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Functional Food Regulation

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FAIRS Subject Report

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Report Highlights:

On May 31, 2009 China announced draft Regulations on Supervision of Functional Foods. This measure was open for domestic comment until July 19, 2009. This report contains an UNOFFICIAL translation of this draft measure.

Executive Summary:

On May 31, 2009 China announced draft Regulations on Supervision of Functional Foods. This measure primarily regulates foods that have a functional or health claim associated with their use. This measure was open for domestic comment until July 19, 2009. This measure was published by the State Council Legislative Office (SCLO).

The following is the description of the measure as posted on the SCLO website: "In order to further

enhance the transparency of government legislative work to improve the quality of the draft administrative regulations, the State Council Legislative Affairs Office decided that the Ministry of Health submitted to the State Council for consideration of the "health food Supervision and Management Regulations (draft)" and its description published the full text to solicit views of the community in order to further study, the revised report to the State Council executive meeting. Hereby notify the related matters are as follows:

The relevant units and people in the June 19, 2009, through the following three ways to express their views:

(A) Log in Chinese Government's Legal Information Network (Web site: <http://www.chinalaw.gov.cn>), through the web site home page on the left of the "[opinion on the draft laws and regulations collection system](#)," comments on the manuscript.

(B) The views in correspondence sent to: Box 1750, Beijing (Zip Code: 100017), and in the envelope marked "health food supervision and management regulations for comment," the words.

(C) by e-mail be sent to: BJSP@chinalaw.gov.cn

May 31, 2009”

This measure has not been notified to the World Trade Organization.

This report contains an UNOFFICIAL translation of this draft measure.

General Information:

BEGIN TRANSLATION

Regulations on Supervision of Functional Foods (Draft for Approval)

Chapter I: General Provisions

Article 1. These Regulations are formulated in accordance with the *Food Safety Law of the People's Republic of China* (hereinafter the “Food Safety Law”) for the purposes of safeguarding the health and life safety of people and maintaining stringent regulation of functional foods.

Article 2 For the purpose of these Regulations, “functional food” means the food declared and legally approved to provide particular health care functions. Functional foods shall be suitable for specified populations, provide adjustment of organic functions without any acute, sub acute or chronic harm to human body, and not claim to cure any disease. Functional food products and their

specifications shall be approved by the state food and drug administration authority.

The nutritional additives intended to supplement vitamins or minerals shall be deemed as functional foods under these Regulations.

Article 3 These Regulations shall apply to production and trading of functional foods within the People's Republic of China as well as supervision and administration thereof.

Article 4 Producers and traders of functional foods shall produce and trade functional foods in accordance with laws, regulations and pertinent standards, assume responsibility for the society and the public, ensure safety of functional foods, receive public supervision and assume social responsibility.

Article 5 The state food and drug administration authority shall take overall charge of supervising functional foods. Relevant departments of the State Council shall take charge of supervising functional foods within their respective duties.

Local food and drug administration authorities at the county level or above shall take charge of supervising functional foods within their respective jurisdiction. Relevant departments of local governments at the county level or above shall take charge of supervision and administration in relation to functional foods within their respective duties.

Article 6 The functional food industry association shall enhance industry self-discipline, direct enterprises to lawful production and trading, boost trustworthiness across the industry and publicize knowledge on safety of functional foods.

Article 7 Any organization or individual shall have the right to report any violation of these Regulations during production or trading of functional foods, request information on quality and safety of functional foods from relevant authorities, and provide comments and suggestions on supervision of functional foods.

Chapter II: Registration of Functional Foods

Article 8 The state food and drug administration authority shall formulate and publicize the assessment guidelines and the scope of functions of functional foods.

The state food and drug administration authority shall adjust and publicize the assessment guidelines and the scope of functions of functional foods from time to time in line with technological advancement and social needs.

Article 9 The ingredients and by-product of functional foods shall not cause any harm to human body and shall meet national standards on food safety and pertinent requirements.

