Meeting Summary

National Toxicology Program
Center for the Evaluation of Risks to Human Reproduction

Expert Panel Evaluation of Soy Infant Formula
December 16-18, 2009

The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) convened an expert panel on December 16-18, 2009, in Alexandria, Virginia to evaluate soy infant formula.

The 14-member, independent, scientific panel reviewed and evaluated the available scientific data on soy infant formula. In their deliberations, the expert panel considered the quality and strength of the scientific evidence that soy formula or its isoflavone constitutents might cause adverse effects on human development. The expert panel also identified gaps in the available scientific data on the possible effects of soy formula and suggested areas where additional research is needed.

Soy formula is an infant food made using soy protein and other components. It is fed to infants as a supplement or replacement for human milk or cow milk formula. Soy formula contains isoflavones, naturally occurring compounds found primarily in beans and other legumes including soybeans, peanuts, and chickpeas. The three main isoflavones in soy formula are genistein, daidzein, and to a smaller extent, glycitein.

All members of the panel served as individual experts and not as representatives of their employers or other organizations.

The NTP and expert panel use a five-level scale to express their conclusions to characterize the likelihood of an adverse human health effect resulting from exposure to a substance or chemical, in this case soy infant formula. The concern levels range from highest to lowest:

- Serious Concern
- Concern
- Some Concern
- Minimal Concern
- Negligible Concern

Expert Panel Conclusions
The Expert Panel expressed minimal concern for adverse developmental effects in infants fed soy infant formula.

The panel voted 10 yes, 2 no in favor of the conclusion. The two panel members voting no included one member who expressed negligible concern and one member who expressed some concern.

This conclusion is based on:

- Lack of clarity on whether studies in experimental animals treated with genistein only can be extrapolated to infants fed soy infant formula, i.e., exposure to a single isoflavone versus soy infant formula.
- Interpretation of findings from experimental animals as demonstrating adverse effects, i.e., advanced vaginal opening, effects on the mammary gland in the context of interspecies comparisons.
- Although there are a large number of experimental animal studies published on genistein or soy, there are only a limited number of studies where experimental animals were treated only during the relevant life stage of birth to weaning. Multigenerational studies do not permit discerning effects attributed to gestational or lactational exposure.
- However, a number of studies in experimental animals and one study in humans reported effects related to the reproductive system and this elevates the concern from "negligible" to "minimal."
- Studies of sufficient quality in humans have not been conducted to address the concerns raised from the experimental animal findings or to identify previously unrecognized endpoints.

Background
The NTP convened a panel in 2006 to evaluate soy formula and genistein. The NTP did not complete the evaluation or issue a final opinion on this topic. Since 2006, a substantial number of new publications have been published for these substances; therefore, CERHR determined that an updated evaluation of soy formula was needed before NTP could develop its opinion on this topic. The panel considered all of the data and not just information published since 2006.

The expert panel, with assistance from CERHR staff, prepared an updated expert panel report that was released for public comment on October 19, 2009, and finalized at the December expert panel meeting.

Information about the CERHR evaluation of soy infant formula is available at:
http://cerhr.niehs.nih.gov/chemicals/genistein-soy/SoyFormulaUpdt/SoyFormula-mtg.html

Next Steps
Following the December 2009 meeting of the expert panel, the NTP will solicit public comment on the expert panel report. The NTP will use the expert panel report, public comments, and any new scientific literature deemed relevant to the evaluation to prepare the NTP Brief that expresses the NTP's level of concern conclusions for soy infant formula.

The draft NTP Brief is tentatively scheduled for release for public comment in March 2010 and peer reviewed by the NTP Board of Scientific Counselors at a meeting on May 10, 2010, at the National Institute of Environmental Health Sciences in Research Triangle Park, NC. Following the peer review, the NTP will finalize its conclusions on soy infant formula and release the NTP Monograph containing the NTP Brief, expert panel report and public comments. The NTP

Monograph on Soy Infant Formula will be available to the public, appropriate regulatory authorities, and health professionals for use to make personal or public health decisions.

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The National Toxicology Program (NTP) is an interagency program established in 1978. The program was created as a cooperative effort to coordinate toxicology testing programs within the federal government, strengthen the science base in toxicology, develop and validate improved testing methods, and provide information about potentially toxic chemicals to health, regulatory, and research agencies, scientific and medical communities, and the public. The NTP is headquartered at the NIEHS. For more information about the NTP, visit http://ntp.niehs.nih.gov

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