internationally consistent regulations and guidelines. Similar international cooperation led to the recent international acceptance of test methods recommended by ICCVAM that identify eye irritation hazards and substances that may cause allergic contact dermatitis. ●

(Debbie McCarley is a special assistant in NICEATM.)

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Best Paper Selected

Dr. Barry Delclos, research pharmacologist at the FDA's National Center for Toxicological Research, has been selected to give the Elsevier Award lecture at the European Teratology Society Conference on September 5-8, 2010, in Barcelona, Spain. The European Teratology Society Council identified a paper written by Delclos, "Overlapping but distinct effects of genistein and ethinol estradiol (EE₂) in female Sprague-Dawley rats in multigenerational reproductive and chronic toxicity studies" as first choice among papers published in *Reproductive Toxicology* (Apr 27(2):117-132, 2009).

Dr. Delclos will present the paper at a lecture on the afternoon of September 7.

The NTP has conducted multigenerational and toxicology and carcinogenicity studies on genistein and ethinyl estradiol, which are reported in NTP Technical Reports [TR-539](#), [TR-545](#), [TR-547](#), and [TR-548](#). ●

Citation: Delclos, K.B., Weis, C.C., Bucci, T.J., Olson, G.R., Mellick, P.W., Sadovova, N.V., Latendresse, J.R., Thorn, B.T., and Newbold, R. *Reprod. Toxicol.* (April 2009) (27(2):117-132, 2009) <http://dx.doi.org/10.1016/j.reprotox.2008.12.005>

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Olden Honored for Scientific Achievement

Article by Eddy Ball reprinted from *eFACTOR*, July 2010

NIEHS Director Emeritus Ken Olden, Ph.D., recently added yet another award to his long list of honors. At the annual gala of the Bronx Community College (BCC) Foundation held at the New York Botanical Garden, Olden was one of five distinguished New Yorkers recognized for their support of a quality educational environment at BCC, according to a June 1 [press release](#) issued by The City University of New York.

At the gala, organized around the theme "Building on a Dream," Olden received the Robert L. Clarke Award for Scientific Achievement. The award is named for one of BCC's most beloved chemistry professors.

Olden is founding dean of the new **CUNY School of Public Health**, the first of its kind school of public health with an urban focus. In 2011, the new program will begin offering graduate programs in its new facility, which celebrated its groundbreaking in November 2009.

Olden served as director of NIEHS/NTP from 1991 to 2005, and he remained at the Institute as principal investigator of the Laboratory of Molecular Carcinogenesis Metastasis Group until he left for New York in September 2008 (see [story](#)).

Also receiving awards at the event were four other BCC supporters:

- **Allan Dobrin**, CUNY executive vice chancellor and chief operating officer
- **Van Thompson**, project manager for the New York office of Skanska USA Buildings, Inc.
- Howard Stein, New York businessman and BCC supporter
- Beverly Spitzer, New York entrepreneur and BCC supporter

Founded in 1957, BCC is the oldest of six community colleges in the CUNY system. Its campus overlooks the Harlem River at University Avenue and West 181st Street. In addition to its 30 associate degree and certificate programs, BCC also has initiatives that are normally not associated with community colleges. These include the National Center for Educational Alliances (NCEA), which is currently collaborating with South African Further Education and Training Colleges, and the Center for Sustainable Energy, which promotes the use of renewable and efficient energy technologies in urban communities. ●

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NTP Satellite Symposium

In conjunction with the annual meeting of the Society of Toxicologic Pathology held in Chicago June 20-25, 2010, the NTP pathology group of the Cellular & Molecular Pathology Branch (CMPB) held another successful NTP Satellite Symposium on June 19, this time entitled, "Pathology Potpourri." Chaired by Dr. Susan Elmore of CMPB, this interactive symposium on interpreting pathology slides has become a popular pre-meeting event. During each talk, the speakers projected a series of histopathologic images on one screen with a choice of diagnoses/answers on a separate screen. The approximately 200 members of the audience voted on the best choice for the diagnosis using wireless keypads with results displayed on the screen for discussion. The objectives of this interactive symposium were to provide continuing education on interpreting pathology slides, generate lively and productive debates, and have a good time! ●

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Olden, above, shown during a lecture at Harvard University, has said he hopes the CUNY School of Public Health will be "the Mecca, the epicenter for modern public health."

