

Questionnaire of Overseas Manufacturer Registration Management for Exported Dairy Products

Description:

Dairy goods mentioned in this questionnaire include colostrums, raw milk and dairy product. Colostrums is milk within 7 days after calving by milk yielding animals. Raw milk is defined as milk with constant components pumped from the breasts of healthy milk yielding animals which are comply to Chinese relevant requirements. Dairy products are foods that were processed from milk (including raw milk, Reconstituted milk or other sterilized liquid milk), sterilized milk, fermented milk products, milk powder, cream, condensed milk, cheese, whey powder, milk-based infant and follow up formula powder and other milk and milk products.

Dairy manufacturer means overseas manufacturer that is producing, processing and storing dairy product and applies for China registration.

Competent authority of applicant country (region) refer to the organisation/institution which will recommend dairy products producers to be registered by the Certification and Accreditation Administration of the People's Republic of China (CNCA) in China; and the organisation/institution will be liable for the management and control (accreditation) of the compliance of the recommended dairy products producers. The competent authorities include the official authorities which are responsible for the safety of dairy products, institutions with official authorisation, industry associations, etc.

Relevant documents to be submitted shall be in Chinese or in English and the corresponding documents shall be provided in both hard copies and electronic versions.

Information about the Competent Authority of applicant country (region)

Country/Region:	
Name of the Competent Authority:	
Seal of the Competent authority:	
Office address:	
Contact:	
Tel/Fax <u>:</u>	
Email:	_



1. General Information

1.1 Please attach a copy of map and overview of applicant country (region) to indicate the content below (if applicable):

- (a) Organization chart of central, regional or local competent authorities
- (b) The number and distribution of pastures and dairy manufacturers
- (c) Major consignment/exportation port for dairy goods exported to China
- 1.2 The number of dairy cattle inventory of the country (if applicable): Annual cow milk output (ton):

Annual dairy products output (ton):

1.3 Please classify the total amount of dairy goods exported to China in the last 2 years (if applicable).

	Total amount of dairy product exported to	
product category	China (10 ⁴ tons)	
	Year of xx	Year of xx
Milk powder (excluding milk-based infant and		
follow up formula powder)		
milk-based infant and follow up formula powder		

Product category: please refer to remarks of dairy goods and dairy product category in "Implementation Contents for Registration of Overseas Producers of Import Dairy Products" (AQSIQ Announcement No.62, 2013) to fill in the table. The amount of milk-based infant and follow up formula powder should be excluded from the total amount of milk powder exported to China and be filled in separately.

2. Competent Authority

2.1 Structure of Competent Authority

2.1.1 Please provide the name, address and functions of competent authority on central level

2.1.2 Please provide an organization chart of central competent authorities

2.1.3 Please describe the relationships between central and local competent authorities (if applicable)

2.1.4 Please provide the number of executive officers in central and local competent authorities 2.1.5 Please describe the financial source of the budget of the central competent authority and its affiliated agencies

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2.2 Official Control Program

2.2.1 Please describe the official control program on dairy enterprises, including:

- (a) Whether the competent authorities keep an official control on dairy enterprises?
- (b) Whether the competent authorities require the dairy enterprises to apply for registration/license before or after the production? What information is required to be submitted by the dairy enterprises while applying for registration/license?
- (c) Is on-site inspection required when competent authorities review dairy enterprises' application information? If yes, please describe in detail the scope of official inspection over newly established dairy enterprises, especially the scope of official inspection over HACCP system. Please provide blank forms for reference if official inspection forms are available.
- (d) Shall the authoritative approval procedure of the registration/license application of dairy companies be carried out by central or relevant local competent authorities? How long is the valid period of the registration/license?
- (e) Shall information modification, qualification suspension and invalidation procedure be carried out by central or relevant local competent authorities?
- (f) How shall central competent authority communicate with relevant local competent authorities to maintain consistency of registration/license information of dairy producers?
- (g) Please provide reference regulations and standards in the form of attachment.

