

China Strengthens Control Over Infant Formula Production

In response to the discovery of toxic bacteria in products imported from a New Zealand dairy producer, the Chinese government has published a series of draft guidelines and regulations on infant formula production. These regulations, issued on August 2, 2013, include (a) draft *Review Guidelines for Conditions for Infant Formula Production License*, (b) a draft *Regulation on Prohibition of Infant Formula Production under CMO, OEM, or Repackaging Arrangements*, (c) draft *Administrative Measures on Registration of Infant Formula*, and (d) a draft *Regulation on Supervision and Inspection of Quality and Safety Management of Infant Formula Producers* (collectively, the “**Draft Regulations**”). The Draft Regulations demonstrate the Chinese government’s determination to strengthen the quality control over infant formula products, in hopes of restoring consumer confidence in Chinese dairy products and reshaping the national infant formula industry.

The highlights of the Draft Regulations are:

1. An infant formula producer must register with the provincial Food and Drug Administration at least 60 days prior to its production. No production activity should be conducted before the completion of such registration, including the registration of its product formula, the raw materials, excipients, suppliers thereof, and the product packages and labels.
2. An infant formula producer shall not produce products on behalf of others under a contract manufacturing (CMO) arrangement, or products under a brand owned by others under an OEM arrangement. It also shall not produce products under a trademark or brand registered by itself outside of China. Repackaging production is not permitted; the producer must not produce products with the same formula but under different product names or brands.
3. The producers will assume the primary liability for the product safety. The producers are required to establish the quality control departments with qualified quality control professionals. They will need to implement the Hazard Analysis and Critical Control Point (HACCP) system and Good Manufacturing Practices (GMP) to control the product quality. The producers should ensure the traceability of their products and establish and implement the product recall system, including voluntary recalls, as well as mandatory recalls.
4. The producers need to control or own their milk sources. The purchase of materials, manufacturing process, product inspection, sampling, storage and release, and research and development capabilities must comply with various mandatory requirements. The Draft Regulations also substantially raise the requirements for the manufacturing facilities and equipment. By using pharmaceutical production standards as reference, the Draft Regulations intend to comprehensively raise standards for the infant formula production in China.

If you would like to discuss the foregoing or any other related matter, please contact [Katherine Wang](#) or your usual Ropes & Gray advisor.