COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 500.450 Volatile N-Nitrosamines in Rubber Baby Bottle Nipples

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Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs

BACKGROUND:

A German study on the occurrence of volatile N-nitrosamines (nitrosamines) in rubber baby bottle nipples was presented at the meeting of the American Chemical Society in the spring of 1981. FDA's subsequent investigation of the problem revealed the presence of nitrosamines in rubber nipples marketed in the United States and showed that the nitrosamines could migrate into foods, such as milk and infant formula, that contact the nipple during the conventional sterilization process. FDA expressed concern to the industry over infant exposure to nitrosamines, many of which are carcinogens, and informed manufacturers that appropriate measures must be taken to reduce nitrosamine formation in rubber nipples to the lowest level that is technologically feasible. Manufacturers altered product formulas and manufacturing processes to reduce nitrosamine formation. Available data indicate that nipples containing 10 ppb or less are now possible under existing manufacturing processes.

REGULATORY ACTION GUIDANCE:

Nitrosamines in nipples at levels greater than an established action level are considered avoidable contamination under section 406 of the Federal Food, Drug, and Cosmetic Act.

An action level of 10 ppb for individual nitrosamines applies to both consumer and hospital rubber baby bottle nipples initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 1985.

Samples shall be analyzed according to the method published in Food and Chemical Toxicology, Vol. 20, pp. 939 to 944, 1982 and using the modification described in FDA memorandum dated April 6, 1984, which calls for the addition of 2g $Ba(OH)_2$ to the solution to be distilled.

Confirmation tests should be performed only for nitrosamines that exceed the 10 ppb level.

For shipments of baby bottle nipples, both consumer and hospital nipples, made after January 1, 1985, the following represent criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

and

1. The level of any individual volatile N-nitrosamine in each of 3 aliquots from a composite of 12 rubber baby bottle nipples exceeds 10 ppb,
2. The identity of the nitrosamine that exceeds the 10 ppb level is confirmed by gas chromatography-mass spectrometry.

Material between asterisks is new and revised

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