2.2.2 Please describe the supervision and administrative situation of competent authorities towards dairy producers.

- (a) Please describe the supervision frequency towards dairy producers and the rationale for determining supervision frequency.
- (b) Please list the focusing items/contents during supervision implementation. Will a written report be required? If yes, please provide a blank written report template.
- (c) Please describe the reporting procedure of supervision results. Is it required report the results to superior authorities or be published? Or under what circumstance should it be reported to superior authorities and published?
- (d) How shall competent authorities proceed when issues of different degrees occur at a dairy producer? Shall they report to superior authorities about the issues and measures so as to be approved?
- (e) How shall central and local competent authorities communicate to maintain consistency of the implementation at local levels?
- (f) Please provide reference regulations and standards in the form of attachment.



2.2.3 Please describe how competent authority manages the exporting registration/accreditation of dairy products producers which apply for the registration in China, including:

- (a) Regarding the registration of dairy products producers in China, if another institution other than competent authority is involved, please describe the jurisdiction and managing scope of the institution. Please provide the name, address, contact information and financial sources of the institution.
- (b) Please describe how the competent authority or the relevant institution will communicate the relevant Chinese laws, regulations and standards to the producers and how to treat the difference between laws, regulations and standards between importing countries and home country (region).
- (c) Please describe how the competent authority or the relevant institution will manage the exporting registration/accreditation of dairy products producers which apply for the registration in China to ensure the products to be exported to China by dairy products producers meet the relevant Chinese laws, regulations and standards. Please describe in detail the requirement on recommendation procedure of registration in China of dairy products producers, application criteria, reviewing scope, approval qualification, information updates, etc
- (d) If violations against the relevant Chinese laws, regulations and standards by dairy products producers are discovered, what kind of measures will the competent authority or the relevant institutions take to ensure these products not be exported to China?
- (e) Before resuming the exporting registration and accredited qualification, how will the competent authority or the relevant institution verify if the corrective and preventive measures taken by the dairy products producers are effective?
- (f) How will the competent authority or the relevant institution ensure timely communication on the information of the relevant dairy products producers with the CNCA and keep coherent?

3.2 Responsibilities of Competent Authority

3.2.1 The relationship between central and local competent authority

3.2.2 Please describe how the various departments coordinate (jurisdiction and scope of management) if other official sectors other than the competent authorities are involved in the heath control and supervision. Please provide information about other official departments (including their name, address and contact information).

- (a) What official measures shall be taken in case any dairy producers are complained about violating relevant rules and regulations as well as standards of applicant state (region) or import country?
- (b) What are the tracking and recalling requirements by competent authorities at each phase of dairy stock breeding, production and transportation of raw milk, dairy processing, sale,

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storage and exporting?

3. Human Resource

3.1 Government (Official) Assessors

3.1.1 Please provide the total number of officers in competent authorities at all levels (national, regional and territorial boundaries) relevant to dairy company supervision.

3.1.2 Please provide the number of officers with relevant qualifications and their respective scope of work.

3.1.3. Please provide the training arrangement for official supervising personnel provided by competent authorities during the last three years.

3.2 Non-governmental (official) Assessors

3.2.1 Are there any non-governmental (official) assessors authorised/accredited/entrusted by official bodies to conduct assessment, monitoring, sampling and inspection tasks at each phase of dairy stock breeding, production and transportation of raw milk, dairy processing, sale, storage and exporting? If yes, please introduce the content of their work.

3.2.2 Please describe the qualifications, total number, name of institution, qualification requirement of the institution, and scope of work, authorised responsibilities, requirements on surveillance after official authorisation/accreditation/entrustment and the requirement on charging of the non-governmental (official) assessors authorised/accredited/entrusted by official bodies.

3.2.3 Please describe how to avoid conflict of interest between non-governmental (official) assessor and the assessee?

4. Official Control on Dairy Products Production Chain

4.1 Please provide the name of the competent authority in charge of dairy stock health and its responsibility scope.

4.1.1 How does the official control on stocks in raw milk producing place be carried out, e.g. by animal registration and farm registration?

