

Remarks:

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REGULATION ON ADMINISTRATION OF SANITARY REGISTRATION AND ENROLLMENT FOR ESTABLISHMENTS OF FOOD FOR EXPORT

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General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

CHAPTER 1 GENERAL PROVISIONS

Article 1

In order to strengthen the supervision on the establishments of food for export and ensure the safety and sanitation quality of export food, this regulation is formulated in accordance with the relevant regulations of the Law of the People's Republic of China on Food Sanitation, the Law of the People's Republic of China on Import & Export Commodity Inspection and their implementing regulations.

Article 2

China implements the system of sanitary registration and enrollment on establishments producing, processing and storing of food for export (hereinafter referred to as establishments of food for export).

Only after obtaining the certificates of sanitary registration or enrollment, can the establishments engaged in producing, processing and storing of food for export in the People's Republic of China be allowed to produce, process and store food for export.

Article 3

Certification and Accreditation Administration of the People's Republic of China (hereinafter referred to as CNCA) shall be in charge of the sanitary registration and enrollment of the establishments of food for export all over the country. The local entry & exit inspection and

quarantine bureaus (hereinafter referred to as local Provincial CIQ) set up and headed directly by General Administration of Quality Supervision and Inspection and Quarantine of the People's Republic of China (hereinafter referred to as AQSIQ) shall be responsible for the registration and enrollment within their respective administrative areas.

The local entry & exit inspection and quarantine authorities set up by AQSIQ (hereinafter referred to as local CIQ) shall not accept applications for export of food from establishments without sanitary registration or enrollment.

Article 4

CNCA shall, according to the risk levels of food for export, promulgate and adjust the List of Export Foods subject to Sanitary Registration or Enrollment (hereinafter referred to as Registration List, Appendix 1). Sanitary registration administration shall be enforced on the establishments producing, processing and storing food in the Registration List. Sanitary enrollment administration shall be enforced on the establishments producing, processing and storing food out of the Registration List.

CHAPTER 2 APPLICATION

Article 5

The establishments of food for export which apply for the sanitary registration should establish sanitary control system on the basis of Sanitary Requirements for Establishments of Food for Export (Appendix 2).

The establishments of food for export which apply for the sanitary enrollment should establish sanitary control system based on product characteristics with reference to Sanitary Requirements for Establishments of Food for Export.

Article 6

The establishments of food for export should apply to the local Provincial CIQ for sanitation audit on location selecting and construction design before their premises are newly built, enlarged or reformed. Construction can be made only after passing the reviewing.

Article 7

Before producing, processing and storing food for export, the establishments of food for export should apply to the local Provincial CIQ for sanitary registration or enrollment by filling in and submitting the Application Form for Sanitary Registration/Enrollment of Establishments of Food for Export (in triplicate). Applications should be submitted respectively by the establishment, its subsidiary establishment or joint establishment, and processing workshops which are not located in

the same place of the establishment.

Article 8

Relevant documental informations such as sanitary control system, premise layout, workshop layout and process flow diagram should be submitted by the establishment of food for export , together with the Application Form for Sanitary Registration/Enrollment of Establishments of Food for Export.

CHAPTER 3 AUDITING AND CERTIFICATION

Article 9

After the local Provincial CIQ receives the Application Form for Sanitary Registration and relevant documents submitted by the establishment of food for export, an auditing group consisting of a chief auditor and one or two qualified auditors should complete reviewing of the said application form and relevant documents within 10 working days. If the application form and relevant documents are not in accordance with the requirements, the said local Provincial CIQ should notify the establishment of food for export within 10 working days to make amendments and supplements within 30 days. If the amendments and supplement are not made within the specified period, the application should be considered as withdrawn. If the application form and relevant documents are in accordance with the requirements, the head of the auditing group should make an auditing plan and work out the auditing schedule with the establishment of food for export so as to carry out the audit in time.

