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China, People's Republic of
Food and Agricultural Import Regulations and
Standards
Admin. Measures for Food Additive Hygiene
2002

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Report Highlights:

This is an UNOFFICIAL English translation of the People's Republic of China *Admin. Measures for Food Additive Hygiene* and should be used as a guide only. Exporters should carefully discuss regulations and their application with Chinese importers to ensure that their interpretation of the regulation is accurate.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Beijing [CH1], CH

This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Beijing, People's Republic of China for US exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that US exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Summary

The following is an UNOFFICIAL translation of the Ministry of Health Decree No. 26 on the *Administrative Measures for Food Additive Hygiene*. On December 11, 2001, the MOH executive committee approved the amended *Administrative Measures for Food Additive Hygiene*. These measures have been published and will take effect on July 1, 2002. The *Administrative Measures for Food Additive Hygiene*, published on March 15, 1993, shall be annulled. Decree No. 26 was signed by MOH Minister Zhang WenKang on March 28, 2002.

These measures explain the application procedures for the production, or new use, of food additives. The measures also indicate the application procedures to request a change in the scope or dosage of food additives. The measures address production, marketing, and use of food additives, along with labeling and monitoring requirements. The means for punishing food additive producers, marketers, and users who are not in compliance with food additive regulations are indicated in Chapter Six of these measures.

Inquiries regarding applications to alter the scope or tolerance of a food additive should be sent to:

Ministry of Public Health

Department of Hygiene Regulation and Supervision

Add: 44 Houhai Beiheyuan
Beijing 100725, P. R. China

Contact: Ms. Zhang Lingping
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Or to,

China Food Additive Standard Technology Division

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Administrative Measures for Food Additive Hygiene

Chapter I. General Provisions

Article 1. Based on *the Food Hygiene Law of the People's Republic of China* (CH1042), these measures are promulgated to accelerate the administration on hygiene of food additives, prevent food contamination, and protect consumers' health.

Article 2. These measures shall apply to the production, marketing, and use of food additives.

Article 3. Food additives shall comply with national hygiene standards and requirements.

Article 4. The Ministry of Health shall be responsible for the monitoring and administration of food additive hygiene.

Chapter II. Review and Approval

Article 5. The following food additives must be approved by the Ministry of Health before production, marketing, or use:

- 1). New food additive varieties not listed in the *Food Additive Hygiene Standards* (CH1046) or other MOH published lists.
- 2). Varieties listed in the *Food Additive Hygiene Standards* or other MOH published lists requesting an increase in application scope or dosage.

Article 6. All applications for production or use of new food additive varieties must include the following information:

- 1). Application form
- 2). Name of material and its source of origin
- 3). Chemical structures and physical/chemical features
- 4). Production techniques
- 5). A toxicology safety assessment report produced by a testing agency accredited by the health administrative department at the provincial level or above, and hygienic testing reports on three consecutive batches of the product
- 6). When microorganisms are being used to produce food additives, a MOH accredited agency must provide both appraisal reports on bacteria type and safety assessment documents.
- 7). Scope of application and dosage
- 8). Reports on the effects of experimental use
- 9). Testing methodologies of the food additives in food
- 10). Product quality standards or norms
- 11). Product samples
- 12). Label (including instructions)
- 13). Foreign certificates or documents demonstrating the product has been approved for use, as well as other domestic and foreign safety related documents.
- 14). Other documents stipulated by MOH

Article 7. The following documents shall be supplied when applying for an increase in the scope of application or dosage:

- 1). Application form
- 2). Category, dosage, and production techniques of the intended food
- 3). Reports on the effects of experimental use
- 4). Testing methodologies of the food additives
- 5). Product sample
- 6). Label (including instructions)

7). Foreign certificates or documents demonstrating the product has been approved for use, as well as other domestic and foreign safety related documents.

8). Other documents stipulated by MOH

Article 8. The procedures for review and approval of food additives are:

1). The applicant shall apply to the local health administrative department at the provincial level, providing the documents stated in Articles 6 and 7.

2). The health administrative department at the provincial level shall produce a preliminary opinion for MOH approval after finishing preliminary review of the application with regard to its completeness, legitimacy, and consistency.

3). MOH shall arrange regular expert meetings for technical review on application documents-applications will be approved based on experts' technical reviews and opinions.

Article 9. For new varieties of imported food additives or imported food additives that will increase the scope of application or dosage, the manufacturer or import agent shall apply to MOH with the following materials in addition to the documents stated in Articles 6 and 7:

1). Certificates from the government of the exporting country (region) or its authorized agency, demonstrating that the product has been approved for production and marketing

2). Review or accreditation documents of the manufacturer, produced by the related agency or organization from the country of origin

Food additives in imported food must comply with the *Food Additive Hygiene Standards*. If they are not in compliance with the food additive must be approved by MOH based on the provisions of these measures before they can be imported.