4.1.2 How to ensure the health status of the dairy stock in raw milk production place meet the requirement of raw milk production? Are there any regulation and surveillance on the health status of animals and veterinary drugs usage? Please list the relevant laws, regulations and standards in the form of attachment.

4.1.3 Please provide authoritative requirements on raw milk and its collection, microbiological indicators for raw milk, time and temperature control requirement of raw milk collection. Please list the relevant laws, regulations and standards in the form of attachment.

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4.2 Please provide the name of competent authority in charge of raw milk transportation control and its responsibility scope.

4.2.1 How does the official control of raw milk transportation vehicles be implemented, e.g. is registration required?

4.2.2 Please describe the official requirements on raw milk transportation vehicles.

4.2.3 Please describe the official requirements on qualification of the raw milk transportation personnel.

4.2.4 Please describe how to guarantee that raw milk after transportation meets the requirement for dairy products processing, especially the sanitary condition and indicators of banned or restricted substances. Please list the relevant laws, regulations and standards in the form of attachment.

4.3 In the basic principles or self-control conditions required by competent authorities for registration/licensing application of dairy producers, is the establishment of HACCP included? Please list the relevant laws, regulations and standards in the form of attachment.

4.4 Please describe the requirements on traceability and recall by the competent authority at each phase of dairy stock breeding, production and transportation of raw milk, dairy processing, sale, storage and exporting. Please list the relevant laws, regulations and standards in the form of attachment.

4.5 What kind of information of producers and distributers does the competent authority require dairy products producers to list on the final products? How to ensure the traceability of the information of producers and distributors? Please list the relevant laws, regulations and standards in the form of attachment.

5. Administration on Milk-based Infant Formula Food

Does the administration of milk-based infant formula food by competent authorities in the country (region) differ from the supervision of other common dairy products? If yes, please provide following information:

5.1 Name and the responsibilities of the competent authority in charge of the safety and qualify of milk-based infant formula.

5.2. Is there any authoritative controls on the producers of milk-based formula food for infants and young children? How does the competent authority ensure producers of infant and young children formula comply with the laws, regulations and standards of home country (region) and

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importing countries? Please list the relevant laws, regulations and standards in the form of attachment.

5.3 Please describe if producers of milk-based formula food for infants and young children are required by competent authority to register/ apply for licence before or after production? What kind of application information is required during the application for registration/license? What are the differences between this information and the information required for other common dairy products producers?

5.4 Please describe the differences in sanitary condition for producers of milk-based formula food for infants and young children and for other common dairy producers during registration/license application?

5.5 Please describe the authoritative requirements on a producer of milk-based formula food of infants and young children to guarantee that raw materials and auxiliary materials comply with safety and quality requirements.

5.6 Does the competent authority take effective controls on the formula of producers of milk-based formula food of infants and young children? If yes, how does the competent authority conduct pre-production approval and supervision on producers of milk-based formula food of infants and young children?

5.7 Please describe the food safety standards of food additives for milk-based formula food for infants and young children required by competent authorities. Please list the relevant laws, regulations and standards in the form of attachment.

5.8 Please describe the requirements on traceability and recall for producers of milk-based formula food for infants and young children by the competent authority. If the final products of producers of infant and young children formula are not sold in home country(region), how does the competent authority conduct surveillance and supervision on these types of producers and their exported products?

5.9 What kind of information of producer and distributer does the competent authority require producers of infant and young children formula to list on the final products, e.g. registration number, name and address of producer and distributor? How to ensure the traceability of information of producer and distributer? Please list the relevant laws, regulations and standards in the form of attachment.

5.10 If information above does not cover the difference between the regulation of infant and young children formula (both powder and liquid products) and other dairy products, please provide other information and documents for further explanation.

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6. Equivalency statement on law & regulation

Please provide supporting documents to prove equivalency to Chinese dairy related GMP (see attached form)

7. Competent Authority Statement

We here declare the manufacturer that we recommend to Certification & Accreditation Administration of the People's Republic of China(CNCA) and its products exported to China comply with the requirement of relevant Chinese laws, regulations and National Food Safety Standard.

Name / Title : _____

Signature : _____

Competent Authority Chop : _____