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Regulation on Inspection and Quarantine of Imp and Exp Dairy Product

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Approved By:

Melinda Meador

Prepared By:

Wu Bugang

Report Highlights:

The General Administration of Quality Supervision, Inspection and Quarantine of China has published the Administrative Measures on Inspection, Quarantine and Supervision of Import and Export of Dairy Products, which will take effect on May 1, 2013. A draft version was notified to the WTO as G/SPS/N/CHN/355 on March 23, 2011. (see GAIN report 3/24/2011). This measure is targeting increased oversight of dairy products, both imported and domestic, and reflects China's implementation under the 2009 Food Safety Law of a system wide focus on traceability and on product standards.

The report contains an unofficial translation of the final measure.

General Information:

BEGIN TRANSLATION

Administrative Measure on Inspection, Quarantine and Supervision of Import and Export of Dairy Products

Chapter I General Principle

Article 1 In order to enhance inspection, quarantine and supervision of imported and exported dairy products, this Measure is formulated in accordance with the *Law on Food Safety of the People's Republic of China* (hereinafter referred to as Food Safety Law) and its implementation regulations, the *Regulation on Supervision and Management of Dairy Quality and Safety*, *Law on Inspection of Imported and Exported Commodities of the People's Republic of China* and its implementation regulations, the *Law on Quarantine of Imported and Exported Animals and Plants of the People's Republic of China* and its implementation regulations, and the *State Council's Special Rule on Enhancement of Safety Supervision and Management of Food and Other Products* (hereinafter referred to as Special Rule).

Article 2 Dairy products described in this Measure include colostrum, raw milk and milk products.

Colostrum refers to milk produced from postpartum dairy stocks within 7 days.

Raw milk refers to natural milk without any change of component that is milked from udders of healthy dairy stocks that comply with relevant regulations by Chinese government. Colostrums, milk produced during antibiotics using period and withdrawal period, and alterative milk shall not be used as raw milk.

Milk products refer to foods use milk as main ingredient, such as: pasteurized milk, sterilized milk, modified milk, fermented milk, cheese and processed cheese, cream, butter, anhydrous cream, condensed milk, milk powder, whey powder, whey protein powder and milk-based infant formula foods. Those produced from fresh milk and without heat sterilization are called raw processed dairy products.

Article 3 General Administration of Quality Supervision, Inspection and Quarantine (hereinafter referred to as AQSIQ) is in charge of supervision and management of inspection and quarantine of imported and exported dairy products.

AQSIQ's local inspection and quarantine agencies of imported and exported goods (hereinafter referred to as CIQ) are responsible for supervision and management of inspection and quarantine of imported and exported dairy products in their respective regions.

Article 4 Producers and marketers of imported/exported dairy products shall operate their business according to the law and regulations, behave on an honest and accountable basis to ensure food

safety, take responsibility to the public and society, accept social supervision and carry out social responsibility.

Chapter II Import of Dairy products

Article 5 AQSIQ assesses the food safety management systems and food safety conditions of countries or regions that export dairy products to China in accordance with related Chinese laws and regulations, and conduct retrospective reviews in accordance with the safety conditions and needs of supervision and management of imported dairy products.

For the countries or regions that export dairy products to China for the first time, the competent authorities shall provide materials to AQSIQ for assessment, including legal system and organizations of veterinarian health and public health, veterinarian service system, safety and health control system, residuals monitoring system, animal epidemics inspection and monitoring conditions, and categories of products planned to export to China.

AQSIQ will gather experts for assessment according to the law, and send experts to conduct field investigation in the country (region). If the risk is identified as acceptable and relative requirements for inspection and quarantine, including certificates is confirmed, the dairy products meeting the requirements are allowed to be exported to China. Both sides can sign the protocol to confirm inspection and quarantine Requirements.

Article 6 AQSIQ implements a registration system for overseas food producers (hereinafter referred to as overseas producers) that export dairy products to China. Registration is executed subject to AQSIQ's regulations.