(Photo courtesy of Harvard University)

Center for the Evaluation of Risks to Human Reproduction (CERHR)



Role of Environmental Chemicals in the Development of Diabetes and Obesity Workshop

January 11-13, 2011

Raleigh Marriott Crabtree Valley • 4500 Marriott Drive, Raleigh, NC

There has been increasing interest in the concept that environmental chemicals may be contributing factors to the epidemics of diabetes and obesity. The NTP is holding a workshop to evaluate the science associating exposure to certain chemicals or chemical classes with the development of

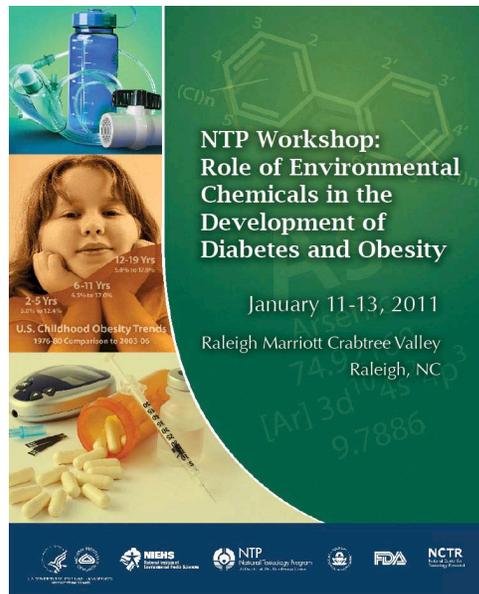
diabetes and obesity in humans. Participants at the workshop will:

- Evaluate strength/weaknesses, consistency, and biological plausibility of findings reported in humans and experimental animals for certain environmental chemicals including arsenic and cadmium, PCBs, DDT/DDE, other organohalogenes, bisphenol A, phthalates, and organotin.
- Identify the most useful and relevant endpoints in experimental animals and *in vitro* models.
- Identify relevant pathways and biological targets for assays for the Toxicology Testing in the 21st Century high throughput screening initiative ("Tox21").
- Identify data gaps and areas for future evaluation/research

The format of the workshop includes both plenary talks and breakout groups.

The workshop is open to the public with time set aside in the agenda for public comments during the plenary session on the first day. The public can attend the breakout groups as observers. A literature review document will be prepared prior to the meeting. Information about the workshop and on-line registration are available from the NTP website (<http://cerhr.niehs.nih.gov/evaluations/chemicals/obesogens/Obesogens.html>). Registration is on a first come basis and is limited to 100 people or by contacting Dr. Kristina Thayer (see contact information below).

This workshop is sponsored by the [National Institute of Environmental Health Sciences/NTP](#), [U.S. Environmental Protection Agency](#), and the [FDA National Center for Toxicological Research](#). ●



Contact Information: Dr. Kristina A. Thayer, Director CERHR, NIH/NIEHS, P.O. Box 12233, MD K2-04, Research Triangle Park, NC 27709; T: (919) 541-5021; FAX: (919) 316-4511; thayer@niehs.nih.gov

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Report on Carcinogens Moves Toward Completion

Article by Thaddeus Schug reprinted from *eFACTOR*, July 2010

The [12th Report on Carcinogens \(RoC\)](#) came closer to completion during an NTP Board of Scientific Counselors (BSC) meeting on June 21-22 in Rodbell Auditorium. NTP scientists presented draft substance reports for the final three compounds being considered for possible listing in the report for BSC consideration and public comment, including glass wool fibers used in insulation and filtering systems, cobalt-tungsten carbide: powders and hard metals found in cutting tools – and formaldehyde, a widely used chemical found in resins and plastics and used for medical preservation.

Along with other business, the BSC heard a Center for the Evaluation and Risks to Human Reproduction (CERHR) proposal for a literature review of the potential health effects of exposure to cancer chemotherapy *in utero*.

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12th Report on Carcinogens

Mary Wolfe, Ph.D., director of the NTP Office of Liaison, Policy and Review, opened the presentations with an overview of the multi-step scientific review process used for the RoC. Wolfe explained, “each phase of the review process offers opportunities for public input and scientific deliberation” (see 2009 [NTP Board Peer Reviews Draft Cancer Reports](#)). She added that “the board is charged with determining whether the scientific information cited in each draft substance profile is technically correct, clearly stated, and supports the NTP’s preliminary decision regarding its listing in the RoC.” The NTP will review BSC and public comments before recommending final classifications for the substances for the 12th RoC.



NTP Associate Director John Bucher, Ph.D., left, and BSC Chair Raymond Novak, Ph.D., looked on during Howdeshell’s concept proposal for evaluating cancer chemotherapy during pregnancy.