Conventionally, the catalogue of substances eligible for either foods or traditional Chinese medical materials shall be formulated and publicized by the health administration department of the State Council.

Article 10 Functional foods shall be approved by the state food and drug administration authority according to law and granted the Certificate of Product Registration. Functional foods issued the Certificate of Product Registration shall bear the functional food label specified by the state food administration authority.

Nutritional additives shall be subject to safety review by the state food and drug administration

authority according to law, and to record filing management.

Article 11 The applicants for China-made functional foods shall be legal persons or other entities lawfully incorporated in China.

The applicants for imported functional foods shall be lawful foreign functional food manufacturers.

Applicants shall be responsible and liable for the safety and declared functions of the subject products.

Article 12 Applicants shall conduct research and development in accordance with pertinent requirements of the State prior to applying for registration of functional foods.

Article 13 An applicant for registration of any functional food shall, in accordance with requirements of the state food and drug administration authority, file an application with the food and drug administration authority of the local province, autonomous region or municipality directly under the Central Government, submit the research and development report, formula, manufacturing processes, in-house standards, label, specifications, safety performance and function assessment data and samples, and provide relevant supporting documents. The food and drug administration authority of the local province, autonomous region or municipality directly under the Central Government shall, within 30 days of taking in application, conduct field inspection and take samples for testing, give an opinion and then report to the state food and drug administration authority.

An applicant for registration of any imported functional food shall file an application with the state food and drug administration authority. The state food and drug administration authority shall, within 30 days of taking in application, take samples for testing and, as necessary, conduct field inspection.

Article 14 The state food and drug administration authority shall conduct technical review and administrative approval on safety, functionality and quality controllability of the functional foods for which an application is filed for registration, and examine and approve the specifications and in-house standards of producers. Functional foods that meet requirements shall be approved for registration and granted the Certificate of Product Registration; Functional foods that fail to meet requirements shall be rejected from registration and given reasons in writing.

In the case of imported functional foods that meet requirements, the state food and drug administration authority shall notify the state sentry-exit inspection and quarantine authority of the results of technical review and administrative approval.

Article 15 The Certificate of Product Registration for functional foods shall remain valid for five years. If continued production or import thereof is desired after the validity expires, the applicant shall apply for re-registration within three months prior to expiration of the validity.

Re-registration will be rejected in any of the following cases:

- (1) failing to apply for re-registration within the specified timeframe;
- (2) falling beyond the approved scope of functions;
- (3) production or sale never occurs during the validity of the Certificate of Product Registration; or
- (4) other non-compliance with pertinent requirements of the State.

Article 16 The technical review and evaluation agency of the state food and drug administration authority shall conduct technical review and evaluation on functional foods in accordance with

national standards on food safety and pertinent requirements.

Article 17 The labels, specifications and names of functional foods shall meet requirements of the state food and drug administration authority.

Chapter III: Production and Trading of Functional Foods

Article 18 Producers of functional foods shall be responsible for the quality and safety of their products.

Article 19 To start a functional food production business, an application shall be filed with the food and drug administration authority of the local province, autonomous region or municipality directly under the Central Government.

Any new functional food producer shall, prior to production, obtain the Certificate of Product Registration according to law, meet the *Good Manufacturing Practice for Functional Foods*, obtain the Production License for Functional Foods and complete registration with the industrial and commercial administration by presenting the Production License for Functional Foods. The Production License for Functional Foods shall indicate the type of licensed functional food.

Functional food producers desired to produce any additional type of functional food shall indicate the same on the Production License for Functional Foods after the compliance with the *Good Manufacturing Practice for Functional Foods* is verified in inspection.

Article 20 Upon approval by the food and drug administration authority of the local province, autonomous region or municipality directly under the Central Government, functional food producers may accept contract production of functional foods with the same dosage form licensed thereto.