Overseas producer shall be an entity established under official competent authority's approval of the exporting country (region) and comply with related laws and regulations of the exporting country or region.

Overseas producer shall be familiar with and ensure that its dairy products exported to China will be complied with China's national standard of food safety and requirements, and be able to provide test report of items regulated by the national standard. Overseas producer shall clarify the types and brands of dairy products it plans to export to China when applying for registration.

The list of registered overseas producers shall be published on AQSIQ's official website.

Article 7 Dairy products exported to China shall have health certificate(s) issued by the competent authority of the exporting country (region). The certificate shall include information that:

1. the raw materials of the dairy products comes from healthy animals;
2. the dairy products do not have and will not transfer animal epidemics through processing;
3. the dairy producer is under supervision of the competent authority in the region where it operates; and

4. the dairy products are safe and fit for human consumption.

The certificate shall have the official stamp of the country (region)'s competent authority, and the signature of its authorized representative. The destination shall be the People's Republic of China.

The sample of the certificate shall be confirmed by AQSIQ and published on AQSIQ's official website.

Article 8 In the event that a quarantine approval is required, the dairy products are allowed to be imported after obtaining the *Quarantine Import Permit for Animals and Plants of the People's Republic of China* (hereinafter referred to as the Permit).

AQSIQ may adjust and announce the types of dairy products that shall have quarantine approval according to the law.

Article 9 Exporters or agents that export dairy products to China shall submit required information for record to AQSIQ. The exporter or agent shall provide information in accordance with relevant requirements and be responsible for the authenticity of the information.

The list of record shall be published on AQSIQ's official website.

Article 10 The inspection and quarantine agencies document and manage the importers of imported dairy products. The importer shall have professionals in food safety, administrative personnel and rules and regulations ensuring the food safety. The importer shall apply for registration at the local CIQ where it registered the business according to AQSIQ's regulation.

Article 11 The importer of imported dairy products or its agent(s) shall declare inspection to the CIQ at the customs of declaration, while providing materials as follows:

1. necessary certificates, such as contract, invoice, packing list and bill of lading;
2. health certificate which complies with Article 7 under this Measure;
3. A test report of items listed in the corresponding national standards of food safety is required in the event that the dairy is imported for the first time. Imported for the first time refers to the dairy product with exactly identical information including overseas producer, product name, formula, overseas exporter, and domestic importer which is imported from the same port.
4. A copy of the test report when first-time imported, and a test report of items requested by AQSIQ is required for the dairy that is not imported for the first time. The items requested for testing for non first-time import are decided by AQSIQ according to the situation including risk monitoring of dairy and will be published on AQSIQ's official website.
5. The dairy which fails the safety and sanitary requirements (including pathogen, mycotoxin, contaminant, heavy metal and illegal additive) shall provide test report of items listed in the corresponding national food safety standard when imported once again. If all the safety and sanitary requirements are met for the five consecutive shipments, a copy of the test report of items listed in the corresponding national food safety standard and a test report of items requested by AQSIQ shall be provided when imported the next time.
6. Materials including sample of label in original language, Chinese translation of original label and

sample of Chinese label are required when importing pre-packaged dairy.

7. the Permit in the event that quarantine approval is required on the dairy to be imported;
8. certificate of import Permit issued by the Ministry of Health of the People's Republic of China (hereinafter referred to as MOH) in the event that the dairy is imported for the first time and not covered by the national standard on food safety;
9. certificate of Permit issued by related authority in the event that the dairy has a function of health care; and
10. certificate confirmed through diplomatic channel in the event that the dairy is labeled with award, prize or certification.

Article 12 Importer shall ensure the imported dairy products comply with China's national food safety standards and public the type, place of production and brand of its imported dairy products.

The dairy that is not covered by the national standard on food safety shall comply with the requirements included in the certificate of import Permit issued by MOH.

Article 13 The packing and transport tools of imported dairy products shall comply with requirements on safety and health.

