

Measures for the Administration of New Varieties of Food Additives

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Order of the Ministry of Health

(No.73)

The Measures for the Administration of New Varieties of Food Additives, which were deliberated and adopted at the executive meeting of the Ministry of Health on March 15, 2010, are hereby promulgated, and shall come into force from the date of promulgation.

Minister: Chen Zhu

March 30, 2010

Measures for the Administration of New Varieties of Food Additives

Article 1 To strengthen the administration of new varieties of food additives, these Measures are formulated pursuant to the Food Safety Law and the Regulation on the Implementation of the Food Safety Law.

Article 2 The term “new varieties of food additives” refers to:

1. Those which are not included in the national standards for food safety;
2. Those whose use has not been permitted by announcement by the Ministry of Health; and
3. Those whose range of use or dosage has been enlarged.

Article 3 Food additives shall be use when technically necessary and shall have been proved by risk assessment as safe and reliable.

Article 4 The use of food additives must:

1. Not conceal the decomposition or deterioration of foods;
2. Not cover the mass defects which belong to foods or which appear in processing;
3. Not aim at adulteration or counterfeit;
4. Not reduce the nutritive value of foods;
5. Be minimized after realizing the expected result; and
6. Stick to the rule that processing aids for the food industry must be removed before products are finished, unless they are within the allowable residue limit.

Article 5 The Ministry of Health shall be responsible for the examination and licensing of new varieties of food additives and organize the making of the technical evaluation and examination norms for new varieties of food additives.

Article 6 To apply for producing, dealing, using or importing any new variety of food additives, an entity or individual (hereinafter referred as an “applicant”) shall file an application for licensing a new variety of food additive and submit:

1. the generic name, functional classification, dosage and range of use of the additive at issue;
2. materials or documents proving its technical necessity and effects;
3. quality and specifications requirements, manufacturing techniques and inspection methods of food additives, the inspection methods for the additive in question, and other relevant information;
4. safety evaluation materials, including its raw materials for production, sources, chemical constitution, physical properties, manufacturing techniques, a toxicological safety evaluation or inspection report, and a quality and specifications inspection report;
5. a label, description and sample product; and
6. a production or use permit given by any other country (region) or international organization, and other materials helpful for safety evaluation.

To apply for expanding the range of use or dosage of a food additive, an applicant is not required to submit the materials as mentioned in Item 4 of the preceding paragraph, unless these materials are mentioned in the supplementary materials required by technical review.

Article 7 To apply for importing a new variety of food additive for the first time, an applicant shall submit the following materials in addition to those as described in Article 6:

1. Evidentiary materials as issued by the competent department or body of the export country (region), approving the production or distribution of this additive in that country (region); and
2. Evidentiary materials as issued by the competent department or organization of the country (region) where the producing enterprise of this additive is located on the examination or certification of the enterprise.

Article 8 An applicant shall truthfully provide the application materials, reflect the actual situations, take responsibility for the authenticity of the application materials and undertake the corresponding legal consequences.

Article 9 An applicant shall, in the materials as mentioned in Items 1 through 3, Paragraph 1 of Article 6 of these Measures, clearly indicate the contents that do not involve trade secrets and can be disclosed to the public

With regard to the technical necessity and use effects of a new variety of food additive, it is required to solicit the opinions of the general public and also the opinions of the quality supervision department, administrative department for industry and commerce, the food and drug administrative department, the industry and information technology department, the commercial department and other relevant departments and industrial organizations.

A hearing can be held if there is any significant dissent or if it involves any vital interest relationship.

Opinions received from the relevant aspects shall be taken as a reference for technical review.

Article 10 The Ministry of Health shall, within 60 days after accepting an application, organize experts in medicine, agriculture, food, nutrition, craftwork and other fields to make a technical review on the evaluation materials on the technical necessity and safety of the new additive, and reach a technical

review conclusion. If the technical review requires supplementary materials, it shall timely notify the applicant and the applicant shall timely supplement the required materials.

If necessary, the Ministry of Health may organize experts to check and assess the development and production sites of the food additive.

Where it is necessary to validate or inspect the relevant materials and the test results, the Ministry of Health shall notify the applicant of the characteristics to be inspected, the batch number of the products to be inspected, the inspection method, etc. Safety inspection must be made at a qualified inspection institution. In the absence of national standards for food safety inspection methods, priority should be placed on verifying the inspection methods.

Article 11 The specific administrative licensing procedure for new varieties of food additives shall be governed by the Administrative License Law, the Measures for the Administration of Sanitary Administrative License and other relevant provisions.

Article 12 The Ministry of Health shall, based on the technical review conclusion, make a decision to license a new food additive which has technical necessity and meets the food safety requirements and put it on the list of permitted food additives.

For a new additive which lacks technical necessity and fails to meet the food safety requirements, the Ministry of Health shall disapprove its licensing application and give an explanation.

Inedible chemicals or other substances endangering people's health which may be added to foods shall be handled under Article 49 of the Regulation on the Implementation of the Food Safety Law.

Article 13 The Ministry of Health shall, based on the technical necessity and food safety risk assessment results, make and publish the varieties whose use has been permitted by announcement as well as the range of use and dosage thereof as national food safety standards by the prescribed procedure.

Article 14 Under any of the following circumstances, the Ministry of Health shall timely organize a reevaluation of the food additive concerned:

1. Scientific research findings or proofs show that the food additive may have safety problems; or
2. The food additive is no longer technically necessary.

If the reevaluation result shows that the food additive fails to meet the food safety requirements, the Ministry of Health may publish an announcement to cancel the variety which has been approved or to amend its range of use or dosage.

Article 15 These Measures shall come into force on the date of promulgation. The Measures for the Hygienic Administration of Food Additives issued by the Ministry of Health on March 28, 2002 shall be abolished simultaneously.