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Administrative Measures on New Food Additive Varieties (Final)

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Report Highlights:
On April 22, 2010, China's Ministry of Health published on its web site the Administrative Measures on New Food Additive Varieties (Final) for adoption on March 30, 2010. The Measures replaced the *Administrative Measures on Food Additive Hygiene* issued by the Ministry on March 28, 2002.

Executive Summary:

On April 22, 2010, China's Ministry of Health published on its web site the Administrative Measures on New Food Additive Varieties (Final) for adoption on March 30, 2010. The Measures replaced the *Administrative Measures on Food Additive Hygiene* issued by the Ministry on March 28, 2002.

A draft version of the Measures, then called the Administrative Licensing Regulation for New Food Additive Varieties, was notified to the WTO on January 8, 2010 as G/SPS/N/CHN/201. These Measures establish the licensing requirements for new food additive varieties. This report is an informal translation of the document.

General Information:

BEGIN TRANSLATION

Administrative Measures on New Food Additive Varieties (Final)

1. In order to strengthen the administration of new food additive varieties, these Measures are hereby formulated based on the *Food Safety Law* and the *Implementation Regulation on the Food Safety Law*.

2. New food additive varieties refer to:

Food additive varieties that are not covered by the national food safety standards;
Food additive varieties that are not covered by announcements of the Ministry of Health that list food additives allowable for use; and
Food additive varieties intended for enlarged scope of application and/or dosage levels.

1. Food additives should be technically necessary and proven to be safe and reliable based on a risk assessment.

2. Use of a food additive shall comply with the following requirements:

    1. Not intended to cover up food rancidness;

    2. Not intended to cover up quality defects of the food itself or during the food processing;

    3. Food additives not used for adulteration or falsification;

    4. Should not reduce the nutrition value of food;

    5. Reduce dosage levels as much as possible once anticipated effects are achieved;

    6. Food processing aids used in the course of food processing should be removed before the final product is produced, unless a residue level is specified.

3. The Ministry of Health is responsible for examining and licensing new food additive varieties as well as formulating technical evaluation and examining the scope of the new food additive

varieties.

4. An individual or organization (hereinafter referred to as “applicant”) intended for production, operation, use or import of a new food additive variety shall file an application for the licensing along with the following materials:
5. Common name, function category, dose level and application scope of the additive;
6. Documents or certificates to prove technical necessity and use effect;
7. Quality specification requirements, production techniques and testing method for the food additive, as well as the method or instruction to test the additive in food;
8. Safety assessment materials, including raw materials or sources, chemical structure and physical properties, production techniques, toxicology safety assessment documents or testing reports on toxicology, and testing reports on quality specifications;
9. Samples of labeling, instructions and food additive product;
10. Documents of other countries (regions) or international organizations allowing production and use of (the additive) that are helpful to the safety assessment.

Applications for enlarged application scope or dose levels can be waived from providing the documents prescribed in Item 4) of this Article, unless otherwise required for additional submission during the technical review process.

1. To import a new food additive variety for the first time, in addition to the materials specified in Article 6, the following materials shall also be required:
2. Certificates issued by related departments or institutions of the exporting country (region) that allow the production or sale of the food additives in the that country (region); and
3. Examination or authentication certificates issued to the manufacturing enterprise by relevant institutions or organizations in the country (region) where the manufacturing enterprise is located.
4. The applicant shall faithfully submit relevant materials that reflect the truth, be responsible for authenticity of the application materials and bear legal liabilities.
5. The applicant shall indicate what parts of the materials that are submitted under Items 1-3 of Article 6 do not involve business confidentiality and are open to the public.

Information regarding the technical necessity and use effect of a new food additive variety shall be released for public comments. Meanwhile, comments shall also be sought from industry groups and relevant departments including quality supervision, industry and commerce administration, food and

drug administration, industry and information technology, and commerce.
In case of a major discrepancy or involving substantial interests, a public hearing can be organized. Related comments shall serve as the reference basis for technical evaluation.

1. The Ministry of Health shall organize experts in the fields of medicine, agriculture, nutrition, and processing techniques to perform a technical review on the technical necessity and safety assessment materials of the new food additive variety and produce a conclusion about the technical review within 60 days upon receipt of the application. If additional documents are required for the technical review, the applicant should be notified in a timely manner and the applicant shall provide the required documents as soon as possible.

Whenever necessary, experts may go to the research and production sites of the new food additive variety for verification and evaluation.
If verification on relevant materials and testing results is needed, the applicant shall be informed of the testing items, batches, and testing methods. Safety verification testing shall be conducted by qualified testing institutions. In the absence of a national food safety standard on testing method, the testing method shall be verified first.

1. Specific procedures for administrative licensing of new food additive varieties shall comply with the *Administrative Licensing Law*, the *Administrative Measures on Health Licensing* and other pertinent regulations.
2. Based on the conclusion of the technical review, the Ministry of Health shall grant a license to the new food additive variety that is technically necessary and meets the food safety requirements and shall include it in the list of allowable food additives for publication.

For additives that lack technical necessity or fail to meet food safety requirements, the Ministry of Health shall reject the application and provide a written justification.
If inedible chemical substances or other substances that may cause damage to human health are found during the technical review, Article 49 of the *Implementation Regulation of the Food Safety Law* shall apply.

1. Based on the technical necessity and food safety risk assessment results, the Ministry of Health shall formulate and publish the allowable food additive of which variety, application scope, and dose levels have been announced as national food safety standards in accordance with the procedures of establishing national food safety standards.
2. In any of the following cases, the Ministry of Health shall organize a re-evaluation of the food additive in a timely manner.

3. Scientific research or evidence indicates that there exist safety issues with a food additive; or
4. The food additive is no longer technically necessary.

In the case where a food additive does not meet food safety requirements according to a re-evaluation, the Ministry of Health shall revoke the approved food additive variety or revise its application scope and/or dose levels.

The Measures shall come into force upon publication. The *Administrative Measures on Food Additive Hygiene* issued by the Ministry of Health on March 28, 2002 shall be abolished simultaneously.

END TRANSLATION