Article 14 Pre-packed dairy products shall have labels and instructions with Chinese language. These labels and instructions shall comply with Chinese laws and regulations and national standard on food safety.

Article 15 Imported dairy products shall be stored in a location that is designated or approved by the CIQ prior to obtaining the *Qualification of Inspection and Quarantine* (hereinafter referred to as Qualification) . Any unit or individual shall not handle the dairy without CIQ's approval.

Article 16 CIQ shall inspect imported dairy products according to the measures regulated by *Law on Inspection of Imported and Exported Commodities of the People's Republic of China*. Imported dairy products with risks of transmitting animal and plant diseases shall be quarantined according to the *Law on Quarantine of Imported and Exported Animals and Plants of the People's Republic of China*

Article 17 Imported dairy products shall not be marketed or used before being qualified from inspection and quarantine and issued with certificate of imported goods inspection and quarantine by CIQ.

The certificate of imported goods inspection and quarantine shall specify the information, such as the product's name, brand, exporting country (region), specifications, quantity/weight, production date (lot number) and expiry date.

Article 18 CIQ will issue a certificate of disqualification for the imported dairy that fails to pass inspection and quarantine. For those non-compliant with safety, health and/or environmental protection requirements, the CIQ is entitled to command the importer to destroy the goods or issue a notice of goods return according to which the consignee shall return the goods back to the exporting country. Those non-compliant with other requirements may be retreated technically under CIQ's supervision and

are allowed to be marketed and used after being qualified through inspection and quarantine.

Prior to destroy or return, the importer shall isolate the disqualified dairy products and store in a location that is designated or approved by the CIQ, and shall not move them without CIQ's approval.

The importer shall destroy the goods within three months, and report to CIQ the result.

Article 19 The importer shall establish a dairy import and sales recording system to record related information of the imported dairy on an honest basis, including the Qualification No., name, specifications, production date or batch number, shelf life, names and contacts of exporter and buyer, and consignment date. The records shall be authentic and maintained for two years minimally.

CIQ should inspect the import and sales records of the importers in its responsible territory.

Article 20 For imported raw materials of dairy products all of which will be reexported after processing, CIQ is entitled to inspect in accordance with the standard of the import destination country (region) or the contract requirement, and marks "export processing only" on the Qualification issued.

Article 21 CIQ should establish and maintain records of credits of imported dairy importers.

In case of identifying disqualified imported dairy products, CIQ can put the consignee, inspection declarer and agent on the list of bad records; for those with illegal activities and filed administrative penalty, CIQ can put them on the list of companies with illegal records and disclose to the public.

Chapter III Export of Dairy Products

Article 22 AQSIQ implements a registration system towards producers that export dairy products. Registration is executed subject to AQSIQ's regulations.

Exported dairy products shall be come from registered producers of exported dairy products.

Article 23 Dairy stock plants for raw milk export shall register at CIQ. On the basis of risk analysis, CIQ monitors registered plants in terms of animal epidemics, residuals of pesticides and veterinary drugs, environmental polluters and other poisonous and hazardous elements.

Article 24 Dairy stock plants for raw milk export shall establish dairy stock breeding file, recoding the information as the following:

1. varieties, quantities, propagation records, labeling, sources and entry dates of dairy stocks;
2. sources, names, target stocks, time and using quantities of inputs such as feedstuffs, feedstuff additives, and veterinary drugs;
3. records of quarantine, immunization and sterilization;
4. records of dairy stock diseases, deaths and disposal of disqualified raw milk; and
5. records of raw milk production, storage, inspection and sales.

The records shall be authentic and shall be maintained for two years minimally.

Article 25 For breeding of dairy stocks with the purpose of raw milk export, it is not allowed to use feedstuffs, feedstuff additives, veterinary drugs and other elements with direct or potential harms to animals and humans and prohibited by China and importing country (region). Milk produced during regulated drug period and withdrawal period of dairy stocks shall not be exported.

