

Action by the US Federal Government – long overdue ?

The Final Rule and Interim Final Rule of the US Food and Drug Administration, FDA, are effective as of July 10, 2014 : [Infant Formula: Current Good Manufacturing Practices \(CGMPs\); Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors](#)

The full text of the Final Rule can be found here

See : <https://www.federalregister.gov/articles/2014/06/10/2014-13384/current-good-manufacturing-practices-quality-control-procedures-quality-factors-notification>

« The Final Rule will help prevent the manufacture of adulterated infant formula, ensure the safety of infant formula and ensure that the nutrients in infant formula are present in a form that is bioavailable » and « The requirements in the final rule improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula. »

There are two important dates for compliance by formula manufacturers : in one year, by November 12, 2015 manufacturers must meet the requirements related to quality factors for eligible infant formulas¹. But before that, manufacturers must comply with the remaining provisions of this final rule by September 8, 2014.

The process of finalising the Rule has lasted 17 years, with 8 actions beginning in 1996 to November 2013. These actions for review and comments by manufacturers are related to the sufficiency of quality control testing, current good manufacturing practices (CGMP), recordkeeping, and recall requirements for infant formula. The comments on the 2014 Final Rule of the US Food and Drug Administration, FDA, show how hard the companies fought at every stage.

¹ Articles 21CFR 106.96(a), 106.96(e), 106.96(i)(5), 106.100(p)(2) and 106.100(q)(2)