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Regulation on Inspection of Exit-Entry Dairy Products (Draft)

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Report Highlights:

These Measures establish the requirements of inspection, quarantine and supervision for imported and exported dairy products. The comment period ends on May 22, 2011. China has not determined an adoption date of these measures. This report is an informal translation of the document which was notified to the WTO on March 23 as G/SPS/N/CHN/355.

General Information:

BEGIN TRANSLATION

Administrative Measure of Inspection, Quarantine and Supervision on Import and Export of Dairy products (Draft for comments)

Chapter 1 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 implementing 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 implementing regulations, the *Law on Quarantine of Imported and Exported Animals and Plants of the People's Republic of China* and its implementing 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 raw milk and milk products.

Raw milk refers to natural milk without any change in component that is milked from udders of healthy dairy stock that comply with relevant regulations by the Chinese government. Postpartum colostrums after seven days, milk produced during antibiotics use and withdrawal period, and alternative milk shall not be used as raw milk.

Milk products refer to foods produced from milk (including raw milk, reconstituted milk, or other liquid milk sterilized only). Milk products include but are not limited to: pasteurized milk, sterilized milk, modified milk, whey 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 safety 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 behave in an honest and accountable manner to ensure food safety, take responsibility to the public and society, accept social supervision and carry out social responsibility.

Chapter 2 Import of Dairy products

Article 5 AQSIQ defines inspection and quarantine requirements in accordance with Chinese laws and regulations, national standards on food safety, epidemic diseases and situations in China and abroad and results of risk analysis on poisonous and hazardous elements, and they are based on assessment and review.

Article 6 AQSIQ assesses the food safety management systems and food safety conditions of countries (and regions) that export dairy products to China in accordance with related Chinese laws and regulations, and conducts retrospective reviews in accordance with the needs of supervision and management of imported dairy products safety.

For the countries (regions) that export raw milk and raw processed dairy products to China for the first time, AQSIQ assesses the materials provided by the competent authority of the country (region), including the legal system, organizations, veterinarian service system, safety and health control system, residual monitoring system and animal epidemics inspection and monitoring conditions of veterinarian health and public health. If the risk is identified as acceptable through assessment, the countries (regions) will be allowed to export goods to China after both sides sign the Protocol on Inspection and

Quarantine Requirements.

For the countries (regions) that export processed dairy products other than raw processed dairy products to China for the first time, AQSIQ assesses the materials provided by the competent authority of the countries (regions), including sources of raw materials of processed dairy products, processing and producing techniques, and use of ingredients and additives. The countries (regions) will be allowed to export goods to China if the risk is indentified as acceptable through an assessment.

Article 7 AQSIQ implements a registration system for overseas food producers that export dairy products to China. Registration is executed according to AQSIQ's regulations.

Overseas producer of imported dairy products shall be an entity established under official approval of the exporting country (region) and comply with related laws and regulations of the exporting country (region).

Article 8 Dairy products exported to China shall have a 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;
4. the dairy products are proved as fit for human consumption through inspection; and
5. the dairy products comply with China's national food safety standards.

The certificate shall have the official stamp of the issuer or 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 9 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).

In accordance with future needs, AQSIQ may adjust and announce the types of dairy products that shall have quarantine approval.

Article 10 Overseas 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. AQSIQ will publish uniformly the submitted information to the public.

Article 11 The inspection and quarantine agencies document and manage the consignees of imported dairy products. The consignee shall apply for registration at the local CIQ in advance, while submitting the materials below:

1. Application Form of Consignee Registration that is completed with accurate information;
2. Copies of Business Permit, Certificate of Organizational Code, identify certificate of the juridical person and Registration Form of International Trade Operator, and the applicant shall provide originals of the above for inspection;
3. Quality and safety management system;
4. Types and storage locations of dairy products proposed;
5. For the consignee that conducts declaration of inspection by itself, it shall submit the copy of its registration certificate and provide the original for inspection;
6. The company that imports infant formula foods and dedicated dairy products or raw materials for specific groups of people shall provide the contact persons and related contact information of the dealers or domestic users of raw materials; and
7. Other materials required by AQSIQ.

Article 12 The consignee 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. related documents of approval;

3. health certificate that is issued by the competent authority of the exporting country (region) and complies with Article 8 under this Measure;
4. the Permit in the event that quarantine approval is required on the dairy to be imported;
5. 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;
6. certificate of Permit issued by related authority in the event that the dairy has a function of health care; and
7. official certificate of allowing to market in the country of production in the event the infant formula food and/or dedicated dairy for specific groups of people is imported for the first time;

Article 13 Imported dairy products shall comply with China's national food safety standards.

The sensory requirements, raw material requirements and safety and hygienic specifications of the to-be-imported semi-finished products for production of infant formula foods and those for production of dedicated dairy products for specific groups of people shall comply with the requirements on their corresponding finished products as specified in the national standard on food safety.

The dairy that is imported for the first time and 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 14 The packing and transport tools of imported dairy products shall comply with requirements of safety and health. The dairy products shall not be transported together with poisonous and/or hazardous things.

Article 15 Pre-packed dairy products shall have labels and instructions in Chinese. These labels and instructions shall comply with Chinese laws and regulations and national standards on food safety.

The labels of pre-packed dairy products shall be inspected by competent CIQ.

Article 16 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 17 CIQ inspects and quarantines imported dairy products through review of documents, on-site inspection, sensing inspection, and lab inspection.

Article 18 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 and production date (lot number).

Article 19 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 consignee 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 allowed to be marketed and used after being qualified through inspection and quarantine.

Prior to destruction or return, the consignee 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.

