TABLE 1—TESTING RECOMMENDATIONS FOR SUBSTANCES NOMINATED TO THE NTP FOR TOXICOLOGICAL STUDIES—Continued

Substance [CAS No.]	Nominated by [1]	Nomination rationale	Preliminary study recommendations [2]
Triclosan [3380–34–5]	Private Individual and U.S. Food and Drug Administration.	Widespread use in consumer products; frequent and long-term exposure for all age groups; lack of adequate toxicity data for dermal exposures.	—Carcinogenicity studies via dermal administration. —Phototoxicity studies. —Reproductive toxicity studies.

[1] National Institute of Environmental Health Sciences (NIEHS).

[2] The term ''comprehensive toxicological characterization'' in this table refers to the approximate scope of a research program to address toxicological data needs. The types of toxicological studies that would be considered by NTP staff during the conceptualization and design of a research program are biomolecular screening, in vitro mechanistic, in vitro and in vivo genotoxicity, absorption, disposition, metabolism, and elimination, short-term repeat dose (2–4 weeks) in vivo studies, subchronic toxicity (13–26 weeks), chronic toxicity (1–2 years), carcinogenicity in conventional or genetically modified rodent models, organ systems toxicity (immunotoxicity, reproductive and developmental toxicity, neurotoxicity), in vivo mechanistic, toxicokinetics, and other special studies as appropriate (e.g., chemistry, toxicogenomics, phototoxicity).

To facilitate review of proposed research projects by the NTP BSC and the public, NTP staff developed a draft research concept document for each nomination recommended for study. A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program tailored for each nomination. The purpose of these research concepts is to outline the general elements of a program of study that would address the specific issues that prompted the nomination, but also encompass studies that may address larger public health issues or topics in toxicology that could be addressed appropriately through studies on the nominated substance(s). Draft research concepts for the new nominations listed in Table 1 will be available on the NTP BSC meeting page (*http://ntp.niehs.nih.gov/go/165*) by October 9, 2008.

Attendance and Registration

The meeting is scheduled for November 20–21, 2008, beginning at 8:30 a.m. on each day and continuing to 5 p.m. on November 20 and on November 21 until adjournment. The meeting is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the NTP BSC meeting Web site (*http://ntp.niehs.nih.gov/go/165*) by November 13, 2008, to facilitate planning for the meeting. The NTP is making plans to videocast the meeting through the Internet at *http://www.niehs.nih.gov/news/video/live*.

Request for Comments

Written comments submitted in response to this notice should be received by November 6, 2008. Comments will be posted on the NTP BSC meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), phone, e-mail, and sponsoring organization (if any) with the document.

Time will be allotted during the meeting for the public to present oral comments to the NTP BSC on the agenda topics. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the NTP BSC chair. Persons wishing to present oral comments are encouraged to pre-register on the NTP meeting Web site. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to send a copy of their statement to the Executive Secretary for the NTP BSC (see **ADDRESSES** above) by November 13, 2008, to enable review by the NTP BSC prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the NTP BSC and NIEHS/NTP staff and to supplement the record.

Background Information on the NTP Board of Scientific Counselors

The NTP BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the overall program and its centers. Specifically, the NTP BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. NTP BSC meetings are held annually or biannually.

Dated: September 23, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of Plans for Updated Evaluations of Genistein and Soy Formula; Request for Public Comments and Nomination of Expert Panel Members

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Notice of expert panel evaluation of the reproductive and developmental toxicities of genistein and soy formula.

SUMMARY: The CERHR plans to convene an expert panel to conduct updated evaluations of the scientific evidence

regarding the potential reproductive and/or developmental toxicity associated with exposure to genistein and soy formula begun in 2006. The expert panel will consist of approximately 10–12 scientists selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science. CERHR invites the submission of information about ongoing studies or upcoming publications on these substances that might be considered for inclusion in the evaluations and the nomination of scientists to serve on the expert panel (see **SUPPLEMENTARY INFORMATION** below). This meeting is tentatively scheduled for spring or summer 2009, although the exact date and location are not yet set. As plans are finalized, they will be announced in the **Federal Register** and posted on the CERHR Web site *(http://cerhr.niehs.nih.gov).* CERHR expert panel meetings are open to the public with time scheduled for oral public comment.