Article 26 Producers of exported dairy products shall comply with good production standard, establish and implement Hazard Analysis and Critical Control Points (HACCP), and make sure its effective operation.

Article 27 Producers of exported processed dairy products shall establish:

1. receiving and inspection system for raw materials, food additives and related products to record faithfully the names, specifications, quantities, names and contacts of suppliers and dates of receiving;
2. production record files to record faithfully safety management situations in food production process;
3. delivery inspection system to inspect every lot of dairy products to be delivered and maintain inspection reports and sample dairy products;
4. delivery inspection recording system to inspect qualification certificates and safety of dairy products to be delivered, recording faithfully the names, specifications, quantities, production dates, shelf lives, lot numbers, qualification certificate No., names and contacts of buyers and dates of sales.

The records above shall be true and shall be maintained for two years minimally.

Article 28 Producers of exported dairy products shall inspect or commit a qualified institution to inspect raw materials and supportive materials used and finished dairy products to be exported, and issue inspection report.

Article 29 The packing and transport manners of exported dairy products shall comply with safety and health requirements.

For transport tools like containers, ship cabins, airplanes and vehicles used for delivery of perishable dairy products which require refrigeration, the forwarder, container loading unit or their agents shall clean and sterilize the transport tools and containers subject to related regulations and establish records, and shall apply to the CIQ for inspection of loading capacity in terms of hygiene, sanitation, refrigeration and airproof and reinforcement. The dairy products shall not be loaded before the transport tools are inspected or in case the tools are judged as disqualified.

Article 30 The consigner of exported dairy products or its agent shall declare inspection to the CIQ responsible for the region where the producer operates, while in accordance with AQSIQ's regulations on inspection declaration.

Article 31 CIQ formulates the plan of exported dairy random inspection based on the risk of exported dairy products, safety and health quality management level of the producer, product safety and health

quality records, track record of export, and requirements of the importing country (region). The CIQ inspects exported dairy products according to:

1. Inspection and quarantine requirement outlined in agreement, protocol and memorandum between China and the importing country (region);
2. Laws and regulations of the importing country (region);
3. Inspection and quarantine requirements specified in trade contract or letter of credit; and

The dairy products from the importing country (region) without above standards or requirements shall be inspected in accordance with China's laws and regulations and national standard on food safety.

Producers and exporters of exported dairy products shall ensure their products comply with the requirements above.

Articles 32 CIQ will issue *Customs Clearance Document of Exported Goods* or *Exchange Certificate of Exported Goods* for exported dairy products qualified from inspection and quarantine, and will issue inspection and quarantine certificate. CIQ will issue Notice of Disqualification of Exported Goods for dairy products disqualified from inspection and quarantine which shall not be exported.

Article 33 The CIQ of the departure port of exported dairy products inspects the conformity of the goods and certificates in accordance with the regulations on certificate exchange of exported goods. For those qualified, Customs Clearance Document of Exported Goods will be issued in exchange of the Exchange Certificate of Exported Goods; and for those disqualified, the CIQ will issue a certificate of disqualification and the products shall not be exported.

The CIQ of the product origin and CIQ of the departure port should build up information exchange mechanism to inform, on a timely basis, safety and health-related problems found during inspection and quarantine of dairy products to be exported and report to superior units according to related regulations.

Article 34 Producers of exported dairy products shall establish product traceability system and related files to ensure effective tracing. The files shall be maintained for two years minimally.

Article 35 Producers of exported dairy products shall establish sample product management system. The conditions and periods of sample maintaining shall be appropriate to the characteristics of the products and the quantity shall meet the requirement of inspection.

Article 36 In case of identifying disqualified exported dairy products, CIQ can put the producers and sellers on the list of bad records; for those with illegal activities and filed administrative penalty, CIQ can put them on the list of companies with illegal records and disclose to the public.

Chapter IV Risk Alert

Article 37 AQSIO and CIQs should collect and process dairy safety information gained from active monitoring, on-site inspection, lab inspection, notification from overseas organizations, notification from domestic organizations, media and online reports, complaints and exposures, and information

forwarded by related authorities.