Article 20 The consignee 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, lot number, shelf life, names and contacts of exporter and buyer, and consignment date. The records shall be maintained for a minimum of two years.

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

Article 21 For imported raw materials of dairy products all of which will be reexported after processing, CIQ is entitled to inspect in accordance with the restrictive standard of the import destination country (region) or the contract requirement, and mark “export processing only” on the Qualification issued.

Article 22 CIQ should establish and maintain records of credits of imported dairy consignees.

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 3 Export of Dairy products

Article 23 AQSIQ implements a registration system towards producers that export dairy products. Registration is executed subject to AQSIQ’s regulations.

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

Article 24 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 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 harm to animals and humans and prohibited by China and importing country (region). Raw milk produced during regulated drug period and withdrawal period of dairy stock shall not be exported.

Article 26 Dairy stock plants for raw milk export shall establish dairy stock breeding files, recoding the information as follows:

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 true and shall be maintained for a minimum of two years.

Article 27 Producers of exported dairy products shall comply with good production standards. The Chinese government encourages producers to implement Hazard Analysis and Critical Control Points (HACCP). Producers of exported infant milk powders shall establish complete HACCP quality and safety control systems.

Article 28 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. post-factory inspection system to inspect every lot of dairy products to be delivered and maintain inspection reports and sample dairy products;
4. post-factory 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 29 Producers and sellers of exported dairy products shall ensure that their dairy products to be exported comply with both China’s national standards on food safety and related standards of the importing country (region) or contract

requirements.

Article 30 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 reports.

Article 31 The packing and transport manners of exported dairy products shall comply with safety and health requirements and shall be qualified from inspection and quarantine.

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 32 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 33 CIQ formulates the plan of exported dairy random inspections 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. China's national standard on food safety;
2. Agreement, protocol and memorandum between China and the importing country (region);
3. Laws and regulations of the importing country (region);
4. Inspection and quarantine requirements specified in trade contract or letter of credit; and
5. Other laws and regulations of China.

Articles 34 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 the Qualification upon an importer's request. CIQ will issue Notice of Disqualification of Exported Goods for dairy products disqualified from inspection and quarantine which shall not be exported.

Article 35 The CIQ of the departure port of exported dairy products inspects the conformity of the goods and certifies 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 for 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 an 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 36 Producers of exported dairy products shall establish product traceability systems and related files to ensure effective tracing. The files shall be maintained for a minimum of two years.

Article 37 Producers of exported dairy products shall establish a sample product management system. The conditions and periods of sampling shall be appropriate to the characteristics of the products and the quantity shall meet the requirement of inspection.

Article 38 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 4 Risk Warning

Article 39 AQSIQ and CIQs should establish a network of collection of safety-related information of imported and exported dairy products to 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 40 Producers and sellers of imported/exported dairy products shall establish risk-related information reporting system, prepare emergency plan on dairy safety risk-related information, and assign an 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 41 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 42 AQSIQ and directly controlled Inspection and Quarantine Bureaus shall notify or report risk warning according to the levels of safety risk information of imported/exported dairy products, and shall:

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

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

Article 43 In the case of an 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 warning and control measures included in Article 42 towards the imported dairy products subject to Chinese laws and regulations.

AQSIQ may adjust risk warning and control Measure 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 exporting country (region) and related dairy producer(s).

Article 44 In the event the safety risk of imported/exported dairy products does not exist any longer or has been reduced to an acceptable level, AQSIQ or its directly controlled Inspection and Quarantine Bureau shall announce to release risk warning and control measure.

Article 45 In case the imported dairy has safety-related problem and has been harmed or would harm human health and lives, the consignee 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 wholesale and retails sales, inform consumers to stop using the products, and create records of recall.

After receiving the report, the CIQ shall conduct inspections and report to superior unit in accordance with the scope affected by the imported dairy and subject to related regulations.

In case the consignee fails to actively implement a recall, the immediate Inspection and Quarantine Bureau will send notice of forced recall to the consignee and report to AQSIQ which may notify or report risk warning and take the measure specified in Article 42 and other measure in order to prevent the occurrence of the harm.

Article 46 In case a safety problem that has harmed or would harm human health and lives is found existing in the exported dairy, the producer shall take measures to prevent and/or reduce the occurrence of harms and report immediately to its local CIQ.

Article 47 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 48 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 5 Legal Obligations

Article 49 In case the seller markets and/or uses imported dairy which is identified through inspection and quarantine as non-compliant with national standards 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 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 a serious situation, the seller will be deregistered.

Article 50 In case the exporter fails to comply with the 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 exported 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 with CIQ.

Article 51 In case the exporter is found doing 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 a crime, the exporter shall bear criminal responsibility.

Article 52 In case the importer fails to establish and comply with dairy import and sales recording systems and takes one of the following activities, it will be ordered to correct and be warned in accordance with Article 89 and Article 87 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 closed down and finally 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 53 In case the importer is found doing other illegal activities not included in Article 52 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 a crime, the importer shall bear criminal responsibility.

Article 54 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 consignee of imported dairy fails to dispose of the disqualified products within the period regulated by the CIQ;
2. the consignee of imported dairy breaches Article 19 under this measure in that it fails to take necessary measures to isolate and store separately the disqualified products before they are destroyed or returned;
3. the consignee of imported dairy moves, without permission, the disqualified products 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 three 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 the real product;
8. The exporter of dairy fails to comply with packing regulations included in this measure.

Article 55 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 6 Attached Articles

Article 56 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 57 This measure is not applicable to dairy products and feedstuff-used dairy products that are imported or exported through express or mailing or brought by passengers.

Article 58 AQSIQ is responsible for interpreting this measure.

Article 59 This measure goes into effect from dd/mm/yy.

END TRANSLATION