DATES: Comments received by November 17, 2008 will be made available to CERHR staff and the expert panel for consideration in the evaluation and posted on the CERHR Web site. Nominations of scientists received by November 17, 2008 will be considered for this panel and for inclusion in the CERHR Expert Registry.

ADDRESSES: Public comments and any other correspondence should be submitted to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC–32, Research Triangle Park, NC 27709 (mail), 919–541–3455 (phone), 919–316–4511 (fax), or *shelby@niehs.nih.gov* (e-mail). Courier address: CERHR, 79 T.W. Alexander Drive, Building 4401, Room 102, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

Background

Genistein (CAS RN: 446–72–0) is a phytoestrogen found in some legumes, especially soybeans. Phytoestrogens are non-steriodal, estrogenic compounds that occur naturally in some plants. In plants, nearly all genistein is linked to a sugar molecule and this genistein-sugar complex is called genistin. Genistin and genistein are found in many food products, especially soy-based foods such as tofu, soy milk, and soy infant formula, and in some over-the-counter dietary supplements. Soy formula is fed to infants as a supplement or replacement for human milk or cow milk.

On March 15–17, 2006, CERHR convened an expert panel to conduct evaluations of the potential reproductive and developmental toxicities of genistein and soy formula. CERHR selected genistein and soy formula for expert panel evaluation because of (1) The availability of numerous reproductive and developmental toxicity studies in laboratory animals and humans, (2) the availability of information on exposures in infants and women of reproductive age, and (3) public concern for effects on infant or child development. The expert panel reports were released for public comment on May 5, 2006 (**Federal Register** Vol. 71, No. 94, pp. 28368, May 16, 2006). Next, on November 8, 2006 (**Federal Register** Vol. 71, No. 216, pp. 65537, November 8, 2006), CERHR staff released draft NTP Briefs on Genistein and Soy Formula that provided the NTP's interpretation of the potential for genistein and soy formula to cause adverse reproductive and/or developmental effects in exposed humans. CERHR has not completed these evaluations, finalized the briefs, or issued NTP–CERHR monographs on these substances. Since 2006, a substantial number of new publications related to human exposure or reproductive and/or developmental toxicity have been published for these substances and CERHR has determined that updated evaluations of genistein and soy formula are needed.

Request for Comments

The CERHR invites the public and other interested parties to submit information and comments on genistein and soy formula including toxicology and epidemiologic information from completed and ongoing studies, information on planned studies, and information about current production levels, human exposure, use patterns, and environmental occurrence.

Request for the Nomination of Scientist for the Expert Panel

The CERHR invites nominations of qualified scientists to serve on the expert panel. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry which include: formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, membership in relevant professional societies, and certification by an appropriate scientific board or other entities. Nominations should include contact information and current *curriculum vitae* (if possible) and be forwarded to CERHR (see **ADDRESSES**). Final selection of individuals to serve on the expert panel will be made in accordance with the Federal Advisory Committee Act and Department of Health and Human Services implementing regulations.

All panel members serve as individual experts and not as representatives of their employers or other organizations. Scientists on the expert panel represent a wide range of expertise including, but not limited to, developmental toxicology, reproductive toxicology, epidemiology, general toxicology, medicine, pharmacokinetics, exposure assessment, and biostatistics.

Background Information on the CERHR

The NTP established CERHR in 1998 (**Federal Register**, December 14, 1998, Vol. 63, No. 239, page 68782). CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. CERHR follows a formal process for the evaluation of selected substances that includes opportunities for public input.

CERHR invites the nomination of substances for review or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its homepage *(http://cerhr.niehs.nih.gov)* or by contacting Dr. Michael Shelby, CERHR Director (see **ADDRESSES**). CERHR selects substances for evaluation based upon several factors including production volume, potential for human exposure from use and occurrence in the environment, extent of public concern, and extent of data from reproductive and developmental toxicity studies. Expert panels conduct scientific evaluations of substances selected by CERHR in public forums. Following these evaluations, CERHR prepares the NTP–CERHR monograph on the substance evaluated. The monograph is transmitted to appropriate federal and state agencies and made available to the public.

Dated: September 23, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

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