Article 10

Legal Basis for Auditing

(1) Sanitary Requirements for Establishments of Food for Export

(2) Auditing basis for establishments of food for export whose product is included in *the List of Products Requiring HACCP Audit for Sanitary Registration* (Appendix 3) are *Sanitary Requirements for Establishments of Food for Export* ,and Hazard Analysis and Critical Control Point (HACCP)and its Application adopted by Codex Alimentarius Commission. *The List of Products Requiring HACCP Audit for Sanitary registration* is promulgated and adjusted by CNCA.

Article 11

Before auditing on the spot, the auditing group should inform the establishment of food for export of the purpose, basis, scope, procedure and requirements for auditing and listen to the establishment's introduction.

Article 12

The auditing group should carry out the auditing in the ways such as asking questions, reviewing records, checking on-the-spot and testing samples and keep records.

Article 13

The auditing group should inform the establishment of the audit findings, together with the report on the existing problems and improvement suggestions .

The rectification progress should be reported by the establishment within the specified period to the said local Provincial CIQ.

The head of the auditing group should submit the auditing report to the local Provincial CIQ after finishing the auditing.

Article 14

The local Provincial CIQ should review the report submitted by the auditing group and the rectification progress from the establishment, and make the auditing conclusion within 15 working days. Notification of failure should be issued to the establishment if audit is not passed. Registration should be granted and the registration certificate should be issued to the qualified establishment. Coding rules of registration certificate should be promulgated by CNCA separately.

The establishment of food for export which fails to pass the auditing is not permitted to re-apply for registration within 6 months from the date when the notification of failure is issued. Rectification should be made before re-applying for registration.

Article 15

The term of validity of the sanitary registration certificate and sanitary enrollment certificate is 3 years. The sanitary registration certificate and the sanitary enrollment certificate are printed by CNCA and issued to the establishment by the local Provincial CIQ.

CHAPTER 4 SUPERVISION AND ADMINISTRATION

Article 16

The local Provincial CIQs supervise and administer the registered establishments under their jurisdiction. The main contents for supervision and administration include as follows:

- (1) Whether the establishment continuously conforms to the sanitary registration requirements;
- (2) Whether the sanitary control system is effectively operated;
- (3) The use and management of the sanitary registration code;

(4) The condition of safety, sanitation of raw materials, ingredients and finished products and the result of relevant export inspection and quarantine etc.

Article 17

The types of supervision and administration on the registered establishment include:

(1) Routine supervision and administration: the local CIQ sends employees to conduct routine supervision and administration on sanitation registered establishments;

(2) Regular supervision and inspection: The local Provincial CIQ should organize sanitary registration auditors to conduct regular supervision and inspection on sanitation registered establishments. The all-round supervision and inspection should be organized at least once a year on sanitary registered establishments of meat, aquatic product, canned product and casing. Supervision and inspection should be conducted on sanitation-registered establishments producing seasonal products for export according to production season. An all-round supervision and inspection should be conducted at least once in every six months (or in every production season) on establishments which have obtained importing countries' registration approval. For other sanitation-registered establishments, local Provincial CIQ should determine the frequency of supervision and inspection depending on actual situations. Rectification of problems found in routine supervision and inspection should be included in regular supervision and inspection;

(3) Renewal of certificate and re-examination: Application for re-examination should be submitted by the registered establishment of food for export to the local Provincial CIQ 3 months before the expiry date of certificate. The local Provincial CIQ which receives the application should re-examine the establishment according to the audit requirements stipulated in Chapter 3 of this regulation. The certificate should be renewed for the qualified establishment, it should not be renewed for the unqualified establishment or the establishment which does not apply for renewal;

Records should be made in supervision and administration, problems found should be notified to the establishment in written form.

Article 18

During the supervision and administration of the sanitation-registered establishment, for any one of the following violating cases, the local Provincial CIQ should notify the establishment in written form and suspend its application for export until the establishment is confirmed to be in compliance with requirements after rectification:

(1) Factors are found including raw materials, ingredient, and water (ice) used for producing and processing which may result in serious threats to the safety, sanitation and quality of the product and, the safety, sanitation of the product cannot be guaranteed;

(2) Upon export inspection and quarantine, the product is found unacceptable due to safety and sanitation problems.

