

FDA sets safety standards for infant formula

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Rules call for periodic testing for nutritional content, good manufacturing practices.

(HealthDay)—A new rule that aims to ensure the safety of infant formula has been finalized by the U.S. Food and Drug Administration.

An initial version of the rule for manufacturers of infant formula was released in February and the final version contains some modifications and clarifications that were made in response to comments received by the FDA.

The agency said infant formula makers will have to start complying with the final rule by Sept. 8. The rule requires manufacturers to prove that their [infant formulas](#) support normal physical growth and that the products be tested for nutrient content before they are sent to stores and at the end of their shelf life.

The rule also outlines good manufacturing practices specifically designed for infant formula, including mandatory testing for the disease-causing bacteria *Salmonella* and *Cronobacter*.

The new rule applies only to infant formulas meant for healthy infants who do not have unusual medical or dietary problems, the FDA said.

Breast-feeding is strongly recommended for newborns, but most infants in the United States consume at least some infant formula. Among the infants born each year in the United States, about 1 million are fed formula from birth and about 2.7 million rely on formula for at least part of their nutrition by the time they are 3 months old, according to the FDA.

Infant formula comes in three forms—powder, liquid concentrate, and ready-to-feed—and the protein source varies among the different types of formula.

Many companies that sell infant formula in the United States produce safe products and have voluntarily applied many of the [good manufacturing practices](#) and quality-control procedures included in the final rule, but the new rule establishes federally enforceable requirements for the safety and quality of infant formula, the FDA said.

All infant formulas sold in the United States must meet federal nutrient requirements, which are not changed by the new rule.

If an infant formula poses a risk to infants' health, the manufacturer must conduct a recall, the FDA said.

More information: The American Academy of Family Physicians has more about [infant formula](#).

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