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Licensing for New Food Additives

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Report Highlights:

On January 8, 2010 China notified "Administrative Licensing Regulation for New Varieties of Food Additives" to the WTO as G/SPS/N/CHN/201. Comments are due on February 25, 2010. This report contains an UNOFFICIAL translation of this draft measure.

General Information:

Summary

On January 8, 2010 China notified "Administrative Licensing Regulation for New Varieties of Food Additives" to the WTO as G/SPS/N/CHN/201. Comments are due on February 25, 2010. The proposed date of adoption is February 28, 2010.

China's WTO notification relates, "On the basis of the Food Safety Law of China and Food Safety Implementation Regulation of China, it regulates administrative licensing work for new varieties of food additives."

This report contains an UNOFFICIAL translation of this draft standard.

BEGIN TRANSLATION

National Standard of the People's Republic of China

Administrative Licensing Regulation for New Varieties of Food Additive

(Consultative Draft)

Article 1 In order to regulate the Administrative License of new food additives, the Measures are hereby formulated pursuant to the *Food Safety Law* and the *Regulation on the Implementation of the Food Safety Law*.

Article 2 New food additives mean:

- (1) food additives that are not covered by the national standards for food safety;
- (2) food additives that are not specified in the list of food additives allowed to be used; and
- (3) food additives with an enlarged range of use or consumption.

Article 3 The Ministry of Public Health is responsible for examining and granting a license for new food additives, formulating technical evaluation and examination standards for food additives, and designating technical evaluation institutions to accept, handle and technically examine the licensing of new food additives.

Article 4 New food additives shall comply with the *Food Safety Law* and pertinent laws, regulations and standards, and shall be technically necessary and be proven to be safe and reliable through risk assessment.

Article 5 Units and organizations engaged in production, operation, use or import of new food additives (collectively the "Applicant") shall file an application for the licensing of new food additives to the technical evaluation institution, together with the following materials:

- (1) Common name, consumption and range of use of additive;

- (2) Materials or certificates with respect to technical necessity and use effect;
- (3) Quantity specification requirements and testing methods of food additives;
- (4) Safety assessment materials, including raw materials for production or source, chemical structure and physical property, production process, toxicology safety evaluation materials or testing reports, and quality and quality specification testing reports;
- (5) Sample products affixed labels and attached with instructions; and
- (6) Production and use approval materials of other countries and other materials that help safety assessment.

Article 6 Apart from the materials specified in Article 5, the following materials are also required for the new food additives imported for the first time:

- (1) Certificates issued by related departments or institutions of the import country/region that allow the production or sales of relevant food additives in the country/region; and
- (2) Production enterprise examination or authentication certificates issued by relevant institutions or organizations in the country/region where the production enterprise is located.

Article 7 The applicant shall faithfully submit relevant materials, feed back true information, and take the responsibility for the truthfulness of the substantial contents of application materials.

Article 8 Upon acceptance of an application, the Ministry of Public Health shall consult the food safety regulators and related industrial organizations about related contents set forth in Items 1-3 of Article 5 hereof, and concurrently solicit public opinions on the contents that do not involve business secrets.

In case of any material discrepancy or involving substantial interests, the Ministry of Public Health shall hold an evidentiary hearing in accordance with the *Administrative License Law*.

Related opinions shall serve as the basis for technical evaluation.

Article 9 Technical evaluation institutions shall organize experts in the fields of medicine, agriculture, nutrition and process to complete technical examination of the process necessity and safety assessment materials of new food additives within 60 days upon acceptance. Should additional materials be required for technical evaluation, technical evaluation institutions

shall inform the applicant in time, who shall provide assistance.

Whenever necessary, technical evaluation institutions may appoint experts to verify and evaluate the new food additive research, manufacturing and production sites.

If experts consider it necessary to verify related materials and testing results, technical evaluation institutions shall inform the applicant of the testing items, batches and methods. Safety verification testing shall be conducted by qualified testing institutions. In case there is no national standard for food safety testing methods, the testing methods shall be first verification.

Article 10 Specific procedures for Administrative License of new food additives shall comply with *Administrative License Law*, the *Measures for the Administration of Sanitary Administrative Licenses* and other pertinent regulations.

Article 11 The Ministry of Public Health shall solicit social opinions on the new food additives to be approved, according to the opinions of technical evaluation institutions.

Based on the technical evaluation conclusions and public opinions, the Ministry of Public Health shall grant a license for the new food additives that are necessary in process and meet food safety requirements, and publish the list of food additives that are allowed to be used.

For those that lack process necessity and do not meet food safety requirements, the Ministry of Public Health shall reject application and give a written explanation.

In case inedible chemical substances or other substances that may damage human health are found in technical evaluation, provisions in Article 49 of the *Regulation on the Implementation of the Food Safety Law* shall be implemented.

Article 12 Based on the technical necessity and food safety risk assessment results, the Ministry of Public Health shall formulate and publish the list of food additives allowed to be used as the the national standards for food safety, according to the procedures for national standards for food safety.

Article 13 In any of the following cases, the Ministry of Public Health shall reevaluate the food additives in time:

- (1) Food additives involve safety issue based on the scientific research results;
- (2) Food additives are not technically necessary; or
- (3) Production process of food additives changes.

In case a food additive does not meet food safety requirements according to reevaluation, the Ministry of Public Health shall cross off the food additive from food additive standards or revise the range of use and consumption of food additives in time.

Article 14 The Measures shall come into effect as of the date of promulgation. The *Measures for the Hygienic Administration of Food Additives* promulgated by the Ministry of Public Health on December 11, 2001 shall be abolished simultaneously

END TRANSLATION