Article 19

During the supervision and administration of the sanitation registered establishment, for any one of the following violating cases, the local Provincial CIQ should issue notification to withdraw the sanitary registration certificate:

- (1) Cases specified in item 1 or 2 of Article 18 in this regulation, and rectification is not completed in the specified period;
- (2) Due to internal management on raw materials, producing, processing and storing etc., the product causes adverse effects in importing countries for the food safety problems;
- (3) The establishment disguises the actual truth of food safety and sanitation problems which results in serious consequences;
- (4) The establishment refuses to accept supervision and administration;
- (5) Borrowing, fraudulent using, transferring, altering and falsifying of sanitary registration certificate, registration code and sanitary registration mark, or the registration code for the registered food is used for unregistered food by the establishment.

The establishment whose sanitary registration certificate has been withdrawn is not allowed to re-apply for sanitary registration within 1 year from the date when it receives the withdrawing notice.

Article 20

For any one of the following cases, the sanitary registration is automatically invalidated:

- (1) The sanitation registered establishment does not apply for alteration within 30 days after its name, legal person or address is changed;
- (2) The sanitation registered establishment does not apply for re-audit 30 days after its workshop is reformed, enlarged, removed or significant changes occur in its sanitary control system;
- (3) The sanitation registered establishment hasn't exported the registered food for 1 year;
- (4) The sanitation registered establishment fails to apply for re-audit for renewal of certificate by the end of validity term.

Article 21

CNCA undertakes the supervision and administration of sanitation registration on local Provincial CIQ and should organize experts to conduct supervision and random check on the sanitation registered establishments, if necessary.

CHAPTER 5

SUPPLEMENTARY PROVISIONS

Article 22

With reference to Sanitary Requirements for Establishments of Food for Export and the relevant regulations in Chapters 3 and 4 in this regulation, local Provincial CIQs conduct the audit, certificate issuance, supervision and administration of establishments of food for export applying for sanitary enrollment.

Article 23

If the establishment of food for export needs to be registered by importing countries, it must obtain the sanitary registration certificate or sanitary enrollment certificate according to this regulation, and then submit its application to the local Provincial CIQ according to the relevant requirements of Administration Rules on Applying for Importing Countries' Sanitary Registration for Establishments of Food for Export . The local Provincial CIQ will recommend it to CNCA.

Article 24

CNCA is authorized by AQSIQ to explain this regulation.

Article 25

This regulation should go into effect from May 20, 2002. *Detailed Rules for the Sanitary registration of Factories/Storehouses of Food for Export* promulgated by the former State Administration of Import & Export Commodity Inspection of the People's Republic of China should be invalid at the same time.

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Appendix 1:

The List of Products Subject to Sanitary registration/Enrollment of Food for Export

(1) Catalogue of Products for Registration

Category

Product Variety

Z01

Canned Food

Z02

Aquatic Product (excluding live product and dry product)

Z03

Meat and Meat Product

Z04

Tea

Z05

Casing

Z06

Bee Product (excluding bee wax)

Z07

Egg Product (excluding fresh egg)

Z08

Quickly Frozen Fruit and Vegetable, Dehydrated Fruit and Vegetable (excluding dry product)

Z09

Sugar (Cane Sugar, Beet Sugar, only)

Z10

Dairy and Dairy Product

Z11

Drink (including solid drink)

Z12

Wine

Z13

Groundnut, Chestnut, Nut and their Products (excluding roasted product)

Z14

Preserved Fruit

Z15

Cereal Product, Flour and Sugar Products

Z16

Edible Oil

Z17

Flavoring Product(excluding naturally aromatic and pungent dry and powder Product)

Z18

Quickly Frozen Instant Food

Z19

Specific Functional Food

Z20

Food Additive (Edible Glutin, only)

(2) The List of Products Subject to Sanitary Enrollment of Food for Export

Foods not included in the List of Products of Registration

Appendix 2

SANITARY REQUIREMENTS FOR ESTABLISHMENTS OF FOOD FOR EXPORT

Article 1

These requirements are formulated for the purposes of guaranteeing the safety, sanitation and quality of food for export and regulating uniformly the safety, sanitation management of establishments of food for export in accordance with the relevant stipulations of the *Law of the People's Republic of China on Food Sanitation*, and the *Law of the People's Republic of China on Import and Export Commodity Inspection* and its implementation rules.

