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Voluntary _ Public

Date: 2/10/2014

GAIN Report Number: 14006

China - Peoples Republic of

Post: Beijing

China's 2013 Dairy Regulations

Report Categories:

Dairy and Products

Food and Agricultural Import Regulations and

Standards - Certification

FAIRS Subject Report

Food and Agricultural Import Regulations and

Standards - Narrative

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Report Highlights:

In 2013, Premier Li Keqiang ordered Chinese government agencies to strengthen government oversight for domestic and imported dairy/infant formula products. Key government agencies subsequently imposed the regulations listed in this GAIN report. Readers should review the regulations in their entirety (see website links contained herein) for details and the regulations' potential impact.

In May 2013, Premier Li Keqiang ordered the relevant Chinese government agencies to regain consumer trust by strengthening government oversight for domestic and imported dairy/infant formula products. For more information, please read the following article http://news.xinhuanet.com/english/china/2013-05/31/c_132423178.htm

State Council

- 1. China's Food and Drug Administration,
- 2. Ministry of Industry and Information Technology,
- 3. Ministry of Public Security,
- 4. Ministry of Agriculture,
- 5. Ministry of Commerce,
- 6. State Health and Family Planning Committee,
- 7. General Administration of Customs,
- 8. the State Administration for Industry and Commerce, and
- 9. General Administration of Quality Supervision, Inspection and Quarantine

Notice 57 on the Decision made by the China Food and Drug Administration (CFDA) and other

Departments and Forwarded by the General Office of the State Council (GOSC) to Further Strengthen

Quality and Safety of Formula Milk Powders for Infants/Young Children

The quality and safety of formula milk powders for infants and young children (FMPIYC) are important for people's livelihood, the economy and society. Raising the quality and safety of these products, and guaranteeing that infants and young children eat safe and reliable formula milk powders is important for future generations.

All regional governments and competent authorities shall strictly implement the State Council's decision, pay close attention to quality and safety of FMPIYC products, regard it as a keystone for improving overall food quality and safety in China, spare no effort to raise quality and safety levels of FMPIYC products, and rebuild consumer confidence in Chinese-origin milk powders. Local government at all levels shall take responsibility for food safety, strengthen centralized leadership and organizational coordination, develop a detailed program and define explicit responsibility to effectively carry out local quality and safety practices for FMPIYC products. All related authorities shall strictly perform their regulatory responsibility, enhance cooperation, strengthen operational direction and steadily push forward their tasks. China's Food and Drug Administration (CFDA) shall enhance planning and coordination, direct associated authorities to deepen the examination and surveillance of the operations of local authorities and ensure proper implementation of tasks and practices.

Website: www.gov.cn/zwgk/2013-06/20/content_2429394.htm

China's Food and Drug Administration (CFDA)

Detailed Regulation on Verification of Infant Formula Milk Powder Processing Plants

On December 25, 2013, CFDA announced its revision to the verification process of infant formula milk powder processing plants, and discussed how this regulation is linked to its No. 49 Order, (published on

December 16, 2013). This regulation stresses plant responsibilities for quality/safety control and government oversight. The permit verification process must be completed by all infant formula milk powder producers by May 31, 2014.

The official regulation includes three appendices which can be found at the website below:

- Main Standards for Raw/Auxiliary and Packaging Materials for Infant Formula Milk Powder Production
- Test Items and Methods regulated in the "National Food Safety Standard Baby Formula Food" (GB10765)
- Test Items and Methods regulated in the "National Food Safety Standard Older Baby and Infant Formula Foods" (GB10767)

Website: www.sda.gov.cn/WS01/CL1600/95414.html

No. 44 Order on the Regulation of Supervision and Inspection of Infant Formula Milk Powder Processing Plants

On November 27, 2013, CFDA announced its No. 44 Order on the supervision and inspection of infant formula milk powder processing plants. Processing plants must implement these procedures by May 31, 2014. This Order is based on China's Food Safety Law, the Regulation of Supervision and Management on Dairy Product Quality and Safety, and the State Council's Notice to Distribute CFDA and other Agencies' Opinion to Further Strengthen Infant Formula Milk Powder Quality and Safety (Guo Ban Fa [2013] No. 57).

The official regulation includes two appendices.

- Supervision and Verification of Plants Producing Infant Formula Milk Powder
- Audit Form for Plants Producing Infant Formula Milk Powder

Website: www.sda.gov.cn/WS01/CL1598/94711.html

No. 43 Order to Ban Entrustment and OEM Production and Repackaging of Infant Formula Milk Powder

On November 27, 2013, CFDA announced its No. 43 Order to ban entrustment and OEM production, or repackaging of infant formula milk powder. This Order became effective on that announcement date, and includes the following guidance.

- 1. Infant formula milk powder processing plants should not accept entrustments of other organizations or individuals to produce infant formula milk powder for them. Organizations or individuals should not entrust plants to produce infant formula milk powder by contracts or agreements.
- 2. Plants should not produce infant formula milk powder for other brand owners or agents, or fraudulently use other brands.

