

Measures for the Administration of New Resource Food

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The Measures for the Administration of New Resource Food, which were adopted after deliberation at the utive meeting of the Ministry of Health on December 26, 2006, are hereby issued, and shall be effective as of December 1, 2007.

Minister: Chen Zhu
July 2, 2007

Measures for the Administration of New Resource Food

Chapter I General Provisions

Article 1 In order to strengthen the supervision and management of new resource food and protect the physical health of consumers, these Measures have been made in accordance with the Law on Food Hygiene of the People's Republic of China (the "Food Hygiene Law").

Article 2 The new resource food as provided for in these Measures shall include:

- (a) Animals, plants and microorganisms, of which there are no food habits in this country;
- (b) Food raw materials separated from animals, plants and microorganisms, of which there are no food habits in this country;
- (c) New varieties of microorganisms utilized during the food processing; and
- (d) Food raw materials leading to changes of original ingredients or structure as a result of adoption of a new process in production.

Article 3 The new resource food shall comply with the provisions of the Food Hygiene Law and relevant administrative regulations and rules and standards, and shall not generate any acute, subacute, chronic or other potential harm to health.

Article 4 The state shall encourage the scientific research and development of new resource food.

Article 5 The Ministry of Health shall be in charge of the supervision and management of new resource food hygiene across this country. The health administrative authorities of the local people's governments at or above the county level shall be in charge of the supervision and management of new resource food hygiene within their respective administrative regions.

Chapter II Application for New Resource Food

Article 6 An entity or individual producing, dealing in or using new resource food shall report on it to the Ministry of Health for examination and approval prior to the debut of the product on the market.

Article 7 In application for new resource food, the following materials shall be submitted to the Ministry of Health:

- (a) Application form for an administrative permit for new resource food hygiene;
- (b) Research and development report and safety research report;
- (c) Production process introduction and flowchart;
- (d) Standards of product quality;
- (e) Domestic and foreign research and utilization and relevant information on safety;
- (f) Product labels and instructions; and
- (g) Other materials helpful for assessment.

In addition, one unopened product sample or 30 grams of raw material shall be attached.

Where an applicant applies for import of new resource food, the certificates on the permitted production (or sale) in the production country (or region) issued by the relevant authorities or institutions of the production country (or region) or the evidential materials on the history of such food being the traditional food in the production country (or region) shall be submitted.

Chapter III Assessment, Examination and Approval on Safety

Article 8 The Ministry of Health shall establish a system of assessment of new resource food safety. The assessment of new resource food safety shall adopt such principles as hazard assessment and substantive equivalence.

The Ministry of Health shall make and issue the operating rules, technical specifications and standards for the assessment of new resource food safety.

Article 9 The Expert Assessment Committee on New Resource Food of the Ministry of Health (the “Assessment Committee”) shall be in charge of the assessment of new resource food safety. The Assessment Committee shall be made up of experts in such fields as food hygiene, toxicology, nutriology, microorganism, process and chemistry.

Article 10 The Assessment Committee shall assess safety on the basis of the following information and data: source of new resource food, history of traditional utilization as food, production process, quality standard, principal ingredients and content quantities, estimated intake, purpose and scope of use, and toxicology; biological traits of strains, genetic stability, pathogenicity, virulence, etc. of microorganism products, and other scientific data.

Article 11 Where the relevant materials need to be supplemented in the technical examination after the Ministry of Health accepts an application for new resource food, the applicant shall assist.

Where a verification test is necessary, the Assessment Committee shall decide the test items, test batch, test method and test institution of the new resource food verification and whether the on-site examination and drawing and seal of sample shall be conducted, and notify the applicant. The safety verification test shall be usually conducted at a test institution accredited by the Ministry of Health.

Where the on-site examination and drawing and seal of sample are necessary, the provincial health administration authority shall organize the ution.

Article 12 On the basis of the technical examination conclusion and on-site examination results of the Assessment Committee, the Ministry of Health shall conduct the administrative examination, and make a decision on whether to approve the product as new resource food.

In the course of examination, if the product reported is determined as a common food, the applicant

shall be notified, and a decision on terminating the examination and approval shall be made.

Article 13 The specific procedures for the examination and approval of new resource food shall be consistent with the relevant provisions of the Measures for the Management of Health Administrative Permits and the Procedures for Health Administrative Permits for Health-Related Products.

