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Rules for New Food-Related Products

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FAIRS Subject Report

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Report Highlights:

On August 13, 2009, the Ministry of Health (MOH) notified the World Trade Organization of draft national standard “Rules on Administrative Licensing of Food-related New Product Varieties” for public comment. This rule relates to additives, packaging, and other food related products that have previously not been registered for use in China. This measure has the WTO reference number G/SPS/N/CHN/120. Interested parties are encouraged to comment on the draft standard before October 12, 2009. This report contains an UNOFFICIAL translation of G/SPS/N/CHN/120.

Executive Summary:

On August 13, 2009, the Ministry of Health (MOH) notified the World Trade Organization of draft “Rules on Administrative Licensing of Food-related New Product Varieties” for public comment. This measure has the WTO reference number G/SPS/N/CHN/120. On the basis of the 2009 Food Safety Law, this rule relates to additives, packaging, and other food related products that have previously not been registered for use in China.

This is the second draft of this measure that has been released. The first draft was released on May 6 and was reported on in GAIN CH9051. Upon review, this second draft contains enough significant changes in comparison with the draft published in CH9051.

Interested parties are encouraged to comment on the draft standard before October 12, 2009. The date of implementation for this measure is December 1, 2009. This report contains an UNOFFICIAL translation of G/SPS/N/CHN/120.

General Information:

Rules on Administrative Licensing of Food-related New Product Varieties

(Draft for comments)

Chapter 1 General Rules

Article 1 To enhance the management of the administrative licensing of the food-related new product varieties and safeguard the health and life of the public, these Rules are enacted according to the Food Safety Law of the People's Republic of China.

Article 2 The licensing scope of the food-related new product varieties includes:

- I. Food materials or moldings without national food safety standards that are used for food packaging or containerization and machinery that has direct contact with the food during production or packaging.
- II. Additives not included in the Hygienic Standards for Additives Used In Food Containers and Packaging Materials (GB 9685);
- III. Food materials or moldings not included in the list of food packaging materials or containers announced by the Ministry of Health and all operational tools and equipment that have direct contact with food during food production, and their processing additives;
- IV. Additives which are included in the Hygienic Standards for Additives Used In Food Containers and Packaging Materials (GB 9685) or the list announced by the Ministry of Health but with the scope or dosage expanded upon.
- V. New detergent materials which may have food safety risks and are used for food, food production and operational tools and equipment that have direct contact with food during food production and packaging.
- VI. New disinfectant materials which are not included in the List of Food Disinfectant Materials and are used for food, food production and operational tools and equipment that have direct contact with food during food production and packaging.

Article 3 The Ministry of Health is responsible for the administrative licensing of food-related new product varieties and developing relevant rules.

Article 4 The Review Agency of the Ministry of Health is responsible for the declaration acceptance, organizational review, product reporting and approval and other related reviews of the food-related new product varieties.

Article 5 The Review Agency of the Ministry of Health selects corresponding experts from food review professionals to comprise a review committee responsible for the technical audit of the food-related new product varieties safety assessment materials.

Article 6 The specific procedures for the application and acceptance of the administrative licensing of the food-related

new product varieties shall be handled with reference to the Measures for the Administration of Sanitary Administrative Licenses, the Procedures for Sanitary Administrative Licenses of Health-related Products, and other relevant provisions.

Article 7 The administrative licensing of the food-related new product varieties shall be conducted in strict accordance with the relevant national laws, regulations and standards and on principle of risk assessment.

Chapter 2 Application and Acceptance

Article 8 Any unit or individual producing/operating or using the food-related new product varieties within the scope of these Rules shall report their products to the Ministry of Health for examination and approval before their products are put on the market for the first time.

If an additive in the food containers or packaging materials meets the following conditions, such additive shall be an exemptible substance and needn't be reported for examination and approval:

I. The migration volume of the additive is less than 0.01mg/kg (i.e. 10ppb); the additive is not a carcinogenic, mutagenic or reproductive toxic substance; the additive migrating into food does not cause the food ingredients, structure, color, smell or taste to change,

II. There is multi-layer composite packaging with a functional barrier layer and the migration volume of the substance outside the barrier layer is less than 10ppb.

Article 9 If an application for the licensing of food-related new product varieties is made, the following information shall be submitted to the Review Agency of the Ministry of Health:

I. Application for Administrative Licensing of Food-related New Product Varieties;

II. Information on chemical properties (including chemical property, structural formula and CAS number);

III. Purpose and use conditions;

IV. Production process;

V. Enterprise standards;

VI. Toxicological information;

VII. Details of other state-approved uses and related supporting documents;

VIII. In case of entrusted application, a power of attorney shall be provided. And

IX. Other information conducive to review.

Article 10 If the application intends the new varieties of packaging materials, containers and operational tools and equipment that have direct contact with food during food production to be used for food, the migration volume, estimated dietary exposure, methodology and other information thereof shall be submitted in addition to the information

submitted in accordance with Article 9 hereof.