- 3. Plants should not produce infant formula milk powder in China, if plants registered their trademarks, company names and addresses for infant formula milk powder production outside of China.
- 4. Any organization or individual should not purchase infant formula milk powder and directly refill into tanks, bags and boxes or change the original packaging and labeling.
- 5. Plants should not produce infant formula milk powder in different product names by using the same ingredients from the same raw and auxiliary materials.
- 6. Plants should only use cow milk, sheep/goat milk or dairy products (including milk protein, lactose, etc.) to produce infant formula.
- 7. Violators will be investigated and handled by the Health and Family Planning Commission at county levels and above. Suspected criminals will be sent to the judicial system for a criminal sentence.

Website: www.sda.gov.cn/WS01/CL1598/94710.html

Other 2013 CFDA Regulations

October	Further Regulating the Advertisement and Sales Behavior of Breast Milk Substitutes http://www.gov.cn/jrzg/2013-10/29/content_2517537.htm [NHFPC and SAIC also contributed to this regulation.]
November	Provision on Infant Formula Firm Supervision (Draft) http://www.sda.gov.cn/WS01/CL1612/94711.html
December	Further Strengthening the Supervision of the Sale of Infant Formula http://www.foodmate.net/law/shipin/180612.html
December	Announcement on trial of Infant Formula Sale in Drug Store http://www.sda.gov.cn/WS01/CL1349/95314.html
December	Notice on Implementation and Tightening Examination Details of Production License for Infant Formula http://www.sda.gov.cn/WS01/CL0051/95446.html

Ministry of Industry and Information Technology

Action Plan of Improving the Quality of Formula Powder and Enhancing Consumer Confidence: http://www.ce.cn/cysc/sp/info/201306/18/t20130618_21527621.shtml

Detailed Work Plan of Promoting Mergers and Acquisitions within Infant Formula Industry (Draft): http://www.21cbh.com/2013/10-21/5OODUyXzg2NzM5OA.html

National Health and Family Planning Commission (NHFPC)

Updated Measures on New Food Raw Materials

On July 12, 2013, NHFPC issued Order No. 1 to administer safety examinations of new food raw materials. Order No. 1 became effective on October 1, 2013 and replaces the measures on the administration of novel foods (the Ministry of Health (MoH) Order 56 of 2007).

Compared to MoH's Order No. 56, NHFPC's Order No. 1 further specifies China's definition and scope of new food raw materials. It also allows more involvement of the public during the registration of new food raw materials and introduces penalties for applicants who provide false information about new foodstuffs.

Website www.cfda.com.cn/newsdetail.aspx?id=64022

China's Ministry of Agriculture

Administrative Measure on Veterinary and Non-Veterinary Prescription Drugs

On September 11, 2013, MoA announced its No. 2 Order on the Administrative Measure of Veterinary and Non-Veterinary Prescription Drugs, which will become effective on March 1, 2014. Veterinary prescription drugs can only be bought and used by showing veterinary prescriptions. Non-Veterinary prescription drugs can be bought and used according to drug specification for animals. MOA is responsible for announcing the list of veterinary prescription drugs. Veterinary drugs not included in the list are non-veterinary prescription drugs.

Location: http://www.moa.gov.cn/govpublic/SYJ/201310/t20131009_3623326.htm

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

<u>Decree 152: Measure of Dairy Product Import/Export Inspection & Quarantine Management</u>

On January 24, 2013, AQSIQ announced its Decree No. 152 on the Measure of Dairy Product Import and Export Inspection and Quarantine Management, effective May 1, 2013.

Website: www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjl/2013/201302/t20130201_342349.htm

Unofficial translation:

http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Inspection%20and%20Quarantine%20of%20Imp.%20and%20Exp.%20of%20Dairy%20Products_Beijing_China%20-%20Peoples%20Republic%20of_3-12-2013.pdf

Notice 53 on the Implementation of Decree 152

On April 15, 2013, AQSIQ published No. 53 on the implementation of Decree 152. This Notice comes with two appendices:

- 1. Imported Dairy Product Categories Needed Formalities of Quarantine Permit
- 2. List of Test Items for Dairy Products Imported for the Non-First Time

Website: www.xzciq.gov.cn/ywdh/spaq/201311/t20131111_386398.htm

Unofficial translation:

http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Implementation%20Measures%20of%20China's%20Decree%20152%20for%20Dairy%20Products_Beijing_China%20-%20Peoples%20Republic%20of_6-24-2013.pdf

China's National Certification and Accreditation Administration (CNCA)

Registration of Foreign Dairy Processing Plants Exporting to China

On November 22, 2013, CNCA notified all Embassies and Diplomatic Missions in Beijing that all foreign dairy processing plants that export to China must be registered by May 1, 2014.

This regulation has five appendices:

- 1. Questionnaires on Registration of Foreign Plants Producing Dairy Products for Export to China
- 2. Attachment to the Questionnaires Production Regulation and Equivalency Form
- 3. Registration Application Form for Foreign Fluid Milk Plants to Produce Infant Formula Milk Powder Exported to China
- 4. Sample of Official Declaration of Compliance
- 5. List of Dairy Plants Applying for Registration (not infant formula milk powder plants)

Website: www.cnca.gov.cn/rjwzcjgb/xgxz/jkspgwscqyzcxgxz/jkrpjwscqyzcxgwj