Article 14 The Ministry of Health shall announce the approved new resource food in the form of a list. According to the characteristics of different new resource food, the announcement in content shall usually include the name (including Latin name), variety, source, biological traits, process adopted, principal ingredients, edible part, quantity of use, scope of use, population of utilization, quantity of intake, quality standard, etc; and the strain number for new resource food in the category of microorganism.

Article 15 On the basis of the use of new resource food, the Ministry of Health shall announce from time to time a list of new resource food transformed into common food.

Article 16 The Ministry of Health may organize the Assessment Committee to reassess the new resource food that has been approved, under any of the following circumstances:

- (a) With the developments in science and technology, the knowledge of the approved new resource food in edibility safety and nutriology has changed;
- (b) Doubts have been cast on the edibility safety and nutriological quality of new resource food; or
- (c) As required by the supervision and monitoring of new resource food.

Where the reassessment is failed, the Ministry of Health may announce the prohibition of production and business operation and use of such new resource food.

Chapter IV Administration of Production and Business Operation

Article 17 An enterprise engaged in the food production or business operation shall guarantee the edibility safety of the new resource food produced, dealt in or used.

Without being approved and announced by the Ministry of Health as new resource food, the product concerned shall not be produced, dealt in and used as food or food raw material, though consistent with Article 2 of these Measures.

Article 18 An enterprise producing new resource food must comply with the provisions and requirements of relevant laws, regulations and technical specifications.

An enterprise producing new resource food shall apply to the provincial health administrative authority for a hygiene permit, and may produce new resource food only after obtaining the hygiene permit.

Article 19 Before producing or using new resource food, a food production enterprise shall make verification with the announcement of the Ministry of Health to ensure the product to be the new resource food announced by the Ministry of Health or to be substantively equivalent to the new resource food announced by the Ministry of Health.

Article 20 An enterprise producing new resource food or using new resource food to produce other food shall establish a system of gathering and reporting information on the edibility safety of new resource food, and report annually on the edibility safety of new resource food to the local health

administrative authority. If any edibility safety problem is discovered, the enterprise shall timely report it to the local health administrative authority.

Article 21 The product label of new resource food or food product containing new resource food shall comply with the relevant provisions of the state, and the name of new resource food indicated on the label shall be consistent with the one announced by the Ministry of Health.

Article 22 In the production or business operation of new resource food, no statements or implications shall be made on its curative effect or particular health care function.

Chapter V Hygiene Supervision

Article 23 The health administrative authority at or above the county level shall conduct the supervision and selective inspection of the production, business operation and use of new resource food and the everyday hygiene supervision and management, in accordance with the Food Hygiene Law and relevant provisions.

Article 24 The health administrative authority at or above the county level shall regularly inspect the gathering and reporting of information on the edibility safety of new resource food, and timely report the information on the edibility safety of new resource food within its jurisdiction to its superior health administrative authority. After investigating, confirming and handling the reported information on the edibility safety of new resource food, the provincial health administrative authority shall timely report it to the Ministry of Health. The Ministry of Health shall timely study and analyze the information on the edibility safety of new resource food, and make it available to the public.

An enterprise producing, dealing in or using new resource food shall assist the health administrative authority in investigating a food safety problem, and the health administrative authority may criticize, in a bulletin, such an enterprise that conceals and does not report the food safety information.

Article 25 Where new resource food without approval of the Ministry of Health is produced or dealt in, or food containing new resource food as raw materials without approval of the Ministry of Health is produced or processed, the health administrative authority of the local people's government at or above the county level shall impose a punishment according to Article 42 of the Food Hygiene Law.

Chapter VI Supplementary Provisions

Article 26 Definitions of the following terms as mentioned in these Measures:

Hazard assessment shall refer to the scientific assessment of the possibility of adverse effects on the health of a person taking in food containing any harmful substance, including such four steps as harm identification, description of harm characteristics, exposure assessment and description of hazard characteristics.

Substantive equivalence shall mean that certain new resource food is substantively the same as the traditional food or food raw material or approved new resource food by comparison in such aspects as variety, source, biological traits, principal ingredients, edible part, quantity of use, scope of use, and population of utilization, their adopted processes and quality standards are basically the same, and they may be deemed as equally safe and having substantive equivalence.

Article 27 The administration of genetically modified products and product additives shall be subject

to the relevant administrative regulations of the state.

Article 28 These Measures shall be effective as of December 1, 2007, and the Measures for the Administration of New Resource Food Hygiene issued by the Ministry of Health on July 28, 1990 and the Measures for the Administration of Genetically Modified Food Hygiene enacted by the Ministry of Health on April 8, 2002 shall be abolished simultaneously.