

**Comments of IBFAN International Baby Food Action Network
To Codex Committee on Food Additives 43rd session China 14-18 March 2011**

Agenda item 4b CX/FA 11/43/5

**Discussion paper on Food Additive Provisions in the standard for infant formulas
and formula for special medical purposes (CODEX STAN 72-1981)**

IBFAN expresses its support for the three recommendations to be addressed to CCNFSDU.

IBFAN supports the JECFA conclusions: *“Baby foods should be prepared without food additives whenever possible....”*

We also want to voice our concern that all infant formulas actually on the market for infants of less than 12 weeks have food additives that have not been evaluated as safe for this age group.

Formula-fed infants are already in an immunologically deprived status, those infants that need formula for special medical purposes are even more vulnerable

Research needs

As a general principle, IBFAN maintains that no ingredient should be added to formulas unless it has been demonstrated as safe by means of an independent systematic review of all available evidence, which must include an appropriate proportion of independently-funded research.

If the products are to be fed to babies less than 12 weeks, this research must start from birth and take into account special ethical considerations regarding this population.

History of safe use

We do not accept the rationale often put forward by the food industry relating “to safe historic use” more often than not based on company owned phone lines and reports. No independent monitoring is provided to validate such a claim. In its comments on the Conclusion of the International Expert Group on the composition of infant formulae¹, ESPGHAN commented that consumer phone line services are not sensitive enough to detect adverse effects of infants:

“ESPGHAN wishes to emphasize that there is no evidence available to show that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of infant formulae. On the contrary, for example the very severe adverse effects recently induced by an infant formula with inadequate contents of vitamin B1 (thiamine), which resulted in failure to thrive, severe neurological damage, severe lactic acidosis and even infant deaths (2-4), were not detected by the distributor’s consumer phone line services..”

It’s worth noting that in IBFAN’s experience it has been necessary to use Freedom of Information procedures to establish the extent of consumer reports of adverse reactions to formulas to government agencies. For example the 98 reports to the FDA of adverse reactions to DHA in infant formula were only obtained after a specific request made under the Freedom of Information Act.

Thickeners

¹ ESPGHAN Comments on the Circular Letter CL 2005/53-NFSDU and on the Synopsis of comments received until 30 April (prepared by Germany) *“The question arises whether the ranges of nutrient levels in infant formulae that are reported by ISDI, without documented occurrence of side effects, suffice to establish a “history of safe use”, or even of adequacy of such nutrient levels for infant formulae. ISDI suggests that a history of apparently safe use of products might be based on the use of commercially produced infant formula and the monitoring of spontaneous consumer reports of observations that may indicate a problem with a specific batch of formula. In some areas, such as Europe, Israel and the USA, there are consumer phone line services have been established where parents may call in, usually free of charge, to place questions or complaints to the manufacturer or distributor of an infant formula. ISDI explains that such customer reports are monitored and should provide a tool for post-marketing surveillance of infant formula safety. Based on the evaluation of these consumer phone line services and the absence of detected serious side effects, ISDI implies that a history of safe use has been established for the nutrient levels reported in their compilation. ESPGHAN wishes to emphasize that there is no evidence available to show that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of infant formulae.”*
IBFAN COMMENTS CCFA standard for infant formulas and formula for special medical purposes

Thickening agents, emulsifiers and antioxidants are not needed in infant formulas. These non-nutritive ingredients expose infants to needless additives in addition to the large number of foreign substances already present in infant formulas. Formula-fed infants are in an immunologically deprived state and less able to handle unnecessary chemicals. All products covered by this standard must be matched as closely as possible to the breastfeeding gold standard, which of course contains no thickeners or other cosmetic additives. For decades scientists, manufacturers and doctors have doubted in women's ability to provide enough nutrition to her baby by breastfeeding. This doubt still persists in the head of people even now where new knowledge on the composition of breastmilk and lactation physiology is available and these doubts will be fueled by thickeners in infant formulae. This means that thickeners added to infant formula are misleading parents on the nutritional value of the product.

Ingredients are frequently added for cosmetic reasons to please parents, or as processing aids to make manufacturing easier or less expensive. This has nothing to do with providing for the infant's needs.