Article 11 If the application intends the new additive varieties of packaging materials, containers, food production and operation tools and equipment to be used for food, the use scope and use quantity of such additive shall be submitted in addition to the information submitted in accordance with Article 9 hereof.

Article 12 If the application intends new varieties to be used for food disinfectants, the disinfection effect evaluation information shall be submitted in addition to the information submitted in accordance with Article 9 hereof.

Article 13 Any importer applying for an import license of food-related new product varieties shall provide the following information in addition to the information submitted in accordance with Article 9, Article 10, Article 11 or Article 12 hereof:

I. The supporting documents issued by the government of the producing country (region) or the agency identified to permit production and sales; and

II. The supporting documents issued by the relevant agency or organization of the country (region) of the manufacturer in order to review or certify the manufacturer.

Article 14 General requirements for application information:

I. The application information shall be true and lawful.

II. 1 copy of the original application information, 4 duplicates thereof and 1 electronic version shall be provided. The declaration information shall be true, legitimate and effective. The duplicates shall be reproduced from the original, clear and completely the same as their original;

III. A4 size paper shall be used for printing on condition that each item of information shall be clearly marked, arranged in accordance with the provided order and bound into books;

IV. The application information shall be complete, clear and the same item shall be filled in consistently;

V. In addition to inspection reports and official supporting documents, the official seal of the declaration unit or the seal on the perforation shall be affixed to the original application information on each page. In case of an individual application, the seal or signature of the applicant shall be affixed to the application information on each page and a duplicate of applicant's ID card shall be provided; and

VI. Any foreign language in the application information shall be translated into standard Chinese and the translation shall be attached to and put before corresponding foreign language information unless these Rules require the component name, a person's name and foreign address to be indicated in English or Latin, which a Chinese abstract may be attached to any foreign literature.

Article 15 If an application for submission of any supplementary information is made, one copy of original supplementary information shall be submitted, the seal of the application unit (the signature of the applicant) shall be affixed to such supplementary information on each page and the date of such supplementary information shall be

indicated.

Article 16 After receiving the application for food-related new product varieties, the Review Agency of the Ministry of Health shall make a decision on whether to accept such application on the spot or within five working days.

Chapter 3 Review and Announcement

Article 17 The Review Agency of the Ministry of Health shall organize the expert review committee to conduct technical review within 60 days after accepting the application for food-related new product varieties. If the technical review requires any supplementary information, the application unit or individual shall submit such supplementary information within one year, or the application unit or individual shall be deemed to terminate its declaration.

Article 18 In process of technical review of food-related new product varieties, the review committee shall, in accordance with the need, determine whether to conduct on-site review and safety certification test. If on-site review is needed, the Review Agency of the Ministry of Health shall organize relevant experts to carry out such review working with relevant local departments. If a safety certification test is needed, a legal food inspection agency shall be held responsible.

Article 19 With respect to the food-related new product varieties the review committee proposes to be approved, the Review Agency of the Ministry of Health is responsible for reporting to the Ministry of Health the technical review opinions of the review committee and the information intended to be announced.

The Ministry of Health discloses to the public relevant information of the food-related new product varieties intended to be approved to ask for commentary.

The Review Agency of the Ministry of Health is responsible for summarizing and sorting out the comments from different sectors of society, organizing the review committee to study such comments and report the study result to the Ministry of Health.

If the food-related new product varieties do not meet the food safety requirements, the Ministry of Health shall decide not to approve them and shall describe the reasons in writing.

Article 20 The Ministry of Health decides whether to grant a license in accordance with the review opinions of the review body.

Article 21 The Ministry of Health announces to the society the list of approved food-related new product varieties.

Article 22 The Review Agency of the Ministry of Health shall organize the expert review committee to re-evaluate the approved food-related new product varieties if:

I. As science and technology develop, the safety awareness of the approved food-related new product varieties changes;

II. The safety of the food-related new product varieties is in question; or

III. Such re-evaluation is required by the supervision and detection of the food-related new product varieties.

If the food-related new product varieties fail in the re-evaluation and examination, the Ministry of Health may announce and prohibit their production, operation and use.

Chapter 4 Supplementary Rules

Article 23 The following terms herein are defined as follows:

Materials of food packaging, containers and food production along with management tools and equipment refer to the main raw materials used for food packaging, containers and food production and management tools and equipment.

Such examples include resin, ceramics, etc.

Moldings of food packaging materials and containers refer to the products, appliances, films and so on used for food packaging materials and containers.

Raw materials of food detergents and disinfectants refer to the main raw materials of detergents and disinfectants used to wash or disinfect food ware, tableware, the tools and equipment in direct contact with food, or food packaging materials and containers.