Article 2

The establishments engaged in manufacturing, processing and storage of food for export (hereinafter referred to as establishments of food for export) applying for sanitary registration or sanitation enrollment should establish the sanitary control system to ensure the sanitation of food for export, and establish the quality system documentation to guide the operation of such system.

Article 3

These requirements should be the basis for the establishments of food for export to establish their sanitary control system and quality system documentation.

Article 4

The sanitary control system of the establishments of food for export should include the following basic aspects:

- (1) Policy and goal of sanitation quality;
- (2) Organization and its responsibilities;

- (3) Requirements for personnel engaged in production and management;
- (4) Requirements for environmental sanitation;
- (5) Requirements for sanitation of workshops and facilities;
- (6) Requirements for sanitation of raw and auxiliary materials;
- (7) Requirements for sanitation in the course of manufacturing and processing;
- (8) Requirements for sanitation in the course of package, storage and transportation;
- (9) Control of toxic and harmful substances;
- (10) Inspection requirements;
- (11) Requirements of guaranteeing the effective operation of sanitary control system.

Article 5

The establishments of food for export whose products are included in the *List of Products Requiring HACCP Audit for Sanitary registration* must establish and implement HACCP system in accordance with the requirements of Hazard Analysis and Critical Control Point (*HACCP*) System and its Application adopted by Codex Alimentarius Commission.

Article 6

The establishments of food for export should establish and implement the policy, goal and responsibilities of sanitary quality.

Article 7

The establishments of food for export should establish an organization compatible with production to guarantee the sanitary quality of the products, and, meanwhile, corresponding responsibilities and authorities should be specified.

Article 8

Personnel engaged in production and quality control of the establishments of food for export should meet the following requirements:

- (1) Persons being assigned to the post in contact with food production must pass medical examination;
- (2) Personnel engaged in production and quality control must receive medical examination annually. A temporary medical examination may be taken if necessary. Any person suffering from any disease that may adversely affect the food sanitation must be shifted from the post engaged in food production;
- (3) Personnel engaged in production and quality control must maintain their personal hygiene. No articles irrelevant to the production can be admitted into the workshop. Wearing jewelry, watch and makeup is forbidden during working hours. Workers should wash and disinfect hands, and put on working uniforms, caps and shoes before entering the workshop. Working uniforms, caps and shoes should be disinfected regularly;
- (4) Personnel engaged in production and management should receive necessary training. Only

persons passed examination can be assigned to the post;

(5) Sufficient professionals with compatible qualifications should be assigned to the post of sanitary quality control.

Article 9

The establishments of food for export must meet the following requirements for environmental sanitation:

(1) The establishments of food for export should not be located in the areas that can adversely affect the food sanitation. Other products adversely affecting food sanitation are forbidden to be produced or stored in the establishment;

(2) The road surfaces of the factory should be flat and free from accumulated water. The area should be without exposed earth;

(3) The lavatories in the factory should be equipped with facilities for flushing, washing and devices for controlling fly, insect and rodent. The walls should be kept clean, constructed in light color, and made of smooth, flat, waterproof and corrosion-resistant material;

(4) The discharge and disposal of sewage and waste materials from the production should conform to the relevant regulations of China;

(5) Auxiliary facilities compatible with the production capacity and in conformity with sanitary requirements and temporary storing facilities for wastes and rubbish should be established for the storage of raw and auxiliary material and packaging materials in the factory;

(6) The food handling area should be completely separated from the living quarters.