(Photo courtesy of Steve McCaw)

The NTP recommended retaining glass wool fibers listing as “reasonably anticipated to be a human carcinogen” as reported in the 11th RoC, despite objection by the North American Insulation Manufacturers Association (NAIMA) and several other public stakeholders, and the findings of its 2009 expert panel (see [article](#)). NAIMA representatives argued that NTP should follow the recommendations of its independent expert panel and separate glass wool into different categories according to specific criteria related to their size and durability.

In response, NTP’s Gloria Jahnke, D.V.M., noted, “Although not all glass fibers are carcinogenic, there is sufficient evidence from studies in experimental animals and mechanistic data to group them as one class.” NTP scientists also pointed to the lack of any clear scientifically established way to distinguish between those fibers that cause cancer and those that do not without testing each individual product.

Discourse was also animated over NTP’s recommendation to reclassify formaldehyde from a “reasonably anticipated carcinogen” to a “known human carcinogen” (see 2009 expert panel [article](#)). NTP RoC Center Director Ruth Lunn, Dr.P.H., said, “The decision to change the listing status of formaldehyde is based on sufficient evidence in human epidemiology studies with supporting mechanistic information.” Much discussion centered over recent studies linking formaldehyde exposure to forms of leukemia, in addition to less common cancers of the nasopharynx and sinonasal cavity.

Lunn also presented evidence in support of listing cobalt-tungsten carbide: powders and hard metals as “reasonably anticipated to be human carcinogens.”



Lunn, right, and Bucher, left, listened to BSC comments on formaldehyde, which was one of three chemicals reviewed at this meeting.

(Photo courtesy of Steve McCaw)

CERHR proposes evaluation concept

During the day and a half meeting, Kembra Howdeshell, Ph.D., presented a CERHR concept to evaluate literature concerning the pregnancy outcomes of women treated with cancer chemotherapy during pregnancy and follow-up on their offspring exposed *in utero*. According to Howdeshell, a growing number of women are being diagnosed with cancer during pregnancy. Estimates range from 1 in 1,000 to 1 in 6,000. Treatment most often involves some form of chemotherapy. However, nearly all chemotherapy agents are U.S. Food and Drug Administration Pregnancy Category D, which investigational or post-marketing data show risk to the fetus. The evidence of risk of the chemotherapeutic agents usually comes from studies in laboratory animals.

Howdeshell’s proposal is for the NTP to develop a monograph, which “will provide a thorough survey and critical scientific evaluation of the human literature, to determine whether cancer chemotherapy administered during pregnancy affects pregnancy outcomes.” Howdeshell added, “It should provide physicians and their patients with an informed perspective on what is known about the developmental effects following exposure to chemotherapeutic agents *in utero*.” ●

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NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)



New Safety Testing Methods to Identify Allergic Contact Dermatitis Hazards

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) has issued final recommendations on two new versions and expanded applications of the murine local lymph node assay (or LLNA) for testing the allergic contact dermatitis (ACD) hazard potential of chemicals and products. Dr. Linda Birnbaum, Director of NIEHS and NTP, forwarded the recommendations to U.S. Federal agencies on behalf of the Secretary of Health and Human Services. The recommended methods use fewer animals and avoid the discomfort that animals might experience in the traditional test method to evaluate ACD hazard potential.

ICCVAM recommendations:

- The LLNA: BrdU-ELISA, which uses the nucleotide analog bromodeoxyuridine (BrdU) to assess lymph node cell proliferation instead of radiolabeled substances. Dr. Masahiro Takayoshi at the Chemicals Evaluation and Research Institute in Japan developed the LLNA: BrdU-ELISA. Validation studies for the method were completed in coordination with the Japanese Center for the Validation of Alternative Methods (JaCVAM).
- The LLNA: DA, which measures adenosine triphosphate content to assess lymph node cell proliferation instead of using radiolabeled markers. Dr. Kenji Idehara at Daicel Chemical Industries, Ltd. in Japan developed this method. Validation studies for the LLNA:DA were completed in coordination with JaCVAM.

ICCVAM also recommends that the LLNA may be used to test most chemicals and products for ACD hazard potential, which should further reduce the number of animals used for safety testing. Now, more institutions will be able to take advantage of animal welfare benefits afforded by the LLNA, and the availability of methods that do not generate radioactive waste will have environmental benefits.

ICCVAM first recommended the LLNA in 1999. It has since been accepted in the United States and internationally for identifying substances with the potential to cause ACD. Originally, the LLNA was recommended for testing a limited range of substances; however, after evaluating an updated database for LLNA's use to test pesticide formulations, metals, substances in aqueous solutions, and other products, ICCVAM expanded its recommendation on the applicability domain of the LLNA. ICCVAM now recommends that the LLNA may be used to test any chemical or product for ACD hazard potential unless the chemical or product has properties that might interfere with the LLNA's ability to detect sensitizing substances.