Article 38 Producers and sellers of imported/exported dairy products shall establish risk-related information reporting system, prepare emergency plan upon dairy safety risk-related information, and assign emergency liaison; and assign dedicated risk information reporting officer to report to the CIQ in a timely manner of the risk-related information found, including product recall and disposal.

Article 39 CIQ should provide primary advice on the basis of confirmed and filed safety-related information of imported/exported dairy products, and shall report to AQSIQ and notify local governments and associated authorities in accordance with related regulations and procedures.

Article 40 AQSIQ and its directly controlled Inspection and Quarantine Bureaus shall notify risk warning according to the levels of safety risk information of imported/exported dairy products. AQSIQ can announce risk warning and decide to take the following measures:

1. restrict the import/export conditionally, including strong monitoring, enhancement of inspection and command of recall;
2. prohibit the import/export and destroy or return the products; or
3. implement safety emergency plan for imported/exported dairy products.

CIQs are responsible for organizing and implementing risk warning and control Measure.

Article 41 In case of animal epidemic that would affect dairy safety or other significant food safety incidents found in the country (region) that exports dairy products to China, AQSIQ may take risk alert and control method included in Article 40 towards the imported dairy products subject to Chinese laws and regulations.

AQSIQ may adjust risk warning and control methods through assessment on the basis of the change of epidemic, the situation of how the food safety incident is solved, and related materials provided by the competent authority from exporting country (region) and related dairy producer(s).

Article 42 In the event the safety risk of imported/exported dairy products does not exist any longer or has been reduced to an acceptable level, the risk warning notice and announcement and control measure should be released in time.

Article 43 In case the imported dairy has safety-related problem and has been harmed or would harm human health and lives, the importer shall actively recall the products and report to the CIQ of the region, disclose related information to the public, notify wholesalers and retailers to stop wholesales and retails, inform consumers to stop using the products, and create records of recall. After receiving the report, the CIQ should conduct inspection and report to superior unit in accordance with the scope affected by the imported dairy and subject to related regulations.

In case the importer fails to implement recall actively, the immediate Inspection and Quarantine Bureau will send notice of forced recall to the importer and report to AQSIQ. AQSIQ may send notice of forced recall if necessary. AQSIQ may notify or report risk warning and take the Measure specified in Article 40 and other Measure in order to prevent the occurrence of the harm.

Article 44 In case that safety problem that has harmed or would harm human health and lives is found existing in the exported dairy, the producer shall take Measure to prevent and/or reduce the occurrence of harms and report immediately to its local CIQ.

Article 45 During legal execution of responsibilities to inspect, quarantine and supervise imported/exported dairy products, the CIQs is entitled to:

1. enter the sites of production/operation for inspection;
2. review, reproduce, suspend, and impound related contracts, bills, accounting books and other materials;
3. suspend and impound disqualified products, illegally used raw materials, supportive materials, additives and agricultural inputs, and tools and equipment used for illegal production;
4. close down the production/operation site that has significant potential of harming human health and lives

Article 46 CIQ should report to AQSIQ and notify local government and related authorities of the control Measure to be taken in accordance with related regulations.

AQSIQ will notify related authorities of the imported/exported dairy safety information and Measure to be taken in accordance with related regulations.

Chapter V Legal Obligations

Article 47 In case that the seller markets and/or uses imported dairy which is identified through inspection and quarantine as incompliant with national standard on food safety, the CIQ is entitled to confiscate its illegal income, dairy products under illegal sales, and tools, equipment and raw materials according to Article 85 and Article 89 under Food Safety Law. In the event that the value of illegal dairy products is less than 10,000 yuan, a penalty ranging from 2,000 yuan (exclusive) to 50,000 yuan (exclusive) will be imposed; in the event the value is more than 10,000 yuan, a penalty ranging from five times (exclusive) to ten times (exclusive) of the value will be imposed; and in case of serious situation, the seller will be deregistered.