The contractor giver shall be responsible for the quality and safety of products manufactured under the contract; the contract acceptor shall ensure that production complies with the *Good Manufacturing Practice for Functional Foods* and assume corresponding legal liabilities.

Article 21 Functional foods shall be produced in compliance with the *Good Manufacturing Practice for Functional Foods* formulated by the State. The *Good Manufacturing Practice for Functional Foods* encompasses organization and personnel, premises and facilities, equipments, materials, health, validation, documentation, production management, quality management, complaint and safety incident report and self-inspection.

Functional food producers shall maintain records of incoming material inspection and outgoing food inspection as prescribed in Articles 36 and 37 of the Food Safety Law, and keep accurate records of safety management during food production. These records shall be retained for at least two years.

Article 22 To start a functional food wholesale business, an application shall be filed with the food and drug administration authority of the local province, autonomous region or municipality directly under the Central Government; to start a functional food retail business, an application shall be filed with the food and drug administration authority of the local county. When compliance of the *Good Manufacturing Practice for Functional Foods* is verified, the Trade License for Functional Foods will be issued to the applicant, who shall then complete registration with the industrial and commercial administration by presenting the Trade License for Functional Foods.

Article 23 Functional foods shall be traded in compliance with the *Good Trading Practice for Functional Foods*. The *Good Trading Practice for Functional Foods* encompasses management duties, duties, personnel and training, facilities and equipments, purchase and acceptance, exhibition and storage, sale and services, quality management, complaint and safety incident report and self-inspection.

Functional food traders shall maintain records of incoming food inspection in accordance with Article 39.2 of the Food Safety Law and accurately record such information as the food name, strength, quantity, batch number, shelf life, name and contact information of supplier and purchase date, or retain purchase receipts bearing such information. These records and documents shall be retained for at least two years.

Article 24 Imported functional foods granted the Certificate of Product Registration shall be inspected and accepted by the exit-entry inspection and quarantine authority before release by customs upon the certificate of conformity issued by the exit-entry inspection and quarantine authority.

Any exporter of functional foods shall file each intended export with the food and drug administration authority of the local province, autonomous region or municipality directly under the Central Government before going through export procedures with the exit-entry inspection and quarantine authority by presenting the certificate of filing.

The exit-entry inspection and quarantine authority shall supervise, sample and inspect and issue the certificate of conformity to functional foods to be exported in accordance with the certificate of filing issued by the food and drug administration authority. Customs will release such functional foods for export upon the certificate of conformity issued by the exit-entry inspection and quarantine authority.

Article 25 The health administration department of the State Council shall formulate the national food safety standards for functional foods and their ingredients, by-products, packaging materials and inspection codes and methods. The state food and drug administration authority shall communicate the approved in-house standards for imported functional food products to the state exit-entry inspection and quarantine authority as a basis for exit-entry inspection and quarantine authority.

Functional food producers shall produce functional foods in accordance with the national standards for food safety, pertinent requirements of the State as well as the product formula and manufacturing processes approved by the state food and drug administration authority. The production records shall be complete and accurate.

Article 26 Functional food producers shall be responsible for the authenticity of the labels and specifications of their products, which shall be consistent with the approved particulars.

The labels and specifications of functional foods shall specify the applicable populations, excluded populations and active or typical ingredients and their contents in compliance with pertinent requirements of the State, and shall not claim to prevent or cure any disease.

Article 27 The Production License for Functional Foods and the Trade License for Functional Foods shall remain valid for five years. The producer or trader desired to continue production or trading of functional foods after the validity expires shall, within thirty days prior to expiration of the license, apply to the original issuing authority for renewal of the Production License for Functional Foods or Trade License for Functional Foods.

Article 28 Functional food advertisements shall be approved by the food and drug administration authority of the local province, autonomous region or municipality directly under the Central

Government and granted the approval number of functional food advertisements. Any functional food advertisement shall not be released without said approval number.