The traditional LLNA uses radioisotopes, so its use is limited to laboratories qualified to handle and properly dispose of radioactive materials. The current ICCVAM recommendations support the use of two modified, nonradiolabeled versions of the LLNA to assess ACD hazard potential of chemicals and products, with certain limitations.

Compared to traditional guinea pig methods used to test products for ACD hazard potential, the LLNA uses fewer animals and eliminates animal pain and distress. The updated applicability domain for the LLNA and the availability of LLNA methods that do not use radioactivity should allow more institutions to take advantage of the animal welfare benefits of the LLNA.

In October 2009, ICCVAM made recommendations to Federal agencies on performance standards for the LLNA and on a new LLNA protocol and modified procedure that can reduce animal use by 40% or more (see [NTP Update, October 2009](#)). All agencies have accepted or endorsed the ICCVAM recommendations.

Information on the ICCVAM evaluation of the LLNA can be found on the NICEATM-ICCVAM website (<http://iccvam.niehs.nih.gov/methods/immunotox/immunotox.htm>).

continued



ICCVAM Releases 2008-2009 Biennial Report

NICEATM has published the Interagency Coordinating Committee on the Validation of Alternative Methods Biennial Progress Report, 2008–2009, which describes ICCVAM activities and progress. Highlights include the following:

- ICCVAM recommended two *in vitro* safety test methods for determining whether chemicals and products may cause blindness and other severe eye damage. Based on ICCVAM's evaluation, these test methods were adopted by U.S. agencies in 2008 and as international test guidelines in 2009. These are the first scientifically valid alternative test methods to gain regulatory acceptance for ocular safety testing that do not use live animals.
- ICCVAM recommended two *in vitro* assays to assess the potential of chemicals and products to cause acute oral poisoning. One method uses human cells. These assays can reduce animal use by up to 50%. Federal agencies accepted the recommendations in 2008.
- ICCVAM recommended an updated test method protocol and procedures for the murine local lymph node assay (LLNA), a safety test to determine whether chemicals and products may cause allergic skin reactions. The updated test method and procedures reduce animal use by 20 to 50%. Federal agencies adopted the original LLNA test method in 1999 and accepted the updated test method earlier this year. The updated LLNA uses fewer animals and eliminates pain and distress compared to the traditional guinea pig test used for this purpose.
- The United States, together with the European Union, Canada, and Japan, signed an agreement for International Cooperation on Alternative Test Methods (ICATM) in 2009. ICATM will promote enhanced international cooperation and coordination among national validation organizations. This agreement provides a framework for NICEATM and ICCVAM to cooperate with these organizations to speed the scientific validation and adoption of new safety testing methods that may further reduce, refine, and replace animal use while continuing to protect people, animals, and the environment.

The biennial progress report describes how NICEATM and ICCVAM continue to promote the development, validation, and regulatory acceptance of new test methods that will reduce, refine, and replace the use of animals in testing while maintaining and promoting scientific quality and the protection of people, animals, and the environment.

The ICCVAM Biennial Progress Report 2008-2009 (NIH Publication No. 10-7612) can be found at <http://iccvam.niehs.nih.gov/about/ICCVAMrpts.htm>. There is also a link to the report on the home page of the NICEATM–ICCVAM website, <http://iccvam.niehs.nih.gov/>. To obtain a print copy of the report, contact NICEATM at niceatm@niehs.nih.gov.

International Workshop on Vaccine Potency and Safety Testing Planned

NICEATM invites interested persons to register for the upcoming International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing. This workshop will bring together an international group of scientific experts from government, industry, and academia to review the current state of the science, availability, and future need for alternative methods that can reduce, refine, and replace the use of animals for human and veterinary vaccine post-licensing potency and safety testing. NICEATM and ICCVAM are organizing the workshop in cooperation with the European Centre for the Validation of Alternative Methods, the Japanese Center for the Validation of Alternative Methods, and Health Canada. The Society of Toxicology is a cosponsor of the workshop.

The workshop is open to the public and will be held September 14–16, 2010, at the William H. Natcher Conference Center on the main campus of the National Institutes of Health in Bethesda, Maryland. Those interested in attending should register by August 30. There is no registration fee.

NICEATM invites the submission of abstracts for scientific posters to be displayed during the workshop. Posters should address current research, development, validation, and/or regulatory acceptance of alternative methods that may reduce, refine, and replace the use of animals in vaccine post-licensing potency and safety testing. July 29 is the deadline for submitting abstracts (400 words maximum) for posters to NICEATM.