Chapter III. Production, Marketing, and Use

Article 10. Food additive manufacturers shall obtain a hygiene license issued by the health administrative department at the provincial level before engaging in food additive production.

Article 11. When applying for a hygiene license to produce food additives, food additive manufacturers shall provide the health administrative department at the provincial level with the following materials:

1). Application form

2). List of food additives to be produced

3). Production conditions, equipment, and quality guarantee system

4). Production techniques

5). Quality standards or norms

6). Label (including instructions)

Article 12. Food additive manufacturers shall be furnished with work space, equipment, and facility accommodations necessary for product form and quantity.

Food additive manufacturers shall accelerate hygiene management in the course of production so that food additives will not be contaminated, and different varieties will not be mixed.

Article 13. In compound food additive production, the scope of application and dosage for each individual food additive shall conform with the *Food Additive Hygiene Standards* or other MOH published lists with respect to the relevant scope of application and dosage.

Individual food additives with a different application scope shall not be allowed for use in compound food additive production. Inedible substances that exceed the *Food Additive Hygiene Standards* are prohibited in the production of compound food additives.

Article 14. Manufacturers shall conduct product quality inspections in the course of food additive production, supplying a quality inspection certificate for products passing inspection. Products without a quality inspection certificate shall not be marketed.

Article 15. Food additive marketers must be equipped with storage and business facilities capable of accommodating the variety and quantity of food additives being marketed. Food additives must be kept on designated counters (shelves) or places for sale or storage. Food additives shall not be placed together with other inedible products or toxic and harmful substances.

Article 16. Food additive marketers shall ask for copies of the hygiene license and quality inspection certificate when purchasing food additives.

It is prohibited to market food additives in the absence of a hygiene license and quality inspection certificate.

Article 17. The use of food additives must comply with the *Food Additive Hygiene Standards* or other MOH published lists on the scope of application and dosage.

Food additives shall not be used to disguise food spoilage or to doctor or falsify food.

Chapter IV. Labeling Specifications

Article 18. Food additives must have packaging labels and instructions. Label contents shall include: product name, origin, manufacturer's name, hygiene license number, product specifications, formula (or main ingredients), production date, serial number (or code number), shelf life, scope of application, dosage, and usage, and "food additive" must be indicated on the label.

Restrictions or safety concerns should be warned on the labels of food additives.

Article 19. Aside from as stated in Article 18, a compound food additive shall be labeled with individual food additives in a content-based order. The name of each individual variety shall conform with the *Food Additive Hygiene Standards*.

Article 20. The packaging label and product instructions shall be free of publicity claims that increase the application scope or exaggerate effects.

Chapter V. Hygiene Monitoring

Article 21. MOH may repeat a safety assessment on food additives that have potential safety and hygiene concerns. MOH may modify the scope of application and dosage or exercise a ban on the product through public notices.

Article 22. The health administrative department at the county level or above shall conduct selective monitoring inspections on the production, marketing, and use of food additives, making public the results of these monitoring inspections.

Article 23. Food hygiene testing agencies shall conduct tests on food additives based on MOH stipulated standards, norms, and requirements-the testing and assessment reports shall be objective, authentic, and comply with related standards, specifications, and requirements.

Article 24. General hygiene monitoring and management on the production and operation of food additives shall be executed in accordance with the *Food Hygiene Law* and its related regulations.

Chapter VI. Punitive Provisions

Article 25. Producing, marketing, or using food additives not in compliance with the *Food Additive Hygiene Standards* or the provisions of these measures are subject to punishment in accordance with Article 44 of the *Food Hygiene Law*.

Article 26. Failure or falsification of identifying production dates, shelf lives and other required items on the packaging labels or product specifications, or the lack of a label in Chinese are subject to punishment based on the *Food Hygiene Law*, Article 46.

Article 27. A violation of the *Food Hygiene Law* or other hygiene requirements shall be penalized accordingly.

Chapter VII. Supplementary Provisions

Article 28. Definition of the following terminologies referred to in these measures:

Food additive refers to chemically synthesized or natural substances added to food in an effort to improve its quality, color, flavor, and taste for the purposes of preservation, or the required processing techniques.

Compound food additive refers to food additives comprised of two or more varieties of an individual food additive that has been physically blended.

Article 29. MOH shall be responsible for the interpretation of these measures.

Article 30. These measures will take effect on July 1, 2002. *The Administration Measures on Hygiene of Food Additives* published by MOH on March 15, 1993 shall be annulled.