Functional food advertisements shall contain lawful and authentic information without any deception or overstatement and shall not claim to prevent or cure any disease.

Article 29 The applicant for the approval number of functional food advertisement shall be legally qualified producer or trader of functional foods. The trader of functional foods shall obtain approval of the producer thereof when applying for the approval number of functional food advertisement.

The procedures for review of functional food advertisements shall be formulated by the health administration department of the State Council and the state food and drug administration authority in conjunction with the industrial and commercial administration department of the State Council.

Chapter IV: Supervision

Article 30 The local food and drug administration authorities at the county level or above shall be responsible for supervising and inspecting producers and traders of functional foods within their respective jurisdiction, establish operating procedures and management systems for supervision and inspection, formulate the annual supervision plan for functional foods and carry out work in accordance with said annual supervision plan.

Article 31 The state food and drug administration authority shall monitor and assess the safety of functional foods released onto the market and promptly communicate the results to the health administration department of the State Council.

The safety of functional foods may be monitored either proactively or through safety incident reporting.

Article 32 Producers and traders of functional foods and medical or health institutions shall report any safety incident they find suspicious of involving functional foods in accordance with provisions of the Food Safety Law regarding disposal of food safety incidents.

Article 33 The State establishes the functional food recall system.

The food and drug administration authorities may take and publicize such measures as giving an order of recall or suspending production or sale in accordance with the results of monitoring or assessment regarding functional food safety.

Article 34 The food and drug administration authorities shall conduct ongoing inspection on producers and traders of functional foods in accordance with the *Good Manufacturing Practice for Functional Foods* and the *Good Trading Practice for Functional Foods*, as the case may be, and shall have right to take the following actions:

- (1) accessing production and trading premises for field inspection;
- (2) conducting sample inspection on functional foods produced or traded;
- (3) Reviewing and copying relevant contracts, documents and books, batch production records, inspection records and other related data;
- (4) ordering to suspend production or trading and recall products that fail to comply with functional

food standards;

(5) sealing up and seizing products evidenced to fail to meet functional food standards, illegally used raw materials of functional foods, food additives and food-related products, and equipments and tools used for illegal production or trading; and

(6) sealing up premises used for illegal production and trading of functional foods.

Article 35 The food and drug administration authorities at the county level or above may take sealing-up and seizure measures in any of the following cases:

(1) using false Certificate of Product Registration for functional foods;

(2) the functional food fails to comply with standards or contains any additional ingredient without approval;

(3) the product name, label or specifications of the functional food are inconsistent with the approved ones or otherwise violate these Regulations;

(4) the label, specifications or promotional materials claim to prevent or cure any disease; or

(5) there is any other evidence to demonstrate any possible harm to human health.

Where sealing-up or seizure is enforced, a decision on whether to file the case shall be made within seven days of enforcement; where inspection is required, a decision on whether to file the case shall be made within 15 days upon issuance of the inspection report; if the case is ineligible for filing, the enforcement shall be terminated.

Article 36 Any food other than a functional food granted the Certificate of Product Registration shall not claim to be functional, and shall not be promoted or sold in the name of functional food.

Any food not granted the Certificate of Product Registration for functional foods shall not claim to be functional or counterfeit functional foods shall be investigated and punished by the food and drug administration authorities according to law.

Article 37 The local food and drug administration authorities at the county level or above shall, during supervision or inspection, take samples and request relevant information in accordance with the requirements of the state food and drug administration authority, for which the entities and individuals concerned shall provide cooperation.

If any entity refuses to accept sample inspection without justified reasons, the state food and drug administration authority and the food and drug administration authority of the local province, autonomous region or municipality directly under the Central Government may order the entity to suspend sale of functional foods for which the entity rejects sample inspection.