Information about the workshop is available on the NICEATM–ICCVAM website at <http://iccvam.niehs.nih.gov/meetings/BiologicsWksp-2010/BiologicsWksp.htm>. This page also contains links to the workshop agenda, registration form, and abstract submission guidelines.



Implementation Workshop on Alternative Safety Testing Methods

NICEATM and ICCVAM will host the implementation workshop Incorporating Alternative Test Methods into Your Regulatory Safety Testing. This workshop, tentatively planned for January 18-21, 2011, will bring together test method developers and users and representatives of regulatory agencies to review accepted alternative test methods and strategies. Participants will gain a practical understanding of available alternative methods for regulatory safety testing. The Society of Toxicology is a cosponsor of the workshop.

The workshop will be open to the public and held at the William H. Natcher Conference Center on the main campus of the National Institutes of Health in Bethesda, Maryland. More information on the workshop and a registration form will be available on the NICEATM–ICCVAM website later this summer. ●

Committee Advises on Alternative Toxicological Methods

Article by Robin Mackar reprinted from *eFACTOR*, July 2010

Maximizing animal care and welfare, increasing awareness about alternative toxicological methods, vaccine potency testing, validation issues, and hearing updates on federal and international acceptance of alternative methods were just a few of the topics covered at the June 17-18 meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) held on the U.S. Environmental Protection Agency (EPA) campus in Research Triangle Park, N.C.

NIEHS/NTP Director Linda Birnbaum, Ph.D., provided a warm welcome to all, especially to the international partners in attendance, including Joachim Kreysa, Ph.D., of the European Centre for the Validation of Alternative Methods (ECVAM), Soon Young Han, Ph.D., director of the newly established Korean Center for the Validation of Alternative Methods (KoCVAM) and David Blakely, Ph.D., of Health Canada, who joined the meeting by teleconference. Birnbaum praised the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) for their progress, highlighting the endorsement or adoption of 33 new alternative methods. She also mentioned that she just forwarded two of the first “green technology” ICCVAM test method recommendations to federal agencies for their approval.



SACATM members Diggs, left, and Ehrich engaged in discussions about creating more awareness about alternative toxicological method. (Photo courtesy of Steve McCaw)

Updates and discussion

William Stokes, D.V.M., provided an update on activities. He drew attention to a new publication *The Biennial Progress Report 2008–2009: Interagency Coordinating Committee on the Validation of Alternative Methods* which describes ICCVAM activities, test method recommendations, and other progress made during the reporting period. He highlighted some key accomplishments and spoke about upcoming workshops of interest, including the “International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions” to be held in Bethesda, MD on September 14-16, 2010.

Stokes queried SACATM on the topics of outreach, industry participation, and how to address some regulatory responses to methods. The group had many ideas to share about how to create more awareness for study directors and Institutional Animal Care and Use Committees (IACUCs) to make sure they consider alternative methods.

SACATM member Karen Brown, Ph.D., began the discussion by saying outreach efforts need to be expanded beyond the toxicology community to other groups, including industry. “Regulatory agencies and industry have to work together,” said Brown. She suggested inviting industry representatives to workshops and presentations to hear about the savings in time, money, and labor that alternative testing methods can often provide.

continued



Marion F. Ehrich, Ph.D., Sharon Meyer, Ph.D., Linda A. Toth, D.V.M., Ph.D., and others suggested more be done to reach out to laboratory animal veterinarians and personnel. They suggested placing articles in publications that lab technicians read such as Nature's "Lab Animal" as a way to increase awareness about alternative testing methods, as well as getting more concise, yet comprehensive articles into the peer-reviewed literature.

Participants also offered ideas for expanding training grants and other NIH grant mechanisms. George Corcoran, Ph.D., suggested providing travel funds for IACUC members to attend more meetings and workshops.

Helen Diggs, D.V.M., proposed using new media to help create awareness and training for study directors and IACUC members. "I suggest developing Web-based or other training programs that people can access at their leisure," Diggs said. "These are very busy people who don't have time or money to travel to hear about the newest methods."

Members also offered ideas for encouraging industry to submit testing data to NICEATM and providing data for proprietary products from companies without revealing the product identity. ●

(Robin Mackay is the news director in the NIEHS Office of Communications and Public Liaison and a regular contributor to the Environmental Factor)

Contact Information: Dr. William S. Stokes, Director NICEATM, NIH/NIEHS, P.O. Box 12233, MD K2-16, Research Triangle Park, NC 27709; T: (919) 541-2384; FAX: (919) 0947; niceatm@niehs.nih.gov

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