Article 10

The workshops and facilities of food production should meet the following requirements for sanitation:

(1) The area of workshops should be suited to the production capacity with rational layout and permitting sound drainage. The floor surfaces should be constructed of non-slippery, durable, waterproof, corrosion-resistant and non-toxic materials, and they should be flat, slope evenly and sufficiently for liquids to drain off and kept clean. The exits of the workshop and the drainage, ventilation sites should be equipped with the facilities to prevent rats, flies and other insects outside from entering;

(2) The internal walls and ceilings of the workshops should be constructed of non-toxic, light-colored, water and mould resistant materials, easily cleaned and not peeled off. Wall-to-wall and wall-to-floor junctions should be coved or rounded;

(3) The window sills, if existing in the workshops should be sloped inward at least 45°. The doors and windows should be made of light colored, smooth, flat, easily cleanable, waterproof, corrosion-resistant and compact materials;

(4) The lighting fixtures suspended over the food production line in the workshops should be

equipped with protective shield. The illumination degree of the working and examining areas should meet the production and examination requirements, and should not alter the original color of the processed materials;

(5) Facilities of temperature display should be equipped in the procedures and working areas where temperature requirements are necessary. The workshop should maintain properly controlled temperature within a specified range according to processing requirements and be kept well ventilated;

(6) The supplies of power, steam and water for the workshop should meet the production requirements;

(7) Sufficient facilities for washing, disinfecting and drying hands, tools and equipments should be available at the proper areas. The water tap should not be hand-operated;

(8) According to the processing requirements, the facilities for disinfecting galoshes, shoes, and truck wheels should be equipped at the entrances of the workshops;

(9) Changing- rooms should be in connection with workshops. Different changing- rooms should be provided for areas with different hygiene requirements. Lavatories and shower rooms in connection with changing- rooms should be provided according to requirements. Changing- rooms, lavatories and shower rooms should be kept clean and in hygienic condition. The facilities and layouts should not result in potential risk of contamination with the workshops;

(10) Equipment, facilities and utensils should be made of non-toxic, corrosion-resistant, stainless, easily disinfected and durable materials. They should be in the structures easy to clean and disinfect.

Article 11

The incoming raw and ingredient materials for food production must meet the following requirements and should be controlled effectively.

(1) The raw and ingredient materials for food production should meet the requirements for safety and sanitation, and should be prevented from the contamination caused by pesticides, drugs or other toxic substances existing in the air, soil, water, feed and fertilizers;

(2) Animals used as the production materials should come from non-epizootic areas, and should be qualified by quarantine inspection;

(3) The raw and ingredient materials for food production should be accompanied with certificates of inspection and quarantine, and can be used only after being inspected and proved to be qualified upon arriving at the factory;

(4) The raw and ingredient materials over expiry date should not be used for food production;

(5) Water (ice) used for food production should meet the necessary National Standard as *Sanitation Standard of Potable Water*. Testing on water for public health and sanitation should be made at least twice a year. The establishment's self-provided water source should be equipped with effective sanitation assuring facilities.

Article 12

The process of production of food should meet the following requirements:

- (1) The production equipment should be properly laid out, and kept clean and sound;
- (2) Cleaning and disinfection procedures should be strictly implemented on processing equipment, utensils, containers, and areas etc. Containers for storing food should not be in direct contact with floor;
- (3) Cleaning and sanitation must be done before and after the work and checked by specified personnel, and records should be made for the purpose;
- (4) The raw materials, semi-finished products, finished products as well as uncooked and cooked products should be placed and stored separately for being not contaminated;
- (5) According to the product characteristics and process flow diagram, areas with different sanitation requirements such as areas for material treatment, semi-finished product treatment and processing, washing and disinfection of utensils, inner and outer packing of finished product, inspection and storage of finished product should be separated so as to avoid cross contamination;
- (6) The rejected products produced during processing, products fallen onto the floor, and the wastes must be put into special containers with conspicuous marks at fixed areas, and disposed of timely under the supervision of inspectors. The containers and carriers should be timely disinfected;
- (7) Causes for rejected products should be analyzed, and corrective measures should be taken immediately.

Article 13

Package, storage and transportation operations should be under effective hygiene control.