Article 24 If the raw materials included in the List of Food Disinfectant Materials are used to produce disinfectants, the Law on the Prevention and Treatment of Infections Diseases, the Measures on the Disinfection Control and relevant provisions of the Ministry of Health shall be performed.

Article 25 The Review Agency of the Ministry of Health carries out archives administration of the examination and approval information of food-related new product varieties, establishes an examination and approval database of food-related new product varieties and provides search and consulting services in accordance with the relevant provisions.

Article 26 These Rules shall be interpreted by the Ministry of Health. If any document promulgated by the Ministry of Health conflicts with these Rules, these Rules shall prevail.

Annexes:

1. Application for Administrative Licensing of Food-related New Product Varieties
2. Information on the Specific Requirements for the Application for Administrative Licensing of Food-related New Product Varieties

Annex 1. Application for Administrative Licensing of Food-related New Product Varieties

Prepared by the Ministry of Health of the People's Republic of China

Completion Notes

1. This Application may be downloaded from the Ministry of Health website or the Health Monitoring Center website of the Ministry of Health.

Website: <http://www.moh.gov.cn> or <http://www.jdZX.net.cn>

2. The declaration content in this Application and all the declaration information must be printed.

3. The declaration content in this Application shall be complete, clear and shall not be altered.

4. Before filling out this Application, please read relevant regulations and the provisions on declaration acceptance carefully.

Product name	Chinese			
	English			
Product category	<input type="checkbox"/> New Varieties of food packaging materials and containers <input type="checkbox"/> New varieties of food production and operation tools and equipment <input type="checkbox"/> New additive varieties of food packaging materials, containers, equipment and tools, <input type="checkbox"/> New varieties of food detergents <input type="checkbox"/> New varieties of food disinfectants			
Declaration unit / Applicant	Name			
	Address			
	Contact person		Tel	
	ID number of Applicant			
Entrusted agency	Name			
	Address			
	Contact person		Tel	
<p>Guarantee As a product declaration unit, we guarantee that the content declared in this Application and the information attached hereto are true and legitimate, that the duplicates and the originals thereof are consistent and that the data in the attached information are data of such product obtained from research and detection. If the above guarantee is untrue, I would like to assume the corresponding legal liability and all the consequences caused thereby.</p> <p>Declaration unit (seal) Legal representative of declaration unit / Applicant (signature)</p> <p style="text-align: center;">Date:</p>				

<p>Attached information (please mark "√" in the <input type="checkbox"/> before the provided information)</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1. Application for Administrative Licensing of Food-related New Product Varieties <input type="checkbox"/> 2. Information on chemical properties; <input type="checkbox"/> 3. Purpose and use conditions; <input type="checkbox"/> 4. Production process; <input type="checkbox"/> 5. Enterprise standards; <input type="checkbox"/> 6. Toxicological information; <input type="checkbox"/> 7. Details of other state-approved uses and related supporting documents; <input type="checkbox"/> 8. In case of entrusted application, a power of attorney shall be provided; <input type="checkbox"/> 9. The migration volume, estimated dietary exposure, methodology and other information (if the application intends the new varieties of packaging materials, containers and operational tools and equipment that have direct contact with food during production to be used for food); <input type="checkbox"/> 10. The use scope and use quantity of the additives used for food packaging materials and containers (if the application intends the new additive varieties of packaging materials and containers to be used for food); <input type="checkbox"/> 11. The disinfection effect evaluation information (if the application intends new varieties to be used for food disinfectants); <input type="checkbox"/> 12. The supporting documents issued by the government of the producing country (region) or the agency identified thereby to permit production and sales (import application products); <input type="checkbox"/> 13. The supporting documents issued by the relevant agency or organization of the country (region) of the manufacturer to review or certify the manufacturer (import application products); <input type="checkbox"/> 14. Other information conducive to review.
<p>Other issues required to be explained:</p> <p>The following information shall be filled in for imported products:</p> <p>Name of manufacturer:</p> <p>Address:</p> <p>Country (Region):</p>

Annex 2

Specific Requirements for the Information on the Application for Administrative Licensing of Food-related New Product Varieties

I. Information on chemical properties

Information on chemical structure: chemical name, common name, chemical structure, molecular formula, molecular weight, CAS number, etc..

Information on physical and chemical properties: melting point, boiling point, decomposition temperature, solubility,

chemical reactivity, products which may be produced by decomposition or conversion in production or use, the possible interaction with food ingredients, etc..

If the declaration substance is a mixture, then the above information of the main ingredients thereof shall be provided.

II. Purpose and use conditions

Usage information: expected use, scope of use, maximum use limit, and minimum quantity required to achieve the function, and technical effect of use.