Article 38 In the case of any functional food that may pose to human health any harm undetectable by the inspection methods or items provided by the national food safety standards for functional foods, the functional food inspection agency may use any additional inspection method or item. Upon approval by the state food and drug administration authority, the results of such additional inspection methods or items may be used as the basis for decision making by food and drug administration authorities and sentry-exit inspection and quarantine authorities.

Any functional food that may contain drug ingredients may be inspected with the supplementary drug

inspection methods.

Article 39 The state food and drug administration authority and the food and drug administration authorities of the local province, autonomous region or municipality directly under the Central Government shall announce the results of the sample inspection conducted on functional foods.

Article 40 Functional foods shall be inspected in compliance with applicable laws and regulations and on a scientific, impartial, unbiased and open basis. The functional food inspection agency and its personnel shall be obligated to keep confidential any technical data of the inspected entity and refrain from engaging or participating in research, development, production or trade of functional foods related to the inspection.

Article 41 The food and drug administration authorities shall, when sampling functional foods for inspection, purchase the samples at its own cost without charging inspection or other fees. The costs so incurred shall be borne by the government at the corresponding level.

Article 42 Any one who disagrees with the inspection results of the functional food inspection agency shall apply for re-inspection within ten days of receiving the inspection results by submitting a written application and the original inspection report to the functional food inspection agency in charge of re-inspection.

Samples for re-inspection shall be taken from the retention samples kept by the original functional food inspection agency.

The applicant for re-inspection of functional foods shall prepay inspection fee to the re-inspection agency. Where the re-inspection conclusions differ from the original inspection results, the re-inspection fee shall be borne by the original functional food inspection agency.

Article 43 The industrial and commercial administration shall supervise adverting activities for functional foods and handle any violation of the *Advertisement Law of the People's Republic of China* in accordance with law.

The food and drug administration authorities shall inspect advertisements placed for approved functional foods. Any functional food advertisements placed in serious violation of the law shall be announced by the food and drug administration authorities of the local province, autonomous region or municipality directly under the Central Government.

Article 44 Where any functional food advertisement severely deceives customers by, for example, overstating applicable populations and functions, the state food and drug administration authority or the food and drug administration authorities of the local province, autonomous region or municipality directly under the Central Government shall suspend sale of such functional food in the place where the illegal advertisement is placed and order the enterprise that places the illegal advertisement to make an announcement of correction on the local media. The food and drug administration authorities shall not permit resumption of sale thereof until the illegal advertisement is corrected.

Article 45 In the case of any safety incident regarding functional foods, the entity where such incident occurs and the organization receiving and treating victims shall act in accordance with applicable provisions of the Food Safety Law.

Article 46 Local food and drug administration authorities at the county level or above shall promptly verify, handle and reply to consultation, complaints and reports regarding food safety and, if a food safety incident is confirmed, handle the incident in accordance with the Food Safety Law.

Chapter V: Legal Liabilities

Article 47 Any of the following cases shall be subject to punishment by the food and drug administration authorities in accordance with Article 84 of the Food Safety Law:

- (1) producing or trading any product that counterfeits registered and licensed functional food;
- (2) producing or trading functional foods without license; or
- (3) engaging in contract production of functional foods as contract giver or acceptor without license.

Article 48 Any of the following cases shall be subject to punishment by the food and drug administration authorities in accordance with Article 85 of the Food Safety Law:

- (1) trading any functional food whose shelf life has expired;
- (2) producing or selling any functional food that fails to meet national standards for food safety or the filed in-house standards;
- (3) illegally adding any substance that may cause harm to human health; or
- (4) failing to recall or suspend production or trading of products, if the food and drug administration authorities order such recall or suspension.

