Data in Sackett *et al.* paper may be misleading

Sackett *et al.*, in their article entitled "An examination of the migration of selected contaminants from microwave susceptors to food," (November 1991, p. 175) listed nine carcinogens potentially found in susceptor construction obtained from a report published by NFPA and SPI and cited in Ref. 9. For each carcinogen, a so-called virtually safe dose (VSD, daily dose equivalent to an upper bound of risk of one cancer in one million exposed people for a lifetime) was given in μg/person/day. With the exception of two chemicals, chloroform and benzene, the VSDs appear consistent with estimates derived from applying FDA's Center or Food Safety and Applied Nutrition risk assessment methodology (*1-3*).

For benzene, Sackett *et al.* list in Table I a VSD of 9.3 μg/day, a value 5.5 times greater than the 1.7 μg/day reported by Linda Tolleftson of FDA at the 1988 Annual Meeting of the Society of Risk Analysis held in Washington, DC. The VSD listed for chloroform in Table I is 5.8 μg/day. However, application of FDA's risk assessment methodology to the most recent and largest rodent bioassay conducted on chloroform (*4*) results in a VSD of approximately 200 μg/day. Consequently, the VSDs calculated in accordance with FDA's methodology are 35 times higher than that reported in the article. It would be unfortunate were these two reported values to mislead those attempting to comply with FDA's standards.

Another aspect of the article is the authors' use of only 10% of the VSD, thus reserving the remaining 90% for other sources. This practice is equivalent to establishing an upperbound cancer risk estimate of 10^{-7} as the regulatory standard for indirect additives. While there may be specific situations where allocation of risk needs to be considered, as a generic approach, it appears far more conservative than FDA's original intent (*2*). Compare, for instance, this approach to California's cancer risk standard of 10^{-5} per product under Proposition 65.

The authors selected 5% of the diet as the portion of the diet that would contact these packages. While this value is given as an example in the FDA's guidelines (*5*), 5% should not be viewed as inviolable. If adequate data are available to demonstrate that the maximum portion of the diet contacted is significantly less than 5% and that market shifts and changes in consumer preferences would not significantly increase this proportion, then the FDA would be free to incorporate the determined value in their assessment.

Literature cited

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—W. Gary Flamm, Ph.D., F.A.C.T.
Flamm Associates
11760 Indian Ridge Road
Reston, VA 22091