Information on usage conditions: The variety of food which may be in contacted with when used (water-rich food, food rich in fats and oils, acidic food, alcoholic type food, etc.), and the time and temperature of direct contact with food. The area / volume ratio of food containers and packaging materials in contact with food, etc..

III. Information on production process

Production process flowchart and written descriptions as well as technical parameters of each link, etc..

IV. Information on quality standards

Specified requirements, purity, impurity of ingredients and content requirements, as well as the instructions of the basis for the formulation of such standards.

V. Toxicological information

I) If food packaging materials and containers, operational tools/equipment used in food production, and new varieties of processing additives are applied for then the scope of use scope and quantity of use in the processing additives are expanded, toxicological information shall be provided in accordance with the migration level of the new varieties towards food:

1. If the migration level of the new varieties towards food does not exceed 0.01mg/kg, the analytical information on structural activity and on other security research literatures shall be provided.
2. If the migration level of the new varieties towards food is 0.01-0.05mg/kg (including 0.05mg/kg), the information on three mutagenic tests (Ames test, in vitro mammalian cell chromosome aberration test and micronucleus test of bone marrow cells or in vitro
3. If the migration level of the new varieties towards food is 0.05-5mg/kg (including 5mg/kg), the information on three mutagenic tests (Ames test, in vitro mammalian cell chromosome aberration test and micronucleus test of bone marrow cells or in vitro mammalian cell gene mutation aberration test) and a 90-day sub-chronic toxicity test in rats shall be provided.
4. If the migration level of the new varieties towards food is 5-60mg/kg, the information on acute oral toxicity, three mutagenic tests (Ames test, in vitro mammalian cell chromosome aberration test and micronucleus test of bone marrow cells or in vitro mammalian cell gene mutation aberration test), a 90-day sub-chronic toxicity test in rats, reproductive developmental toxicity (two-generation reproduction and teratogenic test), chronic oral toxicity and carcinogenic test shall be provided.
5. If the new varieties are high molecular polymers (the weight average molecular weight exceeds 1,000 daltons), the toxicological information of various monomers of the polymers shall be provided.

II) If the new varieties of food detergents and disinfectants are applied for, the toxicological information shall be provided in accordance with the Procedures and Methods for Toxicological Evaluation of Food (GB/T15193).

VI. Details of other state-approved uses and related supporting documents

Certificates of usage approved by other national government agencies, trade associations or international organizations shall be provided.

VII. Power of attorney

- I) The product name of entrusted application, name of the entrusted unit, entrusted matters and entrustment date shall be indicated, and the official seal of the entrusting unit shall be affixed to or the legal representative shall do the same;
- II) When one supporting document sets out a few products, they shall be applied for at the same time, of which one product must be provided with an original and the others may be provided with duplicates and written statements indicating in which product declaration information their originals are;
- III) Any power of attorney in any foreign language shall be translated into standard Chinese and notarized by a notary organization in China.

VIII. Information on migration test and residues

The data and information on the migration test of the new varieties towards food or food stimulants and the information on migration test detection methods shall be provided in accordance with the purpose and use conditions of the new varieties.

Residue information: The residue data of each component transformed or not transformed in food containers and packaging materials and the information on residue detection methods.

IX. Disinfection effect evaluation information

A report on the actual disinfection effect evaluation and test of the disinfectant made of such substance.

X. The supporting document issued by the government of the producing country (region) or the agency identified thereby to permit production and sales

- I) Such supporting document shall be issued by the competent government departments or trade associations of producing countries or countries (regions) of origin. If its original cannot be provided, its duplicate can be provided on condition that such duplicate shall go through consular certification in China's embassy or consulate in producing countries or countries of origin or be confirmed by the issuing unit after notarization by relevant local organization;
- II) The product name, manufacturer name and unit name of the file issuer shall be indicated, the official seal of the unit shall be affixed to or the legal representative (or the authorized person thereof) shall sign such certificate and the issuance date thereof shall be set forth;
- III) The indicated product name and manufacturer name shall be completely the same as those in the application content; in case of entrusted processing or production in other manners, the application unit shall issue supporting documents when the manufacturer indicated in the supporting documents thereof is not consistent with the application content;
- IV) When one supporting document sets out a few products, they shall be applied for at the same time, of which one product must be provided with an original and the others may be provided with duplicates and written statements indicating in which product application information their originals are; and
- V) Any supporting document in any foreign language shall be translated into standard Chinese and the translation in Chinese shall be notarized by a notary organization in China;

The above information shall be provided in Chinese and the information issued by foreign institutions shall be provided with Chinese abstracts (except supporting documents and the power of attorney).

The test report to be submitted shall be issued by any laboratory of any country with corresponding test conditions or any inspection agency approved by the Ministry of Health of China. In principle, toxicological test information is required to be issued any laboratory of any country complying with the Good Laboratory Practice (GLP) or any inspection agency approved by the Ministry of Health of China.

END TRANSLATION