Article 49 Any of the following cases shall be subject to punishment by the food and drug administration authorities in accordance with Article 86 of the Food Safety Law:

- (1) failing to produce any functional food in accordance with the ingredients, formula, standards or manufacturing processes as approved by the license;
- (2) illegally adding any drug ingredients into functional food; or
- (3) the name, label or specifications of the functional food do not comply with relevant provisions of these Regulations:

Article 50 Any of the following cases shall be subject to punishment by the food and drug administration authorities in accordance with Article 87 of the Food Safety Law:

- (1) the producer or trader fails to establish or follow the incoming material inspection procedures, outgoing food inspection procedures and other relevant procedures; or
- (2) the label, specifications or promotional materials of any functional food claim to prevent or cure any disease.

Article 51 Where a producer or trader of functional foods fails to comply with the *Good Manufacturing Practice for Functional Foods* or the *Good Trading Practice for Functional Foods*, the food and drug administration authorities may order such producer or trader to make corrections within a specified time limit or suspend production or trading, up to revoking the Production License for Functional Foods or Trade License for Functional Food.

Article 52 Where any functional food advertisement is placed without an approval number of functional food advertisement, or any product other than a functional food claims to be functional in its advertisement, the industrial and commercial administration shall impose punishment in accordance with law.

Article 53 Where an enterprise alters the advertisement approved for its functional food in violation of these Regulations, the food and drug administration authorities that grant the advertisement approval number shall revoke the same for that functional food and shall not accept that's enterprise's application for approval of functional food advertisement within one year, and the industrial and commercial administration shall impose punishment upon that enterprise in accordance with law.

Article 54 Any inspection agency that makes errors during testing or inspection shall be subject to disciplinary warning and ordered to make corrections within a specified time frame, up to revocation of the eligibility for functional food inspection under serious circumstances.

Any inspection agency that issues a false testing or inspection report shall be punished in accordance with Article 93 of the Food Safety Law.

Article 55 Where an applicant conceals relevant information or provides false information or samples when applying for registration of functional foods, such application or registration will be rejected, and the applicant shall be prohibited from applying for registration of functional foods within one year.

Article 56 Where any applicant obtains the Certificate of Product Registration for a functional food through deception, bribery or other wrongdoings, the Certificate of Product Registration for that functional food shall be revoked, and the applicant shall be prohibited from applying for registration of functional foods within five years.

Article 57 Any producer of functional foods that fails to promptly report any potential safety hazard in its product to the food and drug administration authorities shall be given a disciplinary warning and ordered to make corrections, up to revocation of the Production License for Functional Foods when serious consequences are caused.

Article 58 Any supervisory authority that fails to perform its duties under these Regulations or commits abuse of powers, dereliction of duties or misconducts for personal gains shall be punished in accordance with Article 95.2 of the Food Safety Law.

Article 59 Any violation of these Regulations that constitutes a criminal activity shall be held criminally liable.

Chapter VI: Supplementary Provisions

Article 60 The food and drug administration authorities of provinces, autonomous regions or municipalities directly under the Central Government may establish technical review and evaluation organizations as necessary.

Article 61 Inspection agencies engaging in testing and inspection for registration of functional foods shall be certified in accordance with the Food Safety Law and comply with pertinent rules and regulations formulated by the state food and drug administration authority.

Registration of functional foods and inspection for registration of functional foods may be provided as paid services. The specific charge rate shall be determined by the financial authority and price administration authority at the corresponding level.

Inspection required for supervision of functional foods shall be carried out by the functional food

inspection agencies designated or approved according to law.

Article 62 For the purpose of these Regulations, counterfeit functional food means a product that falsifying approval number or label of functional foods.

Article 63 Any matter regarding functional foods not covered by these Regulations shall be governed by the Food Safety Law and the Regulations for Implementation of the Food Safety Law.

Article 64 These Regulations shall be effective as of _____.

Where the approval certificate for functional foods granted before these Regulations take effect does not indicate the period of validity, re-registration procedures shall be completed as required by the state food and drug administration authority within one year after these Regulations take effect. The original approval certificate for functional foods shall be invalidated if such re-registration procedures are not completed within the specified time limit or re-registration is not approved.