Article 48 In case that the importer of dairy products takes one of the following activities, it will be commanded to correct and be warned by CIQ in accordance with Article 87 and Article 89 in the Food Safety Law; in case the importer fails to correct, a penalty ranging from 2,000 yuan (exclusive) to 20,000 (exclusive) will be imposed; and in case of serious situation, the exporter will be deregistered:

1. it fails to establish dairy import and sales recording systems;
2. the import and sales recording systems are not complete and/or true;
3. the import and sales records are maintained less than two years;
4. the records are altered or destroyed or there is other incident which causes impossibility of revealing real situation;
5. it makes fake import and/or sales records;

Article 49 In case that the importer is found other illegal activities not included in Article 48 under this

Measure, the CIQ will confiscate its illegal income and dairy products and penalize a sum of three times of product value in accordance with the special Article 8. In case that the activity is judged as crime, the importer shall bear criminal obligation.

Article 50 In case that the exporter fails to comply with Food Safety Law and takes one of the following activities, the CIQ will confiscate its illegal income, dairy products under illegal sales, and tools, equipment and raw materials according to Article 89 and Article 85 under Food Safety Law; in the event that the value of illegal dairy products is less than 10,000 yuan, a penalty ranging from 2,000 yuan (exclusive) to 50,000 yuan (exclusive) will be imposed; in the event the value is more than 10,000 yuan, a penalty ranging from five times (exclusive) to ten times (exclusive) of the value will be imposed; and in case of serious situation, the producer of exported dairy will be deregistered:

1. it exports dairy without inspection declaration or inspection by competent CIQ;
2. it exports dairy that is identified as disqualified through inspection;
3. it exchanges, the dairy products that have been supervised, randomly inspected and issued with inspection and quarantine certificate by CIQ with other dairy products;
4. The dairy to be exported comes from a producer not registered at CIQ.

Article 51 In case that the exporter is found other illegal activities not included in Article 50 under this Measure, the CIQ will confiscate its illegal income and dairy products and penalize a sum of three times of product value in accordance with the special Article 7. In case that the activity is judged as crime, the exporter shall bear criminal obligation.

Article 52 In case of occurrence of one of the following activities, the CIQ will command the organization to correct and will penalize a sum of less than three times of illegal income, if any, and the sum does not exceed 30,000 yuan; in case of no illegal income, the penalty is less than 10,000 yuan:

1. The importer of imported dairy fails to dispose the disqualified products within the period regulated by the CIQ;
2. The importer of imported dairy breaches Article 18 under this Measure that it fails to take necessary Measure to isolate and store separately the disqualified products before they are destroyed or returned;
3. The importer of imported dairy moves, without permission, the disqualified products away from the location designated or approved by the CIQ;
4. The dairy stock plant for raw milk export fails to comply with related regulations when using agricultural chemicals during breeding process;
5. The records of the dairy stock plant for raw milk export are found not true or the records are maintained less than two years;
6. The producer of exported dairy fails to establish or ensure the effectiveness of the traceability system;
7. The producer of exported dairy fails to establish sample product management system or the sample maintained does not conform with real product;
8. The exporter of dairy fails to comply with packing and transport regulations included in this Measure.

Article 53 Related laws and regulations shall apply in case of other illegal activities of producers/operators of imported/exported dairy products, CIQs and/or their staffs.

Chapter VI Attached Articles

Article 54 The consignee and/or consigner of dairy is entitled to apply for re-inspection in accordance with the Management Measure on Re-inspection of Imported and Exported Commodities if it disagrees with the result of inspection and quarantine.

Article 55 Dairy products which are for feedstuff, non-edible or imported/exported through express, mailing or brought by passengers shall be handled in accordance with corresponding regulations.

Article 56 AQSIQ is responsible for interpreting this Measure.

Article 57 This Measure goes into force on May 1, 2013.

END TRANSLATION