- (1) All packaging materials for food must conform to the sanitary standard and be kept clean, free from hazardous and poisonous materials and should be fade proof;
- (2) The rooms for storing packaging materials should be dry and well ventilated and the inner and outer packaging materials should be stored separately to prevent contamination;

(3) The food transportation facilities must meet sanitary requirements and should be equipped with facilities such as freezing, temperature maintaining, water and dust proof facilities according to the characteristics of products;

(4) The temperature and humidity in the pre-chilling rooms, quick freezing rooms, cold storage and storehouse should meet the processing requirements and be equipped with thermometer, and hygrometer when necessary. Temperature automatic recording device should be equipped in quick freezing rooms, cold storage and storehouse and be calibrated periodically. The rooms should be kept clean, disinfected periodically and free from mildew, mice and insects. The materials in the rooms should be kept away from the walls and floors at certain distance. The materials that may adversely affect the food sanitation must not be stored in the rooms, and different types of foods which could cause cross-contamination should not be placed and stored in the same room.

Article 14

The procedures on the storing and using of poisonous and hazardous substances should be strictly implemented so as to ensure the effective control of poisonous and hazardous substances such as the detergent, disinfectant, pesticide, fuel, lubricant and chemical reagent used by the factory and laboratory and avoid the food, food-contact surfaces and food packing materials being contaminated.

Article 15

The check of sanitation quality must meet the following requirements and should be controlled effectively.

(1) The inspection laboratory compatible with the production capacity should be set up in the establishment and staffed with corresponding inspection personnel;

(2) The inspection laboratory should have necessary standards, be equipped with inspection facilities and instruments necessary for inspection, which must be calibrated periodically in accordance with the relevant regulation and procedures and records should be kept;

(3) If the sanitation quality check is carried out by a public laboratory, the laboratory should be correspondingly qualified, and the establishment should sign contract with the laboratory.

Article 16

The establishment of food for export should guarantee the effective operation of sanitary control system and meet the following requirements:

(1) Sanitary control procedures for raw and ingredients, semi-finished products, finished products and production process should be established and implemented effectively. Records

should be kept;

(2) A sanitary standard operating procedure should be established and implemented and records should be kept. Water (ice) used for processing, food contact surfaces, poisonous and hazardous substances and insecticides etc should be effectively controlled;

(3) Operating procedures should be formulated for the critical control steps that can affect food sanitation. These steps should be controlled under continuous supervision and records must be kept;

(4) The controlling procedures for rejected products should be established and implemented, which should include marking, recording, segregating and holding for evaluation, and tracing for the products etc;

(5) The procedures of product marking, quality tracing and product recalling must be established. Timely recalling should be guaranteed when food safety problems are found after the product leaves the factory;

(6) The maintenance procedures for processing equipment and facilities must be established and implemented so as to guarantee the processing equipment and facilities to meet the requirements for production and processing;

(7) Personnel training program should be set up and implemented to guarantee workers on different posts to finish their own work skillfully, and records must be kept;

(8) The internal audit system should be set up in the establishment. The internal audit should be conducted once every six months, and management audit should be carried out once a year, and records should be kept;

(9) Management procedures of marking, collecting, listing, filing, storing, keeping and handling the records concerning the sanitary quality of the products should be formulated and implemented. All records about quality should be genuine, accurate, standardized and traceable for the sanitary quality. The records should be kept for 2 years at least.

Article 17

Only if foods have to be processed through traditional processing technology, can the foods be produced and processed in that way, provided that the sanitary quality is guaranteed.

Article 18

CNCA is responsible for the explanation of these requirements.

Article 19

These requirements shall come into effect from May 20, 2002. *Sanitary Requirements for Factories/Storehouses of Food for Export* promulgated by the former State Administration of Import & Export Commodity Inspection of the People's Republic of China on November 14, 1994 shall become invalid at the same time.

Appendix 3

List of Products Requiring HACCP Audit for Sanitary Registration

Product category

- (1) Canned Food
- (2) Aquatic Products (excluding live, fresh, dry and marinated products)
- (3) Meat and Meat Products
- (4) Frozen Vegetable
- (5) Fruit or Vegetable Juice
- (6) Instant Frozen Food Contained Meat or Aquatic Product