INTERNATIONAL FORMULA COUNCIL

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In response to the NTP-CERHR Expert Panel Meeting to discuss the draft Reports on Genistein and Soy Formula, the International Formula Council (IFC)[*] offers the following statement:

"In addition to the Expert Panel's comments and conclusions on the reproductive and developmental toxicity of genistein and soy formula, the IFC reiterates its view based on the science that the safety of soy-based infant formulas has been adequately addressed previously and that there is no new information that provides sufficient justification for a reevaluation of soy formula safety.

"While an estimated 10% to 20% of all infants in the United States consume soy formula, Dr. Karl Rozman, a toxicology professor at the University of Kansas Medical Center and chairman of the panel said in a March 18 *Wall Street Journal* article that the reports aren't a reason for concern since "less than 1% of genistein in formula and other soy foods is absorbed after digestion in the human body."

"Dr. Jatinder Bhatia, a panelist and a professor at the Medical College of Georgia, echoed Rozman's sentiments in the same article by stating, "We're not talking hundreds of babies, we're talking millions of babies exposed to genistein. We already have a natural experiment in place. After 40 years of soy exposure, we haven't seen a blip on the radar screen. Right now we don't have a problem.

"The IFC reaffirms its position that soy-based infant formula safely provides necessary and appropriate nutrition for normal growth and development in term infants. This view is consistent with that expressed by the 1997 National Institutes of Health/U.S. Food and Drug Administration (FDA) Panel Meeting on the significance of phytoestrogens in infant soy formulas. It also is consistent with the position of the American Academy of Pediatrics (AAP) that the use of soy-based infant formula is a safe and effective alternative to provide appropriate nutrition for normal growth and development in term infants.[1]

"Soy protein has been used in infant feeding for nearly a century. During this period, soy protein-based infant formulas have evolved to become safe and effective alternatives for infants whose nutritional needs are not met with human milk or formulas based on cow's milk.[2] From the early 1960s, modern formulas based on soy protein isolates have been fed safely to over 20 million American infants with no higher documented adverse health conditions than breast-fed or cow's milk formula-fed babies. Modern soy formulas meet all nutritional requirements and safety standards of the AAP Committee on Nutrition (AAP-CON) and the Infant Formula Act of 1980 and its 1986 amendments.[3] Soy formulas are commonly used successfully in infants with Type I cow's milk allergy, lactose intolerance, galactosemia, and as a vegetarian human milk substitute.

"Furthermore, there is no evidence of negative effects on babies fed soy-based formulas or on adults who were fed soy-based formulas as babies. Scientists have known for decades that phytoestrogens like genistein occur naturally in many foods of plant origin, such as wheat, rice, and soybeans.

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[*] IFC is an international association of manufacturers and marketers of formulated nutrition products (e.g., infant formulas and adult nutritionals) whose members are predominantly based in North America. IFC members include all U.S. manufacturers: Mead Johnson Nutritionals; Nestle USA, Inc., Nutrition Division; PBM Products; Ross Products Division, Abbott; Solus Products, LLC; and Wyeth Nutrition.

Phytoestrogens have some similarity in structure to the hormone estrogen, but are *thousands* of times weaker in activity. Estrogen compounds are also present in human milk.

"Many studies support normal growth and development in term infants fed soy infant formula.[2,4,5,6,7,8] Recent concerns raised about the safety of dietary isoflavones in soy infant formulas are based on a relatively small number of animal studies. These animal trials are often characterized by inadequate designs, non-physiological dosages and routes of administration, and conflicting results. The oral-delivery animal studies are inadequate metabolic models for human infants because they generally do not take into account the animal's conversion of oral daidzein to equol, and equol's higher estrogenic potential. Animal data can be suggestive in the absence of human studies, only if the animal models are reliable predictors of effects in humans. The rodent model does not appear to be a reliable model for effects in humans in this particular case. On the other hand, there are many studies in humans that can be used as reliable indicators of safety.

"Currently available human infant and adult data show that soy formulas do not adversely affect human growth, development, or reproduction. In a recent review on the safety of isoflavones, Munro et al. stated clearly, 'There is no conclusive evidence from animal, adult human, or infant populations that indicates that dietary isoflavones may adversely affect human development or reproduction.'[9] Strom et al. evaluated more than 30 developmental and reproductive outcomes in young adults who had been fed soy or milk-based formula in the first 4 months of life.[10]

"Based on the scientific evidence, Susan Baker, MD, the chair of the AAP-CON in 2001, commented, 'Parents can feel confident that soy-based infant formulas are safe. For over 50 years, millions of babies have grown and developed normally on soy-based formulas. Mother's milk is the best nutrition for babies. The American Academy of Pediatrics policy is that soy formulas are safe and effective for babies who are not being breast-fed and cannot tolerate a cow's-milk formula.'

"Breast milk is the ideal and recommended source of nutrition for infant feeding. However, if parents choose or need to formula-feed their infant, physicians and other health care professionals are best qualified to help parents decide when a soy formula may be appropriate for their infant.

"In conclusion, the long history of safe use, the acceptance of soy infant formula feeding by the FDA and the AAP, and long-term human studies indicating an absence of adverse health effects, all clearly demonstrate that soy infant formula is safe and supportive of normal growth, development, and reproduction."

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[10] Strom, B. L., Schinnar, R., Ziegler, E. E., Barnhart, K. T., Sammel, M. D., Macones,G. A et al. Exposure to soy-based formula in infancy and endocrinological and reproductive outcomes in young adulthood. J. Am. Med. Assoc